RISK FACTORS FOR LOWER EXTREMITY AMPUTATION AMONGST ADULT DIABETIC PATIENTS SEEN AT MULAGO HOSPITAL

By

DR. YASIN SEKAMATTE, MBChB (Mak)

Reg. No: 2008/HD11/13699U

A DISSERTATION SUBMITTED TO THE DIRECTORATE OF RESEARCH AND GRADUATE TRAINING AS PARTIAL FULLFILMENT OF THE REQUIREMENTS FOR THE AWARD OF A DEGREE OF MASTER OF MEDICINE IN ORTHOPEDIC SURGERY OF MAKERERE UNIVERSITY, KAMPALA

August, 2014
DECLARATION

I hereby declare to the best of my knowledge that all the work in this dissertation has not been presented for any award in any institution and has never been published anywhere. All of it is original unless otherwise here in stated.

Date;

Investigator: ____________________________ Signature and date: ____________________________

Yasin Sekamatte

I have submitted this dissertation for examination with the approval of the following supervisors

Name: ____________________________ Signature and Date: ____________________________

Dr. Geoffrey Madewo

Dr. Edrisa Mutebi

Dr. Erisa Mwaka Sabakaki

02/05/14
ACKNOWLEDGEMENTS

First, I thank the Almighty God who has blessed me with the gift of life, the opportunity and ability to accomplish this academic endeavor.

I wish to extend my sincere gratitude to the following people for all the assistance and support that they have rendered to me, to make this work a success. To all, thank you very much and may the Lord reward you abundantly.

My supervisors Dr. Geoffrey Madewo, Dr Edrisa Mutebi and Dr Erisa Mwaka who spent their valuable time guiding me and reading the several drafts of the proposal and dissertation.

I am so grateful to the head of department, surgeons, doctors and all staff in the department of orthopedics and the endocrinology unit for the consistent support and patience they exhibited during the process of making this work.

I thank all my fellow classmates for the friendship and support offered during my entire stay and making completion of this book possible.

Am extremely thankful to my parents, Mr. Kiwanuka Abdallah and Mrs. Kiwanuka Hasfa(RIP), brothers and sisters for their emotional and financial support, may God reward all your efforts.
DEDICATION

I dedicate this work to my mentor Dr Jacinto Amandua for the inspiration and guidance to my life as a hardworking and patient medical professional.

I also dedicate it to my parents Mr. Kiwanuka Abdallah and Mrs. Kiwanuka Hasfa (RIP) for the love, support and care they have always given to me.

Lastly, to my beloved wife Mrs. Jalia Sekamatte and children; Hanan, Huda, Hindu and Hyrum.
TABLE OF CONTENTS

DECLARATION ............................................................................................................. Error! Bookmark not defined.
TABLE OF CONTENTS .................................................................................................... v
LIST OF FIGURES ........................................................................................................... vii
ABBREVIATIONS .......................................................................................................... ix
OPERATIONAL DEFINITIONS ....................................................................................... x
ABSTRACT ..................................................................................................................... xi

CHAPTER ONE: INTRODUCTION ............................................................................. 1

1.1 BACKGROUND ........................................................................................................ 1
1.2 PROBLEM STATEMENT ......................................................................................... 2
1.3 STUDY JUSTIFICATION ....................................................................................... 3
1.4 RESEARCH QUESTION ....................................................................................... 3
1.5 OBJECTIVES ........................................................................................................ 3
1.6 CONCEPTUAL FRAMEWORK ............................................................................. 5
1.7 RESEARCH HYPOTHESIS ................................................................................... 6

CHAPTER TWO: LITERATURE REVIEW ................................................................... 7

2.1 Introduction ........................................................................................................... 7
2.2 Magnitude of the problem .................................................................................... 7
2.3 Factors associated with Lower Extremity Amputation in diabetic patients .......... 8
    2.3.1 Socio demographic factors ........................................................................ 8
    2.3.2 Clinical factors ............................................................................................ 8
    2.3.2.1 The role and assessment of Peripheral vascular disease in Diabetes related LEAs .. 8
    2.3.2.2 The role of diabetic neuropathy in LEA and its assessment ....................... 9
    2.3.2.3 Glyceamic control .................................................................................... 10
    2.3.2.4 Type and duration of Diabetes ............................................................... 10
    2.3.2.5 Hyperlipideamia .................................................................................... 11
    2.3.2.6 Hypertension ......................................................................................... 12
    2.3.2.7 Diabetic Foot ulcers ............................................................................. 12
    2.3.2.8 Body Mass Index .................................................................................. 12

CHAPTER THREE: METHODOLOGY ....................................................................... 14

3.1 Study design ........................................................................................................ 14
3.2 Study site ............................................................................................................. 14
3.3 Study duration .................................................................................................................................. 16
3.4 Study population ................................................................................................................................. 16
3.5 Eligibility criteria ................................................................................................................................. 17
3.6 Sample size .......................................................................................................................................... 18
3.7 Sampling procedure ............................................................................................................................ 19
3.8 Data collection tool ............................................................................................................................ 19
3.9 Measurements ....................................................................................................................................... 19
3.9.1 Independent variables .................................................................................................................... 20
3.9.2 Dependent variables ....................................................................................................................... 20
3.10 Data collection, management and analysis ....................................................................................... 21
3.10.1 Data collection procedure ........................................................................................................... 21
3.10.2 Data management ......................................................................................................................... 22
3.10.3 Data analysis .................................................................................................................................. 23
3.11 Quality assurance ............................................................................................................................... 24
3.12 Ethical considerations ....................................................................................................................... 24

CHAPTER FOUR: RESULTS .................................................................................................................. 26
  4.1 FINDINGS ........................................................................................................................................ 26

CHAPTER FIVE: DISCUSSION OF RESULTS ....................................................................................... 33
  5.1 DISCUSSION .................................................................................................................................... 33
  5.2 STUDY STRENGTHS ....................................................................................................................... 42
  5.3 STUDY LIMITATIONS ...................................................................................................................... 42

CHAPTER SIX: CONCLUSIONS AND RECOMMENDATIONS .............................................................. 44
  6.1 CONCLUSIONS ................................................................................................................................. 44
  6.2 RECOMMENDATIONS ...................................................................................................................... 44

REFERENCES ........................................................................................................................................... 45

APPENDICES .......................................................................................................................................... 51
  APPENDIX I: CONSENT FORM ........................................................................................................... 51
  APPENDIX II: TRANSLATED CONSENT FORM IN LUGANDA ...................................................... 54
  APPENDIX III: DATA COLLECTION FORM ........................................................................................ 59
  APPENDIX V: BUDGET .......................................................................................................................... 64
  JUTIFICATION OF THE BUDGET ........................................................................................................ 65
  APPENDIX VI: STUDY TIME TABLE .................................................................................................. 66
LIST OF FIGURES

Fig 1 Conceptual framework ........................................................................................................... 5

Fig 3 Percentage distribution by gender in the 2 groups .......................................................... 26
LIST OF TABLES

Table 1: A comparison of socio-demographic characteristics between the cases and controls.... 27
Table 2: Baseline clinical characteristics of the study participants at enrollment .................. 28
Table 3: Laboratory parameters; Glycemic control and lipid profile characteristics.............. 30
Table 4: Multivariate analysis of factors associated with LEA in diabetic patients.............. 31
<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>DFU</td>
<td>Diabetic foot ulcer</td>
</tr>
<tr>
<td>DM</td>
<td>Diabetes mellitus</td>
</tr>
<tr>
<td>IQR</td>
<td>Interquartile range</td>
</tr>
<tr>
<td>LEA</td>
<td>Lower extremity amputation</td>
</tr>
<tr>
<td>MHDC</td>
<td>Mulago hospital diabetic clinic</td>
</tr>
<tr>
<td>OR</td>
<td>Odds ratio</td>
</tr>
<tr>
<td>SPSS</td>
<td>Statistical package for social sciences</td>
</tr>
<tr>
<td>TCNS</td>
<td>Toronto clinical neuropathy score</td>
</tr>
</tbody>
</table>
OPERATIONAL DEFINITIONS

Adult: Any person aged 18 years and above.

Diabetic foot ulcer: Refers to any wound on a lower extremity of a diabetic patient lasting at least 14 days.

Neuropathy: Is defined as presence of symptoms and signs attributed to diabetes exceeding a score of five on the TCNS.

Type I DM: The type of DM where insulin treatment is initiated within two years of diagnosis and continued for 3 or more months, or patients diagnosed with the disease before 30 years of age (1).

Type II DM: The type of DM in patients diagnosed over 40 years of age, or who are maintained on diet or oral hypoglycemic therapy for > 2 years after initial diagnosis or for at least 3 months at any later point (1).
ABSTRACT

Background

There is an increasing burden of diabetes and its complications worldwide. Many of these, especially Lower Extremity Amputation (LEA) are so debilitating and costly.

LEAs are a preventable health burden and knowledge on their risk factors is necessary for designing and implementing appropriate and cost effective strategies. However, there is no sufficient information available on the risk factors for diabetes related lower extremity amputation in our environment.

Objectives

The objective of the study was to determine the risk factors associated with Lower Extremity Amputation in adult diabetic patients seen at Mulago hospital.

Methods

An unmatched case control study was conducted between August 2013 and January 2014 amongst 128 adult diabetic patients seen at Mulago Hospital.

Cases were 45 adult diabetic patients in whom a decision to carry out a LEA had been made by an orthopedic surgeon during the study period and controls were 83 adult diabetic patients at Mulago hospital selected from those with no indication for amputation during the study period.

Measurements included; socio demographic variables, type and duration of Diabetes Mellitus, history of Diabetic ulcer, blood pressure, BMI, level of Glycosylated haemoglobin (HbA1c), peripheral neuropathy and lipid profile.
Results

Significant risk factors for lower limb amputation were a high level of HbA1c (adjusted OR: 5.60; CI: 1.427-21.992) and history of diabetic foot ulcer (adjusted OR: 6.10; CI: 0.879-9.716).

Diabetic patients with a duration of disease more than 10 years and peripheral neuropathy also had increased but not statistically significant risk association with LEA (adjusted OR: 2.92; CI: 0.879-9.716 and adjusted OR: 3.02; CI: 0.848-10.802 respectively).

Age and sex differences did not significantly influence the risk for amputation in this study (OR: 1.82 (0.538-6.136) P.value 0.335 for age category 40-59 years, OR: 3.65 (1.051-12.685) P.value 0.041* for those 60 years and above and OR: 0.756 (0.357-1.602) P.value 0.466 for male sex).

Conclusions

Those most likely to undergo LEA amongst adult diabetic patients at Mulago hospital were those with poor glyceamic control and history of diabetic foot ulcer. Such patients had an almost 10-fold increase in the risk for amputation considering adjusted odds ratios. They were also likely to have peripheral neuropathy and diabetes for more than 10 years.

Such patients considered to be at high risk of LEA should be closely monitored and aggressively treated to help avert the unwanted possibility of LEA in the Mulago hospital health care system.