

PREDICTING DIABETIC FOOT ULCER RISK USING SENSORY
MONOFILAMENT TEST AMONG DIABETIC PATIENTS ATTENDING
NATIONAL INSTITUTE OF DIABETES AND ENDOCRINE GLANDS.

التنبؤ بقابلية التعرض لقرحة القدم السكري باستخدام الإختبار الحسى بسليكة الشعره الأحاديه لدى
مرضى السكرى بالمعهد القومى للسكر والغدد الصماء.

Thesis Proposal

Submitted for partial Fulfillment of Master Degree in Medical Surgical
Nursing

By

Amira Abd El azeem Mohammed

(B.Sc. Nursing)

Supervisors

Prof. Dr. Manal Moh. Mostafa

Prof.Dr. Atef Bassyouni

*Dr. Hanan Ahmed Elsebaee

Prof. &* Lecturer of Medical- Surgical Nursing

Faculty of Nursing Cairo University

2011

Introduction

Diabetes mellitus (DM) is a syndrome of chronic hyperglycemia due to relative insulin deficiency, resistance, or both. It affects more than 120 million people world-wide, and it is estimated that it will affect 220 million by the year 2020 (Kumar & Clark, 2005). Approximately 5% to 10% of people with diabetes have type 1 diabetes, in which the insulin-producing pancreatic beta cells are destroyed by an autoimmune process; as a result, they produce little or no insulin and require insulin injections to control their blood glucose levels. Type I diabetes is characterized by an acute onset, usually before age 30. Approximately 90% to 95% of people with diabetes have type II diabetes which results from decreased sensitivity to insulin (called insulin resistance) and impaired beta cell functioning resulting in decreased insulin production. There are two other types of diabetes gestational diabetes mellitus and diabetes mellitus associated with other conditions or syndromes (Smeltezer & Bare, 2008).

Diabetic patients are prone to many complications which are classified into macrovascular and microvascular complications (Black & Hawks, 2009). Diabetic neuropathy is one of the common microvascular complications of diabetes mellitus, in which nerves are damaged as a result of high blood sugar levels (hyperglycemia) (National Institute of Health NIH, 2010). The two major categories of diabetic neuropathy are autonomic neuropathy, which can affect nearly all body systems and sensory (peripheral) neuropathy, which affects the peripheral nervous system. About 60% to 70% of diabetic patients have sensory neuropathy which can lead to the loss of protective sensation (LOPS) in the lower extremities, this

significantly increase the risk for foot complications (Dirksen & O'Brien, 2007).

Diabetic foot ulcers are a common and much feared foot complication of diabetes, with recent studies suggesting that the lifetime risk of developing a foot ulcer in diabetic patients may be as high as 25% (Singh, Armstrong & Lipsky, 2005). Diabetic foot ulceration defined as full-thickness penetration of the dermis of the foot in a person with diabetes (Hunt, 2009). Because of poor circulation and neuropathy in the feet, cuts or blisters can easily turn into ulcers that become infected and won't heal and can lead to a loss of the lower extremities (amputation) (American College of Foot & Ankle Surgeons (ACFAS), 2009). Foot ulcer account for more than half of non-traumatic lower limb amputations in the diabetic patients population (Dang & Boulton , 2003).

Therefore the timely prevention and healing of diabetic ulcerations are fundamental for amputation prevention (Schwegler, 2002 & Wu, 2005).

A level of sensory loss that allows patients to hurt themselves without recognizing injury, is a major component of nearly all diabetic ulcerations (Armstrong & Wu, 2007). LOPS is determined by using an instrument called a Semmes-Weinstein 5.07/10 gram monofilament nylon wire (Abbott, 2002). Monofilament sensory test is a simple, noninvasive test used to identify people who have LOPS and who are at risk of developing ulcers. Touch-pressure sensation is evaluated by using a monofilament to measure cutaneous sensation in the feet. The sensory testing device is a 5.07 Semmes-Weinstein nylon monofilament mounted on a holder that has been

standardized to deliver a 10 gram filament force when properly applied (National Health and Nutrition Examination Survey 2001). Insensitivity to a 10-g Semmes-Weinstein monofilament has been shown to greatly increase the risk for diabetic foot ulcers that can lead to amputation (Dirksen & O'Brien, 2007). Therefore, the study will be conducted to predict the diabetic foot ulcer risk using sensory monofilament test among diabetic patients.

Significance of the Study

In 2010, the worldwide prevalence of diabetes was estimated to be 6.4% of the population aged between 20-79 years. By 2030, an increase up to 7.7% is predicted in this group (Beeckman, Duaso & Tremlett, 2011). Also Statistics and Medical Records Department at Kasr El Aini Hospital in Egypt revealed that the number of the inpatients and outpatients diabetics from 2006 until 2010 has been increased as from 10606 pts. at 2006 to 15202 pts. at 2010.

The rising prevalence of diabetes worldwide will mean an increasing prevalence of complications such as diabetic foot ulcer (Shaw, 2010). It is estimated that 15% of diabetics develop a foot ulcer within their lifetime and that up to 70% of all non-traumatic amputations in the world occur in diabetics and every 30 seconds a lower limb lost occurs among them. Many of these amputations which are preceded by a foot ulcer can be prevented by 85% (Sheikh, Jamil & Nawaz, 2010). Therefore, the study will be conducted to predict diabetic foot ulcer risk in diabetic patients using sensory monofilament test.

Aim of the study

The aim of the current study is to predict the diabetic foot ulcer risk using sensory monofilament test among diabetic patients attending The National Institute of Diabetes and Endocrine Glands.

Hypotheses

- The sensory monofilament test may predict the diabetic foot ulcer risk among diabetic patients.

Subjects and methods

Study design:

Cohort study design will be utilized in the present study to predict the diabetic foot ulcer risk among diabetic patients using sensory monofilament test.

Setting:

Outpatient clinics at International Institute of Diabetes and Endocrine Glands.

Sampling:

A convenient sample of adult male and female patients, between 30 and 60 years old, with type 2 diabetes mellitus, have peripheral palpable pulse, will be recruited for this study at the period of six months; patients with diabetic foot ulcer will be excluded from this study.

Tools:

Data will be collected utilizing the following two tools:

Tool I : interviewing questionnaire schedule which cover socio-demographic profile such as age, gender, occupation, level of education, marital status and residence of the patient and the related medical data such as previous and present medical regimen treatment. This sheet will be designed by the researcher.

Tool II: Neurovascular foot assessment sheet to evaluate neurovascular condition of the foot will be designed by the researcher after extensive literature review this tool will include monofilament test, assessing foot deformity, assessing skin condition (color, temperature, and capillary refill), peripheral pulses, nails condition, edema and motion.

Validity

Content validity was reviewed and determined by a panel of seven expert professors in Medical Surgical Nursing specialty.

Pilot study

10% of the sample will be taken to ensure the validity of the proposed tools for collection of data. Feedback from the pilot study was to refine the items of different tools. All items of the tool were ensured for clarity, objectivity, reliability, feasibility of the study tools, So that necessary modification will be done and to determine the time required for filling the sheet.

Procedure

Once official permission was obtained from the director of National Institute of Diabetes and Endocrine Glands, the researcher contacted subjects individually, and socio-demographic data (tool I) will be obtained from the participants then the sensory monofilament test(tool II) will be done for the participants then the test results will be obtained which will determine the risk category for occurrence of diabetic foot ulcer for each patient. After three months follow up for occurring or not occurring of diabetic foot ulcer for these patients will be done, and after another three months another follow up will be done. Pilot study sample will be excluded from the study sample

Ethical considerations

An official permission to conduct the study will be obtained from the directors of outpatient clinics at The National Institute of Diabetes and Endocrine Glands. In addition, a verbal consent will be obtained from each participating patient. The consent will be taken from patients or from their legal guardians. As well as voluntary participation, confidentiality and anonymity of the subjects will be assured.

Once permission is granted to proceed with the proposed study, each patient will be interviewed individually to explain the nature and purpose of the study and to fill out socio-demographic data sheet(tool I) and neurovascular foot assessment sheet((tool II)

The protocol, tools and the informed consent will be reviewed and granted by the faculty ethical committee.

Statistical Design

The collected data will be summarized, analyzed and tabulated. Statistical analysis will be performed through descriptive and inferential statistics to test for differences among the study and control subjects, using the statistical package for the social sciences (SPSS) program.

References

Kumar,P.,&Clark,M.,(2005).Clinical Medicine.(6th ed.) Philadelphia. Sounders Co.,pp.1101.

Smeltezer,S.C., & Bare,B.G., (2008).Brunner and Suddarth's Textbook of Medical-Surgical Nursing. (10th ed.) Philadelphia: J.B. Lippincott Co., pp. 1151.

Black,M.J.,&Hawks,J.H.,(2009).Medical-Surgical Nursing Clinical Management for Positive Outcomes.(8th ed.)USA. Sounders Co.,PP.1101.

National Institute of health(NIH) (2010). Diabetic neuropathy.

Available at <http://www.nlm.nih.gov/medlineplus/ency/article/000693.htm>
Net18 june2011.

O'Brien, P.G & Dirksen, SH. R. (2007) Medical Surgical Nursing Assessment and Management of Clinical Problems.(7th ed.) USA, Mosby, p.p 1285-1286.

Singh, N, Armstrong, D.G.& Lipsky, B.A. (2005). Preventing foot ulcers in patients with diabetes. JAMA 293:217–228

Available at [http:// www.diabetologia-journal.org](http://www.diabetologia-journal.org) .Net May 2011.

Hunt,D.(2009). Diabetes: foot ulcers and amputations available at http://clinicalevidence.bmj.com/ceweb/conditions/dia/0602/0602_backgro und.jspupdated in2011 Net june 2011

American College of Foot and Ankle Surgeons (ACFAS),(2009).Diabetic Complications and Amputation Prevention.Available at: [.http://www.footphysicians.com/footankleinfo/diabetic-amputations.htm](http://www.footphysicians.com/footankleinfo/diabetic-amputations.htm)Net May 2011

Dang, C.N,& Boulton, A.J.(2003). Changing perspectives in diabetic foot ulcer management. *Int J Low Extrem Wounds*, 2:4–12.Available at www.ncbi.nlm.nih.gov/pmc/articles/PMC1994045 .Net may 2011.

Schwegler, B.&Boni, T. et al.(2002). Practical management of diabetic foot. *Ther Umsch*, 59:435–42.Available at: www.ncbi.nlm.nih.gov/pmc/articles/PMC1994045.Net May 2011

Wu, S.C, et al.(2005). The pivotal role of offloading in the management of neuropathic foot ulceration. *Curr Diab Rep*, 5:423–9.Available at: www.ncbi.nlm.nih.gov/pmc/articles/PMC1994045.Net May 2011.

Armstrong, D.G.& Wu, S.C,et al.(2007). Vascular Health and Risk Management.Available at: www.ncbi.nlm.nih.gov/pmc/articles/PMC1994045.Net May2011.

Abbott, C.A.& Carrington, A.L., et al.(2002). The North-West Diabetes Foot Care Study: incidence of, and risk factors for, new diabetic foot ulceration in a community-based patient cohort. *Diabet Med*,19:377–84. Available at: www.ncbi.nlm.nih.gov/pmc/articles/PMC1994045.Net May 2011.

National Health and Nutrition Examination Survey.(2001). Lower Extremity Disease Procedures Manual.Available at: <http://www.cdc.gov/nchs/data/nhanes/le.pdf>.Net June 2011.

Beeckman,D., Duaso,M., & Tremlett,J.(2011). Diabetic foot care: a step forward?, Br J Nurs.(7):398-399.Available at:<http://lib.bioinfo.pl/pmid> .Net June 2011.

Sheikh,M.A., Jamil,A.& Nawaz,H.,(2010). Advanced Glycation End-products and Foot Ulceration in Type 2 Diabetic Patients: A Case Control Study.H Ussain et al. / Int. J. Agric. Biol., Vol. 12, No.1 Available atwww.fspublishers.org Net June 2011.