

PRELIMINARY EXPERIENCE WITH CONSERVATIVE SHARP WOUND DEBRIDEMENT BY NURSES IN THE OUTPATIENT MANAGEMENT OF DIABETIC FOOT ULCERS: SAFETY, EFFICACY, AND ECONOMIC ANALYSIS

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ABSTRACT

Background: Treatment of diabetes costs the United States an estimated \$245 billion annually; one-third of which is related to the treatment of diabetic foot ulcers (DFUs). We present a safe, efficacious, and economically prudent model for the outpatient treatment of uncomplicated DFUs.

Methods: 77 patients (mean age = 54 years, range 31 to 83) with uncomplicated DFUs prospectively enrolled from September 2008 through February 2012. All patients received an initial sharp debridement by one of two orthopaedic foot and ankle fellowship trained surgeons. Ulcer dressings, offloading devices, and debridement procedures were standardized. Patients were evaluated every two weeks by research nurses who utilized a clinical management algorithm and performed conservative sharp wound debridement (CSWD).

Results: Average time to clinical healing was 6.0 weeks. There were no complications of CSWD performed by nurses. The sensitivity for the timely identification of wound deterioration was 100%, specificity = 86.49%, PPV = 68.75% and NPV = 100% with an overall accuracy of 89.58%. The estimated cost savings in this model by having nurses perform CSWD was \$223.26 per encounter, which, when extrapolated to national estimates, amounts to \$1.56 billion to \$2.49 billion in potential annual savings across six to ten-week treatment periods, respectively.

Conclusion: CSWD of DFUs by nurses in a vertically integrated multidisciplinary team is a safe,

effective, and fiscally responsible clinical practice. This clinical model on a national scale could result in significant healthcare savings. Surgeons and other licensed independent practitioners would have more time for evaluating and treating more complex and operative patients; nurses would be practicing closer to the full extent of their education and training as allowed in most states.

Level of Evidence: III

Keywords: financial cost of diabetic foot ulcers, nurses debridement procedures, conservative sharp wound debridement, diabetic foot ulcers

INTRODUCTION

Diabetes and its complications are placing an increasing strain on the U.S. healthcare system and society. In a 2014 National Diabetes Statistics Report, the CDC estimated that 29.1 million people were affected within the United States with a total annual cost of \$245 billion, including \$176 billion in direct medical costs and \$69 billion in reduced productivity.¹ Of the \$176 billion in direct medical costs, approximately one third (\$58 billion) is linked to the treatment of diabetic foot ulcers (DFUs).² In the United States, more than 60% of atraumatic lower extremity amputations occur in diabetic individuals and 80% of those are preceded by an ulcer.² In addition to being a significant source of morbidity and mortality within this population, diabetic foot ulcers are a key contributor to the economic burden on the healthcare system.^{2,5} The prevalence of foot ulcers in diabetic patients is estimated to be 8% annually.⁶ According to the Department of Health and Human Services, Medicare beneficiaries with a DFU are seen in an outpatient setting 14 times per year and hospitalized about 1.5 times per year.⁵

Offloading of ulcers through the use of total contact casting (TCC) or pressure reducing diabetic walking boots has proven to be effective treatment options for diabetic foot ulcers.⁷⁻¹⁰ Appropriate offloading treatment includes sharp debridement of the ulcer and callous.¹¹⁻¹⁴ In the United States, this task has typically been the responsibility of the physician, podiatrist, or other licensed independent practitioner such as Advance Registered Nurse Practitioner (ARNP) or Physician Assistant (PA).

Nursing scope of practice laws are discussed in broad

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terms to allow nurses (RN/BSN/MSN) to practice to the extent of their education and training.^{15,16} Conservative sharp wound debridement (CSWD) is often open to interpretation by hospitals. Therefore, hospitals can facilitate credentialing nurses within their policies and procedures.¹⁷

We propose a safe, efficacious, and fiscally responsible model for the outpatient treatment of uncomplicated diabetic foot ulcers by allowing nurses to perform evaluation and management using a clinical management algorithm and to perform conservative sharp wound debridement after undergoing a standardized training protocol.

METHODS

This study is a part of a larger five-year prospective NIH funded study (1R01NR0098448, PI: SG) to identify the effect of ulcer bioburden in predicting the development of infection-related complications.¹⁸ Subjects were evaluated by one of two orthopaedic foot and ankle surgeons who determined patients were candidates for TCC treatment. Informed consent was gained according to the IRB protocol within the larger study¹⁸. An off-the-shelf diabetic walking boot was used if the patient declined a cast. Patients were enrolled only after giving written consent according to a specific protocol/script. Baseline data was collected which included: age, sex, race, type 1 vs. 2 diabetes mellitus (DM), duration of diabetes (years), duration of the ulcer (days), toe brachial pressure index (TBPI), ankle brachial index (ABI), ulcer location, ulcer dimensions (depth, width, surface area, volume), Hgb A1C, blood glucose, white blood cell (WBC) count, erythrocyte sedimentation rate (ESR), C-reactive protein (CRP), and presence or absence of neuropathy with monofilament testing. Patients were excluded from this study if they presented with (1) significant ischemia (i.e., TBPI or ABI < 0.5); (2) signs or symptoms of active infection (i.e., increasing pain, erythema, heat, edema, or purulent exudate) or osteomyelitis (i.e., positive radiograph or MRI, if radiograph was equivocal according to protocol); and (3) treatment with systemic antibiotics in the prior two weeks. Patients who met all inclusion criteria, except for recent antibiotic use, were instructed to stop their antibiotics if clinically appropriate, and enrolled under a delayed protocol two weeks later.

Initial sharp debridement was performed in a clinic setting by one of two orthopaedic surgeons, or a nurse (RN/BSN/MSN) under direct surgeon supervision, if within their training period according to a written protocol; this included three observations and a minimum of three satisfactory proctored debridement procedures. Patients were placed in a TCC (n=72) or a diabetic walking boot when cast phobia prohibited a TCC (n=5). Patients

were evaluated by nursing research assistants (RN, BSN, MSN) every two weeks. Casts were removed, and wounds were assessed and debrided by nurses, according to protocol. Data were collected, and high-quality digital photographs were taken of the ulcer prior to performing CSWD. All cast application and removal were performed by a single experienced cast technician. This protocol was performed until healing of the wound or the 26-week time point. The patients were reassessed at eight-weeks by the orthopaedic surgeons. If wound deterioration was identified at any visit during the nursing care period, patients were referred back to the orthopaedic surgeon according to the clinical management algorithm (CMA).

No nurses had previous experience performing CSWD. This protocol was approved by, and done in accordance with, the Iowa Board of Nursing Declaratory Ruling No. 91, and the University of Iowa Hospitals and Clinics Institutional Review Board.

CSWD Procedure included:

1. Cleanse the wound with sterile saline soaked gauze.
2. Remove the callous with a sterile scalpel.
3. Excise callous until punctate bleeding tissue is seen.
4. Observe the wound for up to 15 minutes for bleeding.
5. If bleeding continues after 15 minutes, contact physician team member.

Medical decision making for the nurse evaluations was guided by the CMA. This directed urgent referral back to the Orthopaedic surgeon or Emergency Department if wound deterioration was identified; signs of cellulitis or abscess, increased ulcer size, fever, worsening inflammatory markers or increasing white blood count were indicators of deterioration. The ulcer size, depth and appearance were documented in an Access database (Microsoft Inc, Redmond, WA).

To determine the sensitivity and specificity of the nurse's medical decision making using the CMA, a retrospective blinded review of photographs from each nursing encounter was performed by two orthopaedic foot and ankle surgeons. Patient images were randomized and a PowerPoint (Microsoft Inc, Redmond, WA) slide show was used for review of photographs of 48 patients (16 cases and 32 controls) in chronological order. The reviewing surgeons used consensus to score each photo, in a single setting, as either improved/unchanged or regressed. The surgeons graded each case series of photographs in chronological order as unchanged/improved or regressed. Cases were counted as true positive or true negative when surgeons and nurses agreed. Cases in which the nurse's interpretation of the CMA identified a wound as deteriorating, but the photo

was deemed improved/unchanged by the surgeon's evaluation, were counted as false positives. Since all other patients healed uneventfully, it was assumed there were no false negatives.

A cost analysis was performed based on local Center for Medicare Services (CMS) reimbursement rates of Evaluation and Management (E&M) and Current Procedural Terminology (CPT) coding. Prior to and after the study period, a patient was seen in an orthopaedic foot and ankle clinic, with E&M code 99204 for the initial visit and 99213 for all subsequent visits. During the study period, the initial visit with E&M code 99204 was still performed by the physician; nursing visits were coded as unbillable 99211; and the last visit with the physician was coded 99213. In an eight-week treatment protocol, visits with surgeons occurred at the initial and eight-week visit and with the nurses at weeks two, four and six. Facility fees are constant for all visits. Procedural billing for total contact casting (CPT 29445) could be performed by all providers and therefore was not included in the calculations. Reimbursement was estimated based on 100% Medicare reimbursement in the home area (AAOS CodeX).

To determine the feasibility of having a nursing based CSWD system for diabetic ulcer debridement, surveys were sent to 51 state boards of nursing (50 states plus Washington, DC). Surveys queried if CSWD was considered part of nursing practice in a given state. Follow-up emails and phone calls were conducted to encourage completion.

RESULTS

Ninety-six patients met the inclusion criteria and were screened for eligibility from September 2008 through February 2012. Twelve of these were subsequently excluded due to: osteomyelitis (n=6), long-term antibiotics for chronic infections (e.g., chronic urinary tract infection; n=3), ischemia (TBPI or ABI \leq 0.5; n=1), clinical signs of active infection (n=1), and inability to use the off-loading device (n=1). The remaining 84 patients (average age = 54 years, range 31 to 83, SD 11.64) were enrolled in the study; 17 (20%) were enrolled under the delayed protocol, which provided a two-week antibiotic holiday. Seven patients did not return after initial enrollment, leaving 77 patients for data analysis.

During subsequent nurse CSWD visits, 16 of 77 (20%) patients triggered referral back to a surgeon according to the Clinical Management Algorithm. Average time to healing was 6.0 weeks (range, 2 to 26 weeks; SD: 4.85). Patients underwent an average of 4.0 CSWD (range, 1 to 13) during their course of treatment. No complications or excessive bleeding of the 307 CSWD were identified. During the study period (26 weeks), 65 (84%) ulcers

healed, one (1%) required a below knee amputation, eight (10%) were lost to follow up, and three (4%) remained unhealed at the end of 26 weeks. These were among the true positives.

Review of the photographs demonstrated that the nursing clinical decision making based on the CMA had a sensitivity for the timely identification of wound deterioration of 100%, specificity = 86%, PPV = 69% and NPV = 100% with an overall accuracy of 90%.

Cost analysis of E&M and CPT coding demonstrated a cost savings of \$223.26 [$\73.40 (E&M 99213) + $\$73.00$ (E&M facility fee) + $\$76.86$ (CSWD CPT 97597)] for every nursing visit in which the physician was not directly involved. This accounts for savings of \$669.78 for ulcers healing between six and eight weeks and \$893.04 for a ten-week treatment periods. Due to our study protocol requiring a surgeon visit at the eight-week mark, ulcers healing between six and eight weeks generated the same charges. Nurses performed 307 debridement procedures during this study period, saving an estimated \$68,540 in local healthcare dollars. When extrapolated to a national scale, with an estimated 29.1 to 34 million diabetics within the United States¹ and an annual ulcer incidence of 8%,¹⁸ this could result in \$1.56 billion to \$2.49 billion in annual cost savings for a six to ten-week treatment period.

Thirty-six of 51 (71%) state boards of nursing responded to the survey with 33/36 (92%) defining CSWD as within their nursing scope of practice

DISCUSSION

Diabetes is a growing epidemic, and with a predicted physician shortage of 61,700 - 94,700 by the year 2025, other members of the healthcare team will need to take a larger role in the management of these complex patients¹⁹. Increasing the role of nurses to perform CSWD will help reduce the burden of the pending physician shortage.

One of the keys to a successful screening test is having a high sensitivity to reduce the risk of missing or delaying a diagnosis. Guided by the CMA, nurses referred deteriorating wounds with 100% sensitivity. There were eleven "false positives" during this study. This is explained by the design of the CMA which was intended to be conservative and had the desired effect of favoring false positives (referral back to surgeons) over false negatives (missed cases of wound regression). Safety of nurses performing CSWD was demonstrated without any complications or prolonged bleeding in 307 debridement procedures.

In addition to timely healing of ulcers, a critical component to controlling cost associated with management of diabetic foot ulcers is to limit inpatient admissions and amputations.^{2,4} The mean number of admissions among Medicare patients with a prevalent DFU was 0.25 from

2006-2008⁵. Amputations also impact costs; amputation rates from 2.4% to 4.8% have been reported.^{4,20} Only one patient in our study (1.3%) required hospitalization for an amputation during the course of this 26 week study. All other patients were successfully managed in an outpatient setting for the duration of the study.

Medicare expenditures for patients with DFU are, on average, three times higher than diabetic patients without an ulcer.^{3,5} With an estimated 29.1 million within the United States and an annual ulcer prevalence of 8.1%,⁶ annual Medicare/Medicaid cost savings would be in excess of \$1.56 Billion, using the six-week (three visit) model utilized in this study. Our average time to healing (6.0 weeks) is consistent with other published series on total contact casting.⁷⁻¹⁰

The team approach to care of the diabetic foot is not new. Numerous studies have shown the benefits of multidisciplinary approach to diabetic foot care to include reduced inpatient admissions and incidence of amputation.^{2,14,21-23} In Australia, Canada, and Great Britain, nurses routinely perform CSWD for the care of wounds freeing up physicians to see more acute/new patients or perform other more complicated procedures/surgeries.^{12,16,17} Our model of DFU care demonstrates that the efficient use of resources in a vertically integrated multidisciplinary team allowed us to deliver high quality and cost-effective care with an emphasis of allowing each practitioner to practice at the top of their license. This study falls in line with the Center for Medicare and Medicaid Services "focus on improving outcomes, beneficiaries' experience of care, and population health, while also aiming to reduce healthcare costs."²⁴

There are limitations to this study. We did not account for the nursing salaries with a reported national average of \$27/hr. for a RN. This series represents a best-case scenario, as we included only non-infected ulcers in patients with relatively normal perfusion. Including patients with more complex ulcers and extended treatment courses would lead to even larger savings with our model. Additionally, our rate of hospitalization and amputation (1.3%) would increase if more complex ulcers were included. Financial calculations were performed assuming a 100% capture rate and we assumed that all DFUs are amenable to CSWD and TCC treatment.

CONCLUSIONS

CSWD of DFU's by trained nurses in this study of TCC treatment resulted in an average time to healing of 6.0 weeks. The use of a standardized clinical management algorithm resulted in medical decision making by nurses (RN, BSN, MSN who had no prior experience with sharp wound debridement) that detected wound deterioration with 100% sensitivity and 89.58% accuracy.

No complications or prolonged bleeding of 307 nurse sharp wound debridement occurred. This practice is supported by thirty-four of thirty-six state boards of nursing who responded to the survey.

Implementation of this clinical model on a national scale could result in significant annual healthcare savings. It would allow nurses to practice to a fuller extent of their education and training, and free surgeons and other licensed independent practitioners to evaluate and treat more complex and operative patients.

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REFERENCES

1. National Diabetes Statistics Report: Estimates of Diabetes and Its burden in the United States, 2014, U.S.D.o.H.a.H. Services, Editor 2014: Atlanta, GA.
2. **Driver VR, Fabbi M, Lavery LA, Gibbons G.** The costs of diabetic foot: the economic case for the limb salvage team. *J Vasc Surg.* 2010;52(3 Suppl):17S-22S.
3. **Harrington C, Zagari MJ, Corea J, Klitenic J.** A cost analysis of diabetic lower-extremity ulcers. *Diabetes Care.* 2000;23(9):1333-1338.
4. **Hicks CW, Selvarajah S, Mathioudakis N, Perler BA, et al.** Trends and determinants of costs associated with the inpatient care of diabetic foot ulcers. *J Vasc Surg.* 2014;60(5):1247-1254.
5. **Margolis DJ, Malay DS, Hoffstad OJ, Leonard CE, et al.** Economic Burden of Diabetic Foot Ulcers and Amputations: Data Points #3. Data Points Publication Series. 2011: Rockville MD.
6. **Margolis DJ, Malay DS, Hoffstad OJ, Leonard CE, et al.** Prevalence of Diabetes, Diabetic Foot Ulcer, and Lower Extremity Amputation Among Medicare Beneficiaries, 2006 to 2008: Data Points #1. Data Points Publication Series. 2011: Rockville MD.
7. **Cavanagh, PR and Bus SA.** Off-loading the diabetic foot for ulcer prevention and healing. *J Vasc Surg.* 2010;52(3 Suppl):37S-43S.
8. **Lewis J and Lipp A.** Pressure-relieving interventions for treating diabetic foot ulcers. *Cochrane Database Syst Rev.* 2013;1:CD002302.
9. **Myerson M, Papa J, Eaton K, Wilson K.** The total-contact cast for management of neuropathic plantar ulceration of the foot. *J Bone Joint Surg Am.* 1992;74(2): 261-269.
10. **Saltzman CL, Zimmerman MB, Holdsworth RL, Beck S, et al.** Effect of initial weight-bearing in a total contact cast on healing of diabetic foot ulcers. *J Bone Joint Surg Am.* 2004;86-A(12):2714-2719.

11. **Gordon KA, Lebrun EA, Tomic-Canic M, Kirsner RS.** The role of surgical debridement in healing of diabetic foot ulcers. *Skinmed.* 2012;10(1):24-26.
12. **Gray D, Acton C, Chadwick P, Fumarola S, et al.** Consensus guidance for the use of debridement techniques in the UK. *Wound UK.* 2011;7(1):77-84.
13. **Lebrun EA, Tomic-Canic M, and Kirsner RS.** The role of surgical debridement in healing of diabetic foot ulcers. *Wound Repair Regen.* 2010;18(5):433-438.
14. **Pinzur MS, Slovenkai MP, Trepman E, and Shields NN.** Guidelines for Diabetic Foot Care: Recommendations Endorsed by the Diabetes Committee of the American Orthopaedic Foot and Ankle Society. *Foot Ankle Int.* 2005;26(1): 113-119.
15. **Gordon B.** Conservative sharp wound debridement: state boards of nursing positions. *J Wound Ostomy Continence Nurs.* 1996;23(3):137-143.
16. **Rice JC.** Conservative sharp wound debridement - State of play in Australia. *European Wound Management Journal.* 2012;12(2):6.
17. **Rodd-Nielsen E and Harris CL.** Conservative sharp wound debridement: an overview of Canadian education, practice, risk, and policy. *J Wound Ostomy Continence Nurs.* 2013;40(6):594-601.
18. **Gardner SE, Haleem A, Jao YL, Hillis SL, et al.** Cultures of diabetic foot ulcers without clinical signs of infection do not predict outcomes. *Diabetes Care.* 2014;37(10):2693-2701.
19. IHS Inc., The Complexities of Physician Supply and Demand 2016 Update: Projections from 2014 to 2025. Prepared for the Association of American Medical Colleges. Washington, DC: Association of American Medical Colleges, 2016. https://www.aamc.org/download/458082/data/2016_complexities_of_supply_and_demand_projections.pdf
20. **Goldberg JB, Goodney PP, Cronenwett JL, Baker F.** The effect of risk and race on lower extremity amputations among Medicare diabetic patients. *J Vasc Surg.* 2012;56(6):1663-1668.
21. **Krishnan S, Nash F, Baker N, Fowler D, Rayman G.** Reduction in diabetic amputations over 11 years in a defined U.K. population: benefits of multidisciplinary team work and continuous prospective audit. *Diabetes Care.* 2008;31(1):99-101.
22. **Larsson J, Apelqvist J, Agardh CD, Stenstrom A.** Decreasing incidence of major amputation in diabetic patients: a consequence of a multidisciplinary foot care team approach? *Diabet Med.* 1995;12(9):770-776.
23. **Seaman S.** The role of the nurse specialist in the care of patients with diabetic foot ulcers. *Foot Ankle Int.* 2005;26(1):19-26.
24. Centers for Medicare and Medicaid Services. <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/index.html>.