

Foot Care Nurses: Improve Outcomes for Diabetic Patients

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ABSTRACT

At a Southwestern Academic Trauma Hospital, there has been a sharp increase of below the knee amputations due to uncontrolled diabetic patient foot diseases. Diabetic patients, who receive preventative care from foot care nurses, are able to reduce the likelihood of foot infections, and improve their health outcomes. These infections result in high medical costs to the healthcare system, medical professionals and the community. Limited access to Podiatrists in a community can delay healthcare for patients suffering from Diabetes, and can cause lifelong disabilities. The IRB approved research found improved outcomes in diabetic patients with lower foot infections, and amputations under the care of foot care nurses. Research has established that diabetic patients who do not have access to preventative podiatry services are susceptible to severe foot ulcers, life-threatening complications, and increased rates of amputation. In New Mexico, diabetes is growing at an epidemic rate with 241,120 people, or 14.1% of the population. 12,000 new diabetic patients are diagnosed every year. Adults living with diabetes have medical expenses almost 3 times higher, than those who do not have diabetes. In New Mexico, medical expenses are estimated at \$1.6 billion per year. Foot care nurses can significantly reduce these podiatry complications in diabetic patients. Ten clinic nurses became certified in foot care, and created their own Foot Care Clinics. This was a trial of community care to reduce strain on medical professionals, and to ease the burden of expenditures within the healthcare system. Preventative podiatry services resulted in reduced diabetic foot complications, decreased patient suffering and reducing costs to patients and society. As the increase of diabetic patients are diagnosed every year, these foot care nurses can significantly decrease foot issues in patients living with diabetes.

Keywords

Diabetic foot care nursing clinics, Foot ulcers, Patient self-care knowledge and practice, Podiatry, Preventative medicine, Community care.

Introduction

Nursing interventions are necessary for the prevention of diabetic foot ulcerations. In an interview of 23 studies on foot ulcers reported that prevention and treatment interventions were able to reduce over 60% of foot ulcers with an area of 75-80% [1-4]. It is expected that an estimated 600 million people worldwide are expected to have diabetes mellitus in 2035 of which about 50% will develop peripheral neuropathy and it is estimated that 15–25% of these patients will develop foot ulcers [5]. Expenditure on diabetic foot care has been suggested to be about a third of

total resource utilization for treatment of diabetes mellitus and its complications [5].

The total expenditure on diabetic foot care, ulcer prevention represents only a fraction of the costs incurred for treatment of the ulcer and its complications, in a ratio of approximately one to ten: for every dollar spent on prevention, ten are spent on ulcer management [6,7]. If we consider one million patients with diabetes and an annual 2.2% ulcer incidence rate [8], total annual treatment costs for these foot ulcers are \$220 million. It is estimated that half of the cost is spent treating amputations and hospitalization. [4]. That means that if proper ulcer treatment would be able to prevent 20% of hospitalization and amputation (an effect size generally shown in wound healing studies), total treatment costs would decrease significantly [9]. However, if 50% of ulcers can

be prevented with proper preventative care (an average effect size shown in 30 controlled studies on prevention), costs for the same population of patients can be reduced even more significantly [10].

A cost-utility simulation based on Markov modelling showed that intensified preventative care would be cost-effective in at-risk patients if a 25% reduction in foot ulcer incidence is achieved by preventative care from a physician. The associated increase in hospitalization charges was \$48 [12]. These analyses clearly show the cost-saving potential of preventative care. The 100 most recently published randomized controlled trials (RCTs) on the diabetic foot listed in PubMed as of April 12, 2015, 62 are on ulcer healing and only 6 on ulcer prevention; and for every 1 RCT there is on prevention, there are 10 conducted on healing. In New Mexico, there are 130,000 people who have diabetes [11]. In addition, an analysis of the Medicaid health cost data suggested that for each \$1 saved by the elimination of low-cost preventative services provided by podiatric diabetes and at the Southwest Trauma Hospital. It is estimated that diabetic foot disease poses a heavy burden on the healthcare system and the longevity of the patient. About 50% will develop peripheral neuropathy and 15–25% of these patients will develop foot ulcers [6]. Diabetic foot ulcers are a major risk factor for foot infection and amputations. These foot ulcers often result in decreased patient mobility and quality of life.

Methods

At a Southwestern Trauma Center ambulatory care clinic, nurses shifted the priorities to prevention of diabetic foot ulcers and prevented complications and possible hospitalizations. An IRB approved study included ten ambulatory care nurses who completed the foot care certification and created their own clinics. The patients signed a consent form that explained their data would be de-identified, in a collection with other patients' data, and analyzed to see if the number of foot care ulcers were achieved in the population. The primary care providers assisted in referring their diabetic patients to the foot care clinics. Each foot care nurse scheduled their patient's frequency of visits based on the diabetic complications. Within a short-term trial period, the nurses were successful in treating diabetic foot care issues. They saw a decrease in diabetic patients who were formerly at risk for amputation. This decrease was an effect of patients who were educated on the importance of long-term preventative self-care. This included the education about medications, and how to take them effectively, healthy nutrition, and daily exercise. The preventative education the foot care nurses provided patients, helped to meet the needs of high-risk individuals living with diabetes, and to reduce their likelihood of below the knee amputations.

A cost-utility simulation based on Markov modelling showed that intensified preventative care would be cost-effective in at-risk patients if a 25% reduction in foot ulcer incidence is achieved [11]. In addition, an analysis of the Medicaid health cost data suggested that for each \$1 saved by the elimination of low-cost preventative services provided by podiatric physicians, the

associated increase in hospitalization charges was \$48 [12]. These analyses clearly show the cost-saving potential of prevention. Of the 100 most recently published randomized controlled trials (RCTs) on the diabetic foot listed in PubMed as of 12 April 2015, 62 are on ulcer healing and only 6 on ulcer prevention. There are several RCT there is on prevention, there are ten conducted on healing. This randomized controlled trial included the number of hospitalizations and visits to the emergency room due to diabetic complications. These patients with foot ulcers pose a burden on the health care system. In New Mexico, the cost of treating a foot ulcer is approximately \$2,412 [21]. The nurses at the Southwest Trauma Hospital outcomes of diabetic patient's foot ulcers, amputations, and visits to the emergency department and inpatient hospitalizations for diabetic foot care complications. Compared with prevention, this undermines the value for money invested in research and in diabetic foot care. Only three of the 30 controlled studies identified in the 2015 International Working Group on the Diabetic Foot (IWGDF) systematic review on ulcer prevention focus specially on the incidence of the rest foot ulcer [10]. While screening and preventative treatment for patients without foot ulcer history is common practice in many settings, the evidence base supporting such practice is meagre.

In all prospective studies and risk classifications, persons with a previous foot ulcer are found to be at the highest risk for future ulceration [13]. Reported ulcer recurrence rates are 30-40% in the first year after an ulcer episode [14,15], compared with 7.5% annual incidence for patients with peripheral neuropathy and no ulcer history [8]. If the first ulcer is prevented or postponed, ulcer incidence rates will drop substantially. The evidence base for prevention of a first foot ulcer is nearly non-existent [10], we need to ask ourselves if we can prevent a first foot ulcer in persons with diabetes. A, 'no,' as an answer is rather unsatisfactory. It would mean that while millions of persons with diabetes are at risk for ulceration, the healthcare system cannot intervene to prevent the problems awaiting them. This does not reject current opinion and does not abide to consensus-based conducted an IRB approved study that measured the effect of nurses specialized in ambulatory foot care, creating clinics and to record the standards of good-quality care. A, 'yes,' as an answer, we have few clues as support. There are indications that home monitoring of foot temperature, therapeutic footwear, and advice within an education session that patients adhere to can help [10].

Patients may be reluctant to accept preventative treatment considering they did not yet experience a foot ulcer. There is also the cost-effectiveness that may be an issue because ulcer incidence rates are lower. These few clues being unsatisfying on its own, we call out for action; healthcare providers and researchers should combine efforts to build up an evidence base on prevention of a first foot ulcer. Well-rounded insight in the effectiveness of interventions and practices have already been applied throughout healthcare systems internationally. A small percentage of these have been studied. This would include triage of the patient's foot health, treatment of early signs of foot ulceration, advice on proper footwear, and patient education, are listed in the IWGDF Guidance

on Prevention [16]. The use of these interventions is based on low quality of evidence, and or the lack of expert opinions. A better understanding requires recording of interventions and outcomes in a systematic way, as a form of practice-based evidence, that would initially progress our understanding on effective treatment. Furthermore, it requires well-designed large-sample studies on cost-effectiveness, to reduce the strain on the healthcare system, the medical professionals, and the patients themselves.

Interventions to reduce the rates of ulceration are immensely difficult when the rates are at epidemic levels. Current opinions do not abide by consensus-based standards of good-quality care. There are indications that home monitoring of foot temperature, therapeutic footwear, and advice within an education session that patients adhere to can help [10]. Yet, patients may be reluctant to accept such treatment considering they did not yet experience a foot ulcer, and cost-effectiveness may be an issue because ulcer incidence rates are lower. But the use of these interventions is based on low quality of evidence or expert opinion. A better understanding requires recording of interventions and outcomes in a systematic way, as a form of practice-based evidence, to initially progress our understanding on effective treatment. Furthermore, it requires well-designed large-sample studies on cost-effectiveness.

Recurrent foot ulcers: 75% are preventable because of the substantial risk involved, prevention of ulcer recurrence is one of the most important current topics in diabetic foot disease. There is an increased amount of uncertainty of why patients are getting foot ulcers at an alarming rate [17]. A possibility is that reason is that patients consider themselves, or are considered by their caregiver, not to have a foot problem after they heal from a foot ulcer, while we know they have. We therefore agree with colleagues that there is a change of syntax in diabetic foot care management where prevention equals ‘remission’, to increase awareness for the foot problem and to promote the need for adequate follow-up and foot care [18]. Many precipitating factors that caused the ulcer in the rest place, such as peripheral neuropathy, foot deformity, and increased plantar barefoot pressure, have not been resolved after healing (unless the foot is operated on). The transition from a healing device such as a walker or total contact cast to a prevention modality such as therapeutic footwear increases plantar pressure at the healed ulcer location and therefore risk of recurrence. Professional non-adherence to provide recommended treatment, including foot care, therapeutic footwear, and patient education [19]. The final result is patient non-adherence to follow advice on proper foot care or to wear therapeutic footwear [20]. All these reasons reduce efficiency in the prevention of ulcer recurrence. The 2015 IWGDF systematic review on ulcer prevention [10] shows there is some evidence to support integrated foot care, consisting of a combination of professional foot care, patient education, and therapeutic footwear, in the prevention of ulcer recurrence. Self-management is considered important but has only been studied sufficiently and proven effective for the home monitoring of foot skin temperatures as a diagnostic method, in combination with proper follow-up when necessary. Studies on patient education show that while knowledge of foot problems and foot care behavior

can improve ulcer recurrence is not prevented by limited (i.e. one or two sessions) education. There is now high-quality evidence to support the use of therapeutic footwear that has a demonstrated pressure-relieving effect and that is consistently worn by the patient. Finally, foot surgery can be effective in selected patients, but better designed studies are needed before denotive statements about safety and efficacy can be made. Particularly [10] in each of the five aforementioned intervention categories are shown. Except for patient education, the median effect sizes demonstrate to be large, over 60% in three categories, showing their large potential for prevention. For integrated foot care, effect sizes found are <50%, but these are from studies that did not include state-of-the-art interventions. Therefore, one can imagine the effect that may be achieved when effective state-of-the-art single interventions are combined in an integrated foot care interesting is to assess the potential cumulative preventative effect of these interventions. In Table 1, the median effect sizes for all identified controlled studies in the 2015 IWGDF systematic review on ulcer prevention approach: a 75–80% reduction in ulcer recurrence incidence seems possible, although this should be demonstrated in meticulously designed randomized controlled trials. If confirmed, and if such a state-of-the-art integrated approach is implemented in diabetic foot care, Majority foot problems after healing of the ulcer can be prevented, and with that the large burden of foot ulcer recurrence in diabetes.

Adherence Treatment adherence has clearly been shown in the 2015 IWGDF systematic review on ulcer prevention to be a significant factor in outcome [10]. Each of a total eight studies that investigated the effect of adherence on ulcer prevention showed that patients who are adherent to advice given, to undergoing professional care, to monitoring their foot temperatures, or to wearing their therapeutic footwear, have significantly better outcomes than those who are non-adherent. Table 1 shows the mean effect sizes from these studies for the four intervention categories where adherence plays a role. Effect sizes are large in all categories, ranging from 58% to 98%. Interestingly, while the data on efficiency of patient education shows no general effect, positive outcomes are obtained for patients who are adherent to the advice given within the education program. Combining the effect sizes found on treatment adherence with those found on treatment efficacy further supports the large potential in preventative care. This strengthens the proposition that problems with foot ulcers and their complications can be mostly prevented when effective interventions are used in an appropriate way. For this reason, non-adherence should be discussed with patients and should guide treatment choices in clinical practice, much more than is currently the case. It remains a challenge how we can achieve better adherence. It starts with knowing and understanding why a patient does not adhere to a given intervention. For the topic of footwear adherence, the reasons have been explored, but more effort is needed in this area [20,21]. We found no studies in the literature on the effect of interventions that aim to increase treatment adherence in the diabetic foot, and no current trials seem to be underway [10]. Therefore, investigations into factors that determine adherence and into interventions that aim to increase adherence are urgently needed.

Table 1: Effect sizes in foot ulcer risk reduction for five intervention categories as assessed for the 2015 International Working Persons with a previous foot ulcer are in the highest risk category of current risk classifications [2]; for the IWGDF risk classification, this is grade 3.

However, in daily clinical practice, a large variation in disease severity exists within this risk group of patients. Some patients continuously differentiation in level of preventative care, seems indicated. Factors that can be considered for more differentiation in risk are available from prospective studies on ulcer recurrence. These factors can be divided into foot-specific factors (e.g. previous ulcer location [22,23], presence of minor lesions [24], and amputation history [25]), biomechanical factors (e.g. barefoot peak plantar pressure [24,26] and in-shoe peak plantar pressure [24]), biomedical factors (e.g. presence of peripheral artery disease [22,23], HbA1c [23], osteomyelitis of the healed ulcer [23], and elevated C-reactive protein [23]), and behavioral factors (most notably adherence [24]). While some prospective risk factor studies have combined several of these factors [24], a comprehensive multivariate analysis remains to be conducted. Such analyses on large sample sizes can establish more certainty on the relative role of these factors and, subsequently, may help in developing a more detailed risk classification system. An important aspect to be considered in any future study on recurrence is where the ulcer develops. In line with the IWGDF risk recur, whereas others have only one ulcer episode in their life. Differentiation in disease severity within this risk category, with a corresponding classification, we denied a ‘recurrent ulcer’ in the 2015 IWGDF systematic review on ulcer prevention as any ulcer after healing of a first ulcer, regardless of location on the foot [10]. Because none of the studies on recurrence provide specific information on whether the new ulcer developed at the same location as the previous one, another dentition was not possible. Nevertheless, an ulcer that develops at a metatarsal head 6 months after healing of an ulcer at the very same location is clinically clearly different to an ulcer in the same patient that develops after 2 years on the dorsal side of the contralateral foot. To better understand foot ulceration and to better predict outcome in the highest risk group, we ought to consider this difference. Investigations in this area require long-term recording of treatment provided, patient characteristics, and presence, location, and timing of a foot ulcer. Setting up such registries for such recording has proven possible for various aspects of medicine (e.g. surgical registries and cancer registries) and therefore be possible for foot ulcers in diabetes.

Where Healthcare Stands

To better inform clinicians and practitioners about effective treatment to prevent a rest foot ulcer, we need large-scale registries on treatment in daily practice to establish a practice-based evidence base and, in addition, well-designed controlled studies in first line of care that take cost aspects into account. To prevent foot ulcer recurrence, we need to (better) implement currently available state-of-the-art knowledge from well-designed RCTs. The new IWGDF Guidance on prevention provides and practicing clinicians with various recommendations on proper preventative care that

can, if implemented, have a huge positive impact on the patient, economic, and social burden of diabetic foot disease [16]. We hope the following research agenda will guide researchers, clinicians, and funding bodies in prioritizing their limited resources.

RCTs on the cost-effectiveness of interventions to prevent a rest foot ulcer.

- Studies on the effect of interventions on incidence of rest foot ulcers through a practice-based approach by setting up data registries in rest-line foot care.
- RCTs on the cost-effectiveness of a state-of-the-art integrated foot care program to prevent foot ulcer recurrence.
- RCTs on the effectiveness of interventions to improve treatment adherence, and of improved adherence on foot ulcer incidence.
- Comprehensive analyses of predictive factors of foot ulcer recurrence from large-scale data registries that include biomedical, biomechanical, and behavioral factors.
- Studies on the effectiveness of using different time intervals for foot screening for risk factors to determine the optimal time frequency for foot screening.

Conclusions

In this article, we have presented the cost-saving potential of preventative foot care, the gaps in our knowledge on ulcer prevention, the disparity in focus between ulcer prevention and ulcer healing, and the enormous potential in the prevention of foot ulcer recurrence in diabetes. We now need to shift priority in diabetic foot care and research to the prevention of foot ulcers. Two important actions in preventative foot care are a) to do what we say we should be doing, that is, to implement knowledge in daily foot care, and b) to improve treatment adherence. If we can achieve this, an enormous positive effect in ulcer prevention can be expected. International societies such as the prevention of Foot Ulcers in Diabetes. International Diabetes Federation and IWGDF stress the burden of lower-extremity amputation in diabetes and have set goals to reduce amputation incidence by at least 50% [27]. It is now time to act and to set a new target in diabetic foot care. This target is to reduce foot ulcer incidence with at least 75%.

Results

There are 103 patients who participated in the research. Findings include increased patient, nurse and provider satisfaction, fewer patient’s foot ulcers, infections, Charcot fractures and amputations. Findings also include reduced hospitalizations and emergency department visits. The hypothesis is that patients who received specialized care from Certified Foot Care RNs will have better health outcomes compared to patients who do not receive care from the Foot Care RNs.

Conclusions

These research findings demonstrated that the role and practice of the “Foot Care Nurses” significantly decreased diabetic patient’s complications, and increased patient & provider satisfaction. Foot care nurses have a significant impact on patient’s outcomes including reduction of foot care injuries, hospitalizations, ED visits

and patient, provider and staff satisfaction. Diabetic foot problems are common and if left untreated they result in amputations and other costly and devastating problems. These foot ulcers usually begin with neuropathic disease and can be prevented if discovered and treated. Foot injuries usually occur from persistent mechanical stress and/or infection. The diabetic patients who are at risk for ulceration can be treated early if they are clinically identified with careful foot examinations, education and follow-up. Over 50% of foot ulcers reoccur within 3 years and expenses include care of the ulcer episode, social services, home care and additional ulcer recurrences.

These patients should be assessed for ischemia, infection, and mechanical loads on ulcers. Neuropathic ulcer may take 6 weeks to health and off-load if the pressure depends on the patient's adherence to relieving the pressure. With the increase of patients with diabetes and the allocation of cost, time and human resources to care for these patients, it is essential that nurses become actively involved in the prevention and early detection of diabetic foot disease and its complications. Nurses educated in diabetic foot care can contribute to the prevention of foot injury with early detection of changes in foot sensation, infections, and ulcers. They can also participate in the rehabilitation and help prevent further suffering due to foot ulcers and/or amputations. Foot ulceration poses a heavy burden on the patient and the healthcare system, but prevention receives little attention (1). For every dollar spent on ulcer prevention, ten dollars are spent on ulcer healing (2). Additionally, for every randomized controlled trial conducted on prevention, ten are conducted on healing.

Nursing interventions are necessary for the prevention of diabetic foot ulcerations. At a Southwestern Trauma Center ambulatory care clinic, the clinic nurses shifted the priorities to prevention of diabetic foot ulcers and prevented complications and hospitalizations. An IRB approved study included ten ambulatory care nurses who completed the foot care certification and created their own clinics. The patients signed a consent form that explained that their de-identified data would be gathered and analyzed to see if the number of foot care ulcers was achieved in the population. The primary care providers referred their diabetic patients to the foot care nurse. Each "foot care" nurse was able to schedule their patients' frequency of visits based on the diabetic complications. The nurses not only treated the foot care problems, but they also educated the patients and their families on the "self-care" of diabetes including medications, diet, exercise, and preventive strategies. This randomized controlled trial included the number of hospitalizations and visits to the emergency room due to diabetic complications.

In an overview of 23 studies on foot ulcers reported that preventive and treatment interventions were able to reduce over 60% of foot ulcers with an effect size of 75–80%. It is estimated, that nearly 600 million people worldwide are expected to have diabetes mellitus in 2035 of which about 50% will develop peripheral neuropathy and it is estimated that 15–25% of these patients will develop foot ulcers. These patients with foot ulcers pose a burden on the health care system. In NM, there are 250,000 (about half of the population of Wyoming)," people with diabetes and at the SW Trauma Hospital, it is estimated that Diabetic foot disease poses a

heavy burden on the patient and the healthcare system, of which about 50% will develop peripheral neuropathy and 15–25% of these patients will develop foot ulcers.

Diabetic neuropathy is a result of demyelination of axon segments due to chronic hyperglycemia that results in structural and functional impairment. Diabetic foot ulcers are a major risk factor for foot infection and amputations. These foot ulcers often result in decreased patient mobility and quality of life. In New Mexico, the cost of treating a foot ulcer is between \$7,500 to \$21,000. Therefore, the nurses at the SW Trauma hospital conducted an IRB approved study that measured the effect of ambulatory care nurse foot-care clinics on outcomes of diabetic patient's foot ulcers, amputations, visits to the ED and hospitalizations for diabetic foot care complications.

Cost Savings through Prevention

Expenditure on diabetic foot care has been suggested to be about a third of total resource utilization for treatment of diabetes mellitus and its complications. Of the total expenditure on diabetic foot care, ulcer prevention represents only a fraction of the costs incurred for treatment of the ulcer and its complications, in a ratio of approximately one to ten: for every dollar spent on prevention, ten are spent on ulcer management. If we consider one million patients with diabetes and an annual 2.2% ulcer incidence rate, the total annual treatment costs for these foot ulcers are \$220 million. About half of the cost of ulcer treatment is spent on hospitalization and amputations treatment. That means that if proper ulcer treatment would be able to prevent 20% of hospitalization and amputation (an effect size shown in wound healing studies), total treatment costs would decrease significantly. However, if 50% of ulcers can be prevented with proper preventative care (an average effect size shown in 30 controlled studies on prevention. Costs for the same population of patients can be reduced even more significantly. A cost-utility simulation based on Markov modelling showed that intensified preventative care would be cost-effective in at-risk patients if a 25% reduction in foot ulcer incidence is in the first year after an ulcer episode, compared with 7.5% annual incidence for patients with peripheral neuropathy and no ulcer history. Thus, if achieved. In addition, an analysis of the Medicaid health cost data suggested that for each \$1 saved by the elimination of low-cost preventative services provided by podiatric physicians, the associated increase in hospitalization charges was \$48. These analyses clearly show the cost-saving potential of prevention.

Of the 100 most recently published randomized controlled trials (RCTs) on the diabetic foot listed in PubMed as of 12 April 2015, 62 are on ulcer healing and only six on ulcer prevention. So, for every RCT on prevention, ten are conducted on healing. Compared with prevention, this undermines the value for money invested in research and in diabetic foot care. Only three of the 30 controlled studies identified in the 2015 International Working Group on the Diabetic Foot (IWGDF) systematic review on ulcer prevention focus specially on a first foot ulcer [10]. While screening and preventative treatment for patients without foot ulcer history is a

customary practice in many settings, the evidence base supporting such practice is meagre.

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SUPPLEMENT ARTICLE

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Cost savings through prevention

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Adherence Treatment adherence has clearly been shown in the 2015

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