

In patients with Type 2 diabetes, what impact does the American Diabetes Association foot care guidelines have in preventing lower extremity complications?

Kniaka R. Bethel, CNP

Dr. JoAnn Manty, Mentor

Dr. Tyra Ousley, Committee Member

Denice, Taylor, CNP, Preceptor

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Abstract

Guidelines are established to address specific needs of a clinical problem and assist clinicians with decision-making. The complexity of Type 2 diabetes warrants the use of such guidelines to help provide evidence-based treatment. The American Diabetes Association (ADA) foot care guidelines recommend providing education to all patients despite their risk, in order to increase awareness of lower extremity complications and prevent them from occurring. In this project, a diabetic lower extremity educational intervention based on ADA guidelines was provided to 16 Type 2 diabetics over four months. During this time, a reduction in diabetic lower extremity complications was seen. Concluding, if ADA guidelines were followed and lower extremity education were provided to all patients, complications could decrease.

Keywords: ADA guidelines, diabetic neuropathy, diabetic foot ulcers, adherence, compliance.

The prevalence of Type 2 diabetes is increasing at alarming rates. As of 2013, over 25 million Americans were diagnosed with Type 2 diabetes.¹ This number is projected to rise to 552 million by the year 2030, accounting for five percent of the global population.² Clinicians and patients face the daunting task of preventing complications related to Type 2 diabetes and improving patient outcomes. Major complications, such as diabetic foot disease, are becoming more prevalent and carries a 25% lifetime risk of development.³

Neuropathy is indicated as the second leading complication in Type 2 diabetes and increases the risk of lower limb amputations ten to thirty times more than in non-diabetes resulting in the highest rate of hospitalizations for this group.^{4, 5} This accounts for more than 60% of non-traumatic lower-limb amputations that occur as a result of uncontrolled glycemic levels.^{1, 6} Effective control of Type 2 diabetes and its complications is dependent on clinician knowledge and patient self-care. Self-care education is rapidly becoming the most effectively tool at accomplishing diabetic foot-care goals.

Clinicians are required to be knowledgeable of practice standard guidelines and are responsible for education patients regarding prevention and self-care. The ADA guidelines have been in place for decades and were established to serve as evidence-based practice (EBP) standards, providing guidance to clinicians in selecting appropriate options for disease management, treatment and facilitation of care. Despite the longevity of the ADA guidelines, their implementation and integration into clinical care remain subpar.

Statement of Problem

Over half of the lower extremity amputations in the United States can potentially be prevented through education and by maintaining compliance to EBP guidelines.⁷ Guideline integration has shown to be most effective if an educational component is alongside, similar to a

clinician providing education to a patient.⁸ The Centers for Disease Control and Prevention estimates one in every three adults may be diagnosed with type two diabetes by the year 2050, if current treatment mismanagement continues.¹

Background and Significance

Integration of interventions to address the clinical management of diabetes requires educating clinicians regarding the importance of adherence to these practice standards. Poor implementation of interventions can lead to nonsupport of EBP and possible disease mismanagement. Barriers to guideline integration amongst clinicians are not related to the lack of knowledge or resources, instead are due to the limited education clinicians have regarding the importance of adherence to EBP guidelines and their relationship to improving patient outcomes.⁹

Given the worsening of the diabetes epidemic, it is expected that the amount of people affected by lower extremity complications is likely to double, if guidelines are not followed. Utilizing ADA guidelines and applying empiric knowledge to guide evidence-based practice are essential to aid in reducing morbidity and mortality, thus leading to the need for a consensus regarding the treatment of diabetes.

Developing a consensus approach to the management of Type 2 diabetes through evidence-based literature and adherence to practice standard guidelines will assist the clinician in making informed decisions regarding treatment and consequently improving the quality of healthcare being delivered. A treatment consensus concluded that neuropathic and lower extremity diabetic complications can improve significantly if ADA guidelines are followed.¹⁰

The ADA guidelines recommend all people with Type 2 diabetes have a comprehensive annual foot exam including lower extremity neurological evaluation, receive patient education and self-foot care education in order to prevent diabetic foot complications.^{11, 12}

Purpose and Goal

The purpose of this project is to determine the impact adherence to the ADA foot care guidelines have on the development of lower extremity complications in type two diabetics. Integrating the ADA foot care guidelines into the clinical care of the Type 2 diabetes patients, in an attempt to prevent and/or reduce the lower extremity complications associated with this disease is the project goal.

Practice Gap

Adherence to clinical practice guidelines is critical to close the gap of inappropriately managed diabetic foot care. Uniform practice standard for clinicians to educate patients regarding reducing risk factors and decreasing complication is required. This necessitates application of guidelines that are evidence-based and generalizable to the target population. By integrating ADA guidelines into clinical practice as an educational intervention, complications can be reduced.

In evaluation of the practice gap baseline audits found decreased support and implementation of ADA guidelines, resulting in an increase in complication risk due to failure to effectively screen for diabetic foot disease.

Study Question

In Type 2 diabetes patients, will the use of the ADA guidelines contribute to a decrease in recurrence and/or prevention of lower extremity complications compared to clinicians not following standardized guidelines?

Summary of Literature

Numerous complications can occur in a patient with diabetes, however, those of the lower extremities are one of the more common. Considering there are multiple predisposing factors to developing diabetic foot disease, reduction in risk factors such as smoking and hypertension are encouraged. A major contributory factor in the development of diabetic foot disease is neuropathy, which affects more than 50% of people over the age of 60.¹⁴ Neuropathy contributes to half of the three percent of non-traumatic lower-extremity amputations in the United States.¹²

The effect of Non-Adherence on Stakeholders

It is the responsibility of the clinician to screen and educate patients on the importance of diabetic foot care while keeping healthcare costs controlled and reducing the overwhelming stress the disease can have on an organization. The diabetic foot imposes a heavy burden on the healthcare economy. The ADA reported the cost of treating diabetes in 2012 was \$245 billion from \$174 billion in 2007.⁶ Comparatively, the cost of the diabetic foot was estimated to be between \$4.6 and \$13.7 billion in 2003, with 27% representative of diabetic peripheral neuropathy, up from \$1 billion in 1986.¹⁵

It is estimated in 2010, health spending reached over \$2.6 trillion and is projected to surpass that when health reform is fully enacted and millions of uninsured Americans become insured.¹⁶ Multiple studies have shown effective patient education can reduce the incidence of foot ulcers and amputation by 50%, suggesting cost can be reduced and patients at risk of lower extremity ulcers and amputations can be educated and appropriately followed.³ For clinicians, establishing a system of screening as a baseline, foot assessment, educational interventions and appropriate care can significantly increase compliance with the ADA foot care

recommendations. Less than five percent of patients in the United States receive care as recommended by the ADA guidelines.⁶ This is likely related to the clinicians' lack of knowledge regarding their importance and their inability to evaluate and translate EBP guidelines into care.¹⁷ The ADA estimates that at least 50% of amputations can be prevented through proper educational interventions related to foot care.¹⁸

Methods

Retrospective chart review began January 2014 ending July 2014. Data Collection began July 2014 ending March 2015. Clinician implementation of patient education intervention for patients began approximately November 2014. Clinician chart review to ensure intervention implementation was completed March 2015.

Target Population and Sample Size

The target sample size was 30 patients with Type 2 diabetes, without existing lower extremity complications, ages 40-70, male or female of any race. Exclusion criteria consisted of existing lower extremity complications. After screening, the final sample size was 16.

Intervention and Data Collection

After retrospective chart review was completed and institutional review board approval was obtained, random selection revealed 16 patients meet criteria with ICD-9 codes consistent with Type 2 diabetes. The following data assessment tools were completed with these patients after informed consent was obtained:

- (1) The Registered Nurses Association of Ontario Diabetes Foot Risk Assessment Education Program; Self-care Knowledge and Behavior.
- (2) Screening for the High-Risk Diabetic Foot: A 60-second Tool

- (3) The Diabetes Care of Nova Scotia “Diabetic Foot Risk Assessment and The Diabetic Foot in Nova Scotia; Foot Risk Stratification
- (5) (a) The ADA guidelines Standards of Medical Care in Diabetes-2014
- (b) The Registered Nurses Association of Ontario Diabetes Foot Risk Assessment Education Program; Care Tips for the Feet
- (c) The ADA patient education Foot Care, Foot Complications, Steps to Prevent or Delay Nerve Damage, Neuropathy and Peripheral Neuropathy
- (d) Patient information: Foot care in diabetes mellitus (Beyond the Basics).
- (6) Monthly Calendar
- (7) Checklist for Daily Foot Exams and Foot Chart.

Stakeholders (clinicians) received the patient package with focus on the ADA foot care guidelines. Clinician education was provided on ADA foot care guidelines and integrated into practice.

At the initial visit all patients were educated on the ADA guidelines. Several weeks after the initial visit, follow up phone calls were made to document compliance with foot checks or any new or concerning issues. Patients were asked to bring calendars to monthly visits and given a new calendar at that time. All data was maintained on spreadsheets. All patient information was kept in a secured, locked cabinet at research office with allowed access cleared by DNP student and preceptor. Follow up visits were made every 4-6weeks with variations due to scheduling conflicts.

Assumption

The belief is that clinicians providing diabetic foot care education as an intervention can decrease their risk of developing new or reoccurring lower extremity complications. Providing

education and reinforcement of the ADA foot care guidelines, evaluating the clinicians' adherence to the ADA foot care guidelines regarding teaching patients how to decrease their risk and how to perform a proper self-foot assessment is the goal.

Results

Baseline Outcomes

Baseline Data collected through Retrospective Review was based on the evaluation of 6 criteria; (1) if a Screening Risk Assessment for Diabetic lower extremity complications was completed and how often, (2) how often Diabetic education on self-foot exams were taught, (3) if diabetic education was completed for patients at risk for lower extremity complications and the depth of their education measured through discussion regarding self-care, (4) if education material was provided, (5) if teach back or return demonstration were completed regarding foot exams, and, (6) in the patients whom were provided education, what was the rate of reoccurrence considering once a patient has had one lower extremity complication they are more susceptible to developing more. Patients were screened for current and previous ulcers, however, excluded if current ulcers were present.

Success was achieved if patient compliance with self-care was maintained, if no new lower extremity diabetic complications occurred or no recurrence of previous lower extremity complications occurred. Of the 42 eligible patients, 16 patients agreed to participate in the project and meet the appropriate criteria.

Month One

The identified 16 patients in the project during the first month lost only two patients to follow up (13%), nine demonstrated daily compliance with foot checks (56%), four demonstrated moderate compliance with foot checks (25%). Moderate indicates more than five days but less

than seven days out of the week. Intermittent foot checks indicate the patient checked their feet less than five days, more than zero out of seven days out of the week. This was reported by one person (6%). During this month, four patients (36%) developed new or worsening lower extremity issues.

Month Two

The remaining 14 patients in the project, two were lost to follow up (14%), ten demonstrated daily compliance with foot checks (72%), two demonstrated moderate compliance with foot checks (14%), and zero indicated intermittent (0%). During this month, two patients (18%) developed new or worsening foot issues.

Month Three

The remaining 13 patients in the project, one was lost to follow up (8%), ten demonstrated daily compliance with foot checks (76%), one demonstrated moderate compliance with foot checks (8%), and one indicated intermittent compliance with foot checks (8%). During month three, four patients (36%) developed new or worsening issues.

Diabetic self-foot care was reinforced at all visits and comprehensive diabetic foot education reinforced as needed. Month three served as a pivotal point as the end of project for patients at low risk or with unchanged stability. In addition, three patients dropped out of the project due to upcoming surgery, loss of a spouse, or worsening weather. Based on the decreased project participants dwindling to six, the project did not progress past the fourth month despite the targeted goal of three to six months.

Month Four

Of the six patients in the study, during the fourth month, one was lost to follow up (17%), five demonstrated daily compliance with foot checks (83%), and zero indicated moderate or

intermittent compliance. During month four, one patient (10%) developed a new or worsening issues. Once patients were provided with ADA foot care guidelines and a noticeable increase in foot self-care was identified, thus a decrease in complications was expected.¹⁹

Strengths and Limitations

Unforeseen adverse events such as participants discontinuing the project or lost to follow up were experienced. Patient compliance issues with visits, unavailability for phone calls, and unreturned forms at follow up were seen. Major strengths included unrestricted access to research office, and compliance by the majority of patients' at follow up visits and for phone calls.

Summary

The results of month one found the majority of patients demonstrated daily compliance with foot checks at a rate of 56%, four patients (36%) reporting new or worsening lower extremity issues (See Appendix C). Month two results constitute success with majority of patients demonstrating daily compliance with foot checks at a rate of 72% and less new or worsening lower extremity issues (18%). (See Appendix C and D. Month three results constitute success with majority of patients demonstrating daily compliance with foot checks at a rate of 76% and reporting new or worsening lower extremity issues at 36%. Month four results again constitute success with majority of patients demonstrating daily compliance with foot checks at a rate of 83% and reporting new or worsening lower extremity issues at 17%.

Discussion

Intervention Implementation

Stakeholders were educated on the ADA foot care guidelines, became aware of the importance of adherence to the guidelines, were provided with patient education material for foot

care, and provided with a computerized method of documenting patient education. Integration of the change plan has proven successful and a practice change was implemented by stakeholders on 11/2014 as a quality measure for meaningful use within the organization.

Post implementation measurement

Post implementation outcomes measurements are in the form of summative evaluation. Summative evaluations are maintaining professional standards and evaluating patient outcomes, which closely resembles the goal of the capstone project. Summative data, the number of lower extremity complications developed in a three to six month time frame, were evaluated by a post-implementation chart review with documentation on a spreadsheet. Formative evaluation reviewed the integration and implementation of the educational intervention by clinicians through chart review and the success of it through patient survey. At the conclusion of post-implementation reviews, final data synthesis was completed and dissemination of results to stakeholders was presented via written summary.

Future Implications

Beneficial to the stakeholders, the results of this project were used as quality measures to assure compliance with Medicare meaningful use criteria for the organization. The anticipated benefits provided by this capstone project allowed the stakeholders to measure their compliance with the use of the ADA foot care guidelines and evaluate anticipated improved patient outcomes. Organizational authority, control, and implementation were instituted by the stakeholders. Patients stood to gain by the improvement of the quality of care being delivered with evidence based practice. The ability of the nurse leader to influence policy and impact the patient community is greater in the micro rather than the macro context.²⁰

Sustainability

Ongoing collaboration with key stakeholders provides preliminary study data in order to initiate the beginning of the practice change plan. Complex interrelationships among members of a team are essential for successful implementation and sustainability of practice change plans. A successful pilot leads to sustainable change as well organizational adoption and integration into clinical practice .²¹

Elements of sustainability are identified as communication, development of management plans to maintain momentum, well trained leadership to serve as resources, a rewards system including financial, objective, and vigorous performance reviews, and staff satisfaction surveys or focus groups.⁷ Remaining in constant contact and communicating with clinicians and stakeholders as well as embracing feedback for evaluation can strengthen the implementation of EBP change in clinical practice.

Organizational support is a necessity as sustainability is achieved as a supportive foundation. Continued patient education reinforcement is required for patient compliance. Change is guided by a target specific, purposeful intervention that can have positive effects on the quality of care provided to patients with Type 2 diabetes. Implementation of any change plan requires appropriate training and education along with participants willing to overcome the hurdles associated with it. Acceptance and adaptation are key points in sustaining change.

Recommendations

The intention of the ADA guidelines are to guide clinicians in selecting appropriate evidence based practice options for prevention, diagnosis and treatment of patients with Type 2 diabetes. Guidelines should be disease specific, comprehensive, patient centered, modifiable to meet specific patient needs, yet applicable to the majority of the Type 2 diabetes population.

The findings of this project demonstrated the importance of compliance with ADA guidelines by clinicians and patients for the prevention and reduction of lower extremity complications.

Completing an annual comprehensive foot exam including neurological evaluation, providing patient education regarding diabetes and self-foot care increased patient knowledge regarding their risk status and assisted them in preventing lower extremity complications, new or recurrent. Compliance with ADA guidelines is recommended for patients with diabetes and the clinicians responsible for caring for them.

Conclusion

The overall outcome, adherence to the ADA foot care guidelines for the reduction of lower extremity complications, has the potential to significantly improve patient outcomes in Type 2 diabetes patients. Outcomes achieved through results interpretation and evaluation at post-implementation, focused on the rate of prevention and reoccurrence of lower extremity complications in patients managed under ADA guidelines. They were obtained and were consistent with the literature. Successful documentation of ADA guideline adherence and teaching diabetes self-care was seen with clinicians via chart review.

Results constituting success were present, however, self-foot check and follow up were not 100% at times. This resulted in new lower extremity complications in some patients, indicating a failure of adherence to ADA guidelines. Despite clinicians providing foot care education and demonstrating adherence to ADA guidelines, it was still reliant on the patient to follow through with self-care. Both factors to decrease the risk of lower extremity complications. Relying on best practice and best available research served as a benchmark to goal achievement and quality measures.

Reference

1. Centers for Disease Control and Prevention. Diagnosed Diabetes (2013). Retrieved from http://www.cdc.gov/media/releases/2011/p0126_diabetes.html
2. Wild, S., Roglic, G., Green, A., Sicree, R., & King, H. (2004). Global prevalence of diabetes Estimates for the year 2000 and projections for 2030. *Diabetes care*, 27(5), 1047-1053.
3. Boulton, A. J., Vileikyte, L., Ragnarson-Tennvall, G., & Apelqvist, J. (2005). The global burden Of diabetic foot disease. *The Lancet*, 366(9498), 1719-1724.
4. Dallo, F. J., & Weller, S. C. (2003). Effectiveness of diabetes mellitus screen recommendations. *Proceedings of the National Academy of Sciences*, 100(18), 10574-10579.
5. Aalaa, M., Malazy, O. T., Sanjari, M., Peimani, M., & Mohajeri-Tehrani, M. R. (2012). Nurses' role in diabetic foot prevention and care; a review. *Journal of Diabetes & Metabolic Disorders*, 11(1), 24.
6. American Diabetes Association (2011). Diabetes Statistics. Retrieved from <http://www.diabetes.org/diabetesbasics/diabetes-statistics/>
7. Schaper, N. C., Apelqvist, J., & Bakker, K. (2003). The international consensus and practical Guidelines on the management and prevention of the diabetic foot. *Current diabetes reports*, 3(6), 475-479.
8. Benjamin, E. M., Schneider, M. S., & Hinchey, K. T. (1999). Implementing practice guidelines for diabetes care using problem-based learning. A prospective controlled trial using firm systems. *Diabetes Care*, 22(10), 1672-1678.
9. Pogach, L.M., Brietzke, S.A., Cowan, C.L., Conlin, P., Walder, D.J., Sawin, C.T.

- (2004). Development of Evidence-Based Clinical Practice Guidelines for Diabetes. The Department of Veterans Affairs/Department of Defense Guidelines Initiative. *Diabetes Care* 27(2), B82-B89.
10. Nathan, D. M., Buse, J. B., Davidson, M. B., Ferrannini, E., Holman, R. R., Sherwin, R., & Zinman, B. (2009). Medical management of hyperglycemia in type 2 diabetes: a consensus algorithm for the initiation and adjustment of therapy. A consensus statement of the American Diabetes Association and the European Association for the Study of Diabetes. *Diabetes care*, 32(1), 193-203.
11. Fonseca, V., & Clark, N. G. (2006). Standards of medical care in diabetes response to power. *Diabetes care*, 29(2), 476-477.
12. American Diabetes Association. (2014). Standards of medical care in diabetes—2014. *Diabetes Care*, 37(Supplement 1), S14-S80. Retrieved from http://care.diabetesjournals.org/content/37/Supplement_1/S14.full.pdf+html?sid=8ef02134-ed74-4c0a-94ea-66347b48dfcb
13. Khanolkar, M. P., Bain, S. C., & Stephens, J. W. (2008). The diabetic foot. *Quarterly journal of Medicine*, 101(9), 685-695.
14. Giorda, C., Picariello, R., Nada, E., Tartaglino, B., Marafetti, L., Costa, G.,...Gnavi, R. (2012). The impact of adherence to screening guidelines and of diabetes clinics referrals on morbidity and mortality in diabetes. *PloS One* (7)4, 1-8.
16. Huntington, W. V., Covington, L. A., Center, P. P., Covington, L. A., & Manchikanti, L. (2011). Patient Protection and Affordable Care Act of 2010: reforming the health care reform for the new decade. *Pain Physician*, 14, E35-E67.

17. Fineout-Overholt, E., Levin, R. F., & Melnyk, B. M. (2004). Strategies for advancing Evidence based practice in clinical settings. *JONYSNA*, 35(2), 28-32.
18. O'Brien, K. E., Chandramohan, V., Nelson, D. A., Fischer, J. R., Stevens, G., & Poremba, J. A. (2003). Effect of a Physician-directed Educational Campaign on Performance of Proper Diabetic Foot Exams in an Outpatient Setting. *Journal of general internal medicine*, 18(4), 258-265.
19. Kirkman, M. S., Williams, S.R, Caffrey, H.H., & Marrero, D.G. (2002). Impact of a Program to Improve Adherence to Diabetes Guidelines by Primary Care Physicians. *Diabetes Care*, 25(11), 1946-1951.
20. Taft, S. H., & Nanna, K. M. (2008). What are the sources of health policy that influence nursing practice? *Policy, Politics, & Nursing Practice*, 9(4), 274-287.
21. Titler, M. G., Kleiber, C., Steelman, V. J., Rakel, B. A., Budreau, G., Everett, C. L. Q., ...&Goode, C. J. (2001). The Iowa model of evidence-based practice to promote quality care. *Critical care nursing clinics of North America*, 13(4), 497-509.

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name

and school Dr. JoAnn Manty. Capella University
