

**FOOT CARE KNOWLEDGE AND PRACTICE
AMONG TYPE 2 DIABETES MELLITUS PATIENTS
IN HOSPITAL UNIVERSITI SAINS MALAYSIA**

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**DISSERTATION SUBMITTED IN PARTIAL
FULFILLMENT OF THE REQUIREMENTS FOR THE
DEGREE OF MASTER OF MEDICINE
(ORTHOPAEDIC)**



TM

UNIVERSITI SAINS MALAYSIA

2021

**FOOT CARE KNOWLEDGE AND
PRACTICE AMONG TYPE 2 DIABETES
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UNIVERSITI SAINS MALAYSIA**

FROM THE YEAR 2019 TO 2020

STUDY VENUE: HOSPITAL UNIVERSITI SAINS MALAYSIA

ACKNOWLEDGEMENT

I would like to express my deepest gratitude and appreciation to my supervisors, Dr Emil Fazliq Mohd (Department of Orthopaedic), for being a dedicated mentor, supportive lecturer and respected model to me. This study was carried out in year 2019-2020 at Hospital Universiti Sains Malaysia. This study could have not been completed without his continuous support and encouragement.

I would like to express my appreciation towards Dr Kueh Yee Cheng from Department of Biostatistics and Research Methodology, USM and Dr. Chen Xin Wee from Epidemiology and Biostatistics, Department of Public Health, UiTM for their guidance on statistical planning and analysis.

Last but not least, I would like to extend my sincere gratitude to my supportive family, colleagues, The Human Research Ethics Committee of USM (JEPeM), Diabetic Clinic and Orthopaedic Ward staff nurses whom had indirect contribution to this study.

Thank you.

Khaw Yam Chuan

TABLE OF CONTENTS

CONTENTS	PAGE
TITLE	i
ACKNOWLEDGEMENT	ii
TABLE OF CONTENTS	iii - iv
ABSTRAK (BAHASA MALAYSIA)	v - vi
ABSTRACT (ENGLISH)	vii - viii
CHAPTER 1: INTRODUCTION	
1.1 Introduction	2-3
1.2 Objective	4
CHAPTER 2: STUDY PROTOCOL	
2.1 Study protocol	6 - 52
2.2 Ethical approval letter	51 - 53
CHAPTER 3: MANUSCRIPT	
3.1 Title page	55
3.1 Abstract	56 - 57
3.2 Introduction	58 - 59
3.3 Methodology	60 - 62
3.4 Results	63 - 64
3.5 Discussion	65 - 67
3.6 Conclusion	68

3.7	References	69 - 71
3.8	Tables	72 – 74
3.9	Guidelines/Instruction to Authors of selected Journal	75 - 78

CHAPTER 4: APPENDICES

4.1	Additional Figures and Tables	80 - 82
4.2	Raw Data on SPSS Soft Copy	83

ABSTRAK

Pengenalan:

Ulser kaki diabetes (UKD) adalah penyakit kronik yang menyebabkan kematian, morbiditi dan komplikasi seperti amputasi anggota kaki kepada pesakit diabetes di seluruh dunia, . Kajian ini bertujuan untuk mengetahui tahap pengetahuan dan amalan penjagaan kaki di kalangan pesakit diabetes mellitus jenis 2 (DMJ2) serta untuk mengetahui hubungan antara pengetahuan dan amalan penjagaan kaki dengan UKD.

Metodologi:

Kajian keratan rentas dilakukan di Hospital Universiti Sains Malaysia dengan subjek yang direkrut dari Mei 2019 hingga Jun 2020. Mereka direkrut menggunakan kaedah persampelan mudah. Semua dinilai untuk maklumat demografi, indeks jisim badan, ujian monofilamen untuk neuropati dan ujian bukan invasif untuk penyakit vaskular periferal dijalankan oleh pegawai perubatan yang terlatih. Pengetahuan dan amalan penjagaan kaki diperoleh dengan menggunakan soal selidik yang disahkan dan dikendalikan oleh subjek sendiri.

Keputusan:

Di antara 134 pesakit DMJ2, 56 (42.8%) pesakit mempunyai UKD. Umur min (SD) peserta kajian adalah 58.3 (9.9) tahun. Seramai 113 (84.3%) pesakit DMJ2 mempunyai pengetahuan penjagaan kaki yang baik, dan 85 (63.4%) pesakit DMJ2 mempunyai latihan yang baik. Majoriti pesakit DMJ2 dengan UKD mempunyai pengetahuan penjagaan kaki yang baik (87.5%), tetapi amalan yang buruk (62.5%); sementara pesakit DMJ2 tanpa UKD mempunyai pengetahuan yang baik (82.1%) dan amalan yang baik (82.1%). Model Multiple Logistic Regression menunjukkan bahawa amalan penjagaan kaki adalah faktor bebas yang berkaitan dengan UKD ketika usia, neuropati diabetes periferal dan BMI diselaraskan, dengan anggaran

nisbah kemungkinan disesuaikan 0.242 (95% CI: 0.077, 0.761). Pengetahuan penjagaan kaki tidak banyak dikaitkan dengan peningkatan risiko UKD ketika pengganggu lain diselaraskan (AOR: 1.347, 95% CI: 0.296, 6.741).

Kesimpulan:

Amalan penjagaan kaki yang lemah dikaitkan dengan UKD. Selain mempunyai pengetahuan tentang penjagaan kaki, pematuhan terhadap pendidikan mengenai kebersihan kaki, penjagaan kuku dan kasut yang betul sangat disarankan untuk mencegah UKD serta mengurangkan kadar amputasi anggota badan. Kami mencadangkan agar pematuhan amalan penjagaan kaki dinilai dan diperkuat pada setiap lawatan pesakit DMJ2 ke kemudahan rawatan kesihatan.

Kata Kunci: ulser kaki diabetes, diabetes mellitus jenis 2, pengetahuan, amalan

ABSTRACT:

Introduction:

Diabetic foot ulcer (DFU) is a chronic disease which causes significant mortality and morbidity to diabetic patients worldwide, especially complication like lower limb amputation. This study aims to determine the level of foot care knowledge and practice among type 2 diabetes mellitus (T2DM) patients and to determine relationship of foot care knowledge or practice with DFU.

Materials and Methods:

A cross sectional study was conducted in Hospital Universiti Sains Malaysia with subjects recruited from May 2019 to Jun 2020. They were recruited using convenient sampling method. Foot care knowledge and practice were obtained using a validated self-administered questionnaire. All patients were assessed for body mass index, monofilament testing for neuropathy and ankle brachial index for arterial insufficiency by single trained medical personnel.

Results:

Among 134 T2DM patients, 56 (42.8%) patients had DFU. The mean (SD) age of the study participants was 58.3 (9.9) years. A total of 113 (84.3%) T2DM patients had good foot care knowledge, and 85 (63.4%) T2DM patients had good practice. Majority of the T2DM patients with DFU had good foot care knowledge (87.5%), but poor practice (62.5%); while T2DM patients without DFU had good knowledge (82.1%) and good practise (82.1%). The Multiple Logistic Regression model showed that the foot care practice was an independent factor associated with DFU when age, peripheral diabetic neuropathy and BMI were adjusted, with estimated adjusted odds ratio 0.242 (95% CI: 0.077, 0.761). The foot care knowledge was not significantly associated with an increased risk of DFU when other confounders were adjusted (AOR: 1.347, 95% CI: 0.296, 6.741).

Conclusion:

Poor foot care practice was significantly associated with DFU. Apart from having foot care knowledge, adherence to education regarding foot hygiene, nail care and proper footwear is strongly recommended to prevent DFU and lower limb amputation. We suggest that the foot care practice adherence be evaluated and reinforced during every visit of T2DM patients to the health care facilities.

Keywords: diabetic foot ulcer, type 2 diabetes mellitus, knowledge, practice

CHAPTER 1

INTRODUCTION

1.1 Introduction

Diabetes mellitus is a chronic disease that happens when there is an increase in blood glucose concentration (International Diabetes Federation, 2017). It has become a common non-communicable disease in the world. Diabetes mellitus is a worldwide health problem. As indicated by International Diabetes Federation information, 584.25 million individuals are living with diabetes around the world in 2017 and the number is expected to increase to 693 million in 2045 (International Diabetes Federation, 2017). Malaysia National Health Morbidity Survey (NHMS) 2015 reported that prevalence of diabetes mellitus in age group of 18 years and above is 17.5% and is in an increasing trend, compared to NHMS 2011 reported 15.2% (Institute for Public Health, 2011; Institute for Public Health, 2015).

Type 2 Diabetes Mellitus (T2DM) is a global disease with multiple serious complications. Diabetic foot ulcer (DFU) is one of the foremost common complications of diabetes. Life-time incidence for people with diabetes mellitus to develop diabetic foot ulcer is 25% (Singh *et al.*, 2005). Diabetic foot ulcer is defined as full-thickness skin break at least to Wagner classification stage 1 & occurs distal to malleoli. (Abbott *et al.*, 2002)

Diabetic foot ulcer is a major burden to diabetes mellitus patients because the cost of care in diabetic foot ulcer is very high (Boulton *et al.*, 2005). Diabetic patients with diabetic foot ulcers will visit the emergency department more frequently, have more hospital admissions and longer stays at hospital (Driver *et al.*, 2010). The cost of caring for people with diabetic foot ulcers is 5.4 times higher within the year of the primary episode and 2.6 times higher in the year of the second episode, compared to the diabetic patient without a diabetic foot ulcer (Driver *et al.*, 2010)

Amputation is a serious complication of diabetic foot ulcer. People with diabetes mellitus have ten to twenty times higher rate of amputation compare to people without diabetes mellitus(World Health Organization, 2016). The prevalence of lower limb amputation in Malaysia is 11%(Feisul and Azmi, 2013). A study done in Kelantan, Malaysia found that 66 % of the patients who experienced amputation were diabetic and associated with diabetic foot conditions, while 34% were not known to have diabetes mellitus. (Yusof *et al.*, 2007).

In India, diabetic people with low knowledge and low practice have a higher incidence diabetic foot ulcer(Chellan *et al.*, 2012).A study done in Poland revealed that there was no significant difference of knowledge level between diabetic population at high risk of develop foot ulcer and low risk of develop foot ulcer group, but foot care practice within the high-risk group was better than the low risk group(Pollock *et al.*, 2004).Till date, no local research done to show any evidence influence of foot care knowledge or practice on diabetic foot ulcer. In Iran, a study done to reveal that simple face to face education is an effective method to boost foot care knowledge and practice among type 2 diabetic patients(Vatankhah *et al.*, 2009).Therefore, education plays an important role to improve knowledge and practice after knowing the status of knowledge or practice. The objective of this study is to determine the level of knowledge and practice among diabetic patient with or without diabetic foot ulcer. Also, we will like to observe any association of foot care knowledge or practice with diabetic foot ulcer. This information will be a vital step to enhance the efforts given by our health care system to prevent diabetic foot ulcer. This information is additionally useful for future planning or intervention program to prevent diabetic foot ulcer.

1.2 Objectives

General Objective

To determine the association of foot care knowledge & practice on diabetic foot ulcer among T2DM

Specific Objectives:

- 1 To determine the percentage of good foot care knowledge among T2DM patients
- 2 To determine association between foot care knowledge and diabetic foot ulcer
- 3 To determine association between foot care practice and diabetic foot ulcer

CHAPTER 2

STUDY PROTOCOL

2.1 STUDY PROTOCOL SUBMITTED FOR ETHICAL APPROVAL

DISSERTATION PROPOSAL

**TITLE: Foot Care Knowledge and Practice
among Type 2 Diabetes Mellitus Patients in
Hospital Universiti Sains Malaysia**

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1. INTRODUCTION AND STUDY BACKGROUND

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Amputation is a serious complication of diabetic foot ulcer. People with diabetes mellitus have ten to twenty times higher rate of amputation compare to people without diabetes mellitus(World Health Organization, 2016). The prevalence of lower limb amputation in Malaysia is 11%(Feisul and Azmi, 2013). A study done in Kelantan, Malaysia found that 66 % of the patients who experienced amputation were diabetic and associated with diabetic foot conditions, while 34% were not known to have diabetes mellitus. (Yusof *et al.*, 2007).

In India, diabetic people with low knowledge and low practice have a higher incidence diabetic foot ulcer(Chellan *et al.*, 2012).A study done in Poland revealed that was no significant difference of knowledge level between diabetic population at high risk of develop foot ulcer and low risk of develop foot ulcer group, but foot care practice within the high-risk group was better than the low risk group(Pollock *et al.*, 2004).Till date, no local research done to show any evidence influence of foot care knowledge or practice on diabetic foot ulcer. In Iran, a study done to reveal that simple face to face education is an effective method to boost foot care knowledge and practice among type 2 diabetic patients(Vatankhah *et al.*, 2009).Therefore, education plays an important role to improve knowledge and practice after knowing the status of knowledge or practice. The objective of this study is to determine the level of knowledge and practice among diabetic patient with or without diabetic foot ulcer. Also, we will like to observe any association of foot care knowledge or practice with diabetic foot ulcer. This information will be a vital step to enhance the efforts given by our health system to prevent diabetic foot ulcer. This information is additionally useful for future planning or intervention program to prevent diabetic foot ulcer.

2. LITERATURE REVIEW

2.1 Overview of Diabetes Mellitus

Diabetes Mellitus is a serious chronic disease characterized by high blood sugar concentration that occur when the body unable to produce enough insulin or body not response to the insulin that produce (World Health Organization, 2016).

Diabetes Mellitus can be classified into 3 types : Type 1 diabetes, Type 2 diabetes and gestational diabetes (Atlas, 2017). Type 2 diabetes is the most common type of diabetes, it consists 90% among cases of diabetes(Holman *et al.*, 2015).

The global prevalence of diabetes has nearly doubled since 1980, increasing from 4.7% to 8.8% in the age group 20 to 79 years. Globally, there are 425 million people with diabetes in 2017, and this is estimated to increase to 629 million by 2045 (Atlas, 2017).

In South East Asia, estimates in 2017, there will be 82.0 million people living with diabetes, 8.5% of the adult population aged 20-79 years has diabetes(International Diabetes Federation, 2017). In Malaysia, the prevalence of diabetes mellitus among adults of 18 years and above has increase from 15.2 to 17.8%(Institute for Public Health, 2015). Malaysia National Health And Morbidity Survey 2015 reported the prevalence in Kelantan is 18.5%, which is higher than the overall prevalence of diabetes in Malaysia(Institute for Public Health, 2015). Diabetes Mellitus cause a significant mortality and morbidity worldwide.

The prevalence of diabetes mellitus is increasing in trend worldwide has cause a heavy impact and burden, especially diabetic related complication. Diabetic foot ulcer is one of the common complications of diabetes mellitus.

2.2 Diabetic foot problem and its burden among diabetes

The global prevalence of diabetic foot is 6.4%. (International Diabetes Federation, 2017).

Type 2 diabetes mellitus patients have a higher prevalence to develop diabetic foot compare to type 1 diabetes mellitus. Diabetic foot is more common in male diabetic patients compare to female diabetic patients. The prevalence of diabetic foot is high in India, 10.4% (Mehra *et al.*, 2008).

Diabetic foot ulcer is common among diabetic patient. 25% of diabetic patients in their life time will develop diabetic foot ulcer (Singh *et al.*, 2005). The annual risk of diabetic patient to develop diabetic foot ulcer is 1.0 to 1.4% (Singh *et al.*, 2005). In Malaysia, the prevalence of diabetic foot ulcer is 15% (Feisul and Azmi, 2013).

Amputation is one of the serious complications of diabetic foot. A lower limb or a part of lower limb amputation happen every 30 seconds in the world due to diabetes (Diabetes Atlas, 2017). Rate of amputation is 20 times higher in diabetes group compare to non-diabetic group (Moxey *et al.*, 2011). In India, about 10.5% of their diabetic foot patients underwent major amputations (Jain and Varma, 2012). The prevalence of lower limb amputation in Malaysia is 11% (Feisul and Azmi, 2013). A study done in Kelantan, Malaysia found that 66% of the patients who experienced amputation were diabetic and associated with diabetic foot conditions, while 34% were not known to have diabetes mellitus (Yusof *et al.*, 2007).

Diabetic foot ulcer causes significant cost to diabetic patient. An article by Ragnarsan Tennvall *et al.*, revealed that total costs for healing of infected ulcers not requiring amputation are around \$17,500, whereas the price for lower limb amputations are around \$30,000–\$33,500 and depending on the amputation level. (Ragnarson Tennvall and Apelqvist, 2004).

In United states, foot ulcers and infections are the most common reason for hospital admission among diabetic population (Ibrahim, 2017). The 12% of all diabetic hospital

admissions in Malaysia due to diabetic foot complications, while in all total hospital admissions at Hospital Kuala Lumpur is 17% (Ministry of Health, 2004)

Diabetic foot complication also affects the patient quality of life. In Malaysia, a study showed based on SFE36 questionnaire, patient's health related quality of life is affected by diabetic foot complication(Mazlina *et al.*, 2011).

2.3 Associated Risk Factors in Diabetic Foot Problem

The three most common causes of diabetic foot ulcer are trauma, neuropathy and deformity(Reiber *et al.*, 1999). However, diabetic peripheral neuropathy is main primary risk factor for diabetic foot ulcer(Ibrahim, 2017).

There are many other risk factors associated with development diabetic foot ulcer. In a study done in Pakistan showed that poor glycaemic control strongly corelates to incidence of diabetes foot lesion(Akbar and Bilal, 2004). Risk of lower extremity to develop ulcer increase 1.6 times with each 2% increase in HbA1c as well the risk of lower limb amputation will increase by 1.5 times(Akbar and Bilal, 2004). Poor glycaemic control also being reported as one of significant risk factors in a study done in Egypt (Hokkam, 2009)

Besides that, peripheral vascular disease also a risk factor of diabetic foot ulcer (Ministry of Health, 2004). A study in Egypt showed that peripheral vascular disease is one of the important risk factor for diabetic foot ulceration(Hokkam, 2009).

Sociodemographic factors also play an important role as risk factors for development and have been proven by a few studies. In Malaysia, a case control study revealed that age, smoking and race Malay or India are independent risk factors to develop diabetic foot ulcer (Misliza, 2009). In another local study showed that age and education level are independent risk factors for diabetic foot problems(Jamani, 2012). A research done in Iraq revealed that age, male, body mass index, smoking and low social class are risk factors for development of

diabetic foot abnormalities(Mansour and Imran, 2006). An article by Zou et al., showed that age, smoking, hypertension and dyslipidaemia are associated with the prevalence of diabetic at-risk foot(Zou *et al.*, 2015)

2.4 Natural history of diabetic foot

Diabetic foot is a chronic serious complication of diabetes mellitus. In Nigerian, the diabetic foot illness has been accounted for to happen after a mean time frame of 13 years from the diagnosis of diabetes(Ekere *et al.*, 2005).

There are 5 stages in natural history of diabetic foot ulcer: Stage 1 is normal foot, stage 2 is high risk foot, stage 3 is ulcerated foot, stage 4 is infected foot, stage 5 is necrotic foot (Edmonds, 2008). This covers whole spectrum of diabetic foot disease. In Stage 1 and stage 2 must emphasize on preventing the development of ulcer. Stage 3 is very important to manage the ulcer to prevent complication and stage 4 and 5 is managing with complication of foot ulcer (Edmonds, 2008).

2.5 Peripheral Diabetic Neuropathy

The prevalence of diabetic neuropathy is 16 to 66%(Boulton, 2000). Peripheral Diabetic neuropathy is a significant risk factor for developing diabetic foot ulcer(Ibrahim, 2017).

Pathogenesis of diabetic neuropathic is complicated and complex(Vallianou *et al.*, 2009). There are several mechanisms assumed contributed to the pathogenesis(Ziegler, 2006). Polyol pathway activation will lead to accumulation of sorbitol and fructose, depletion myo-inositol and eventually reduce Na-K ATPase activity(Ziegler, 2006). Another mechanism is accumulation of Advance Glycation End product (AGE) bind to a specific receptor in neuron or vessel causing oxidation stress and activation of nuclear factor- κ B(NF- κ B)(Vallianou *et al.*,

2009). Activation NF- κ B will increase level of reactive oxygen species. Hyperglycemia activate protein kinase C (PKC), especially its β II isoform through increased *de novo* synthesis of diacylglycerol (DAG)(Vallianou *et al.*, 2009). The elevated level PKC β will impair endoneurial blood flow(Vallianou *et al.*, 2009).

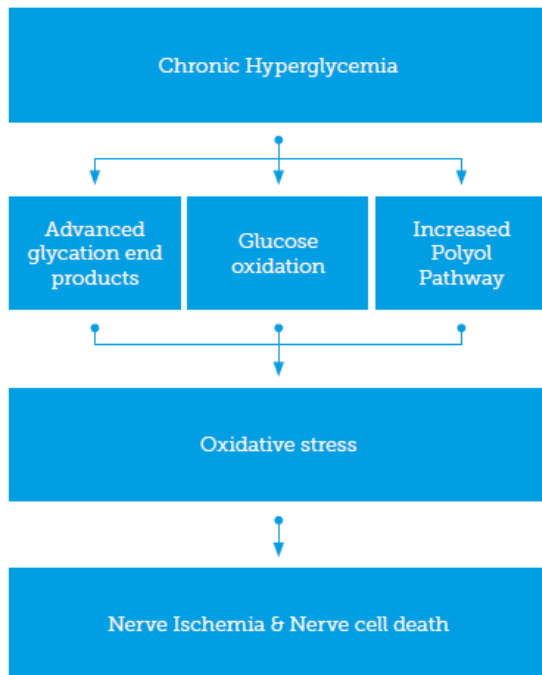


Figure 1: Hyperglycaemia leads to oxidation stress in diabetes, through AGE formation, glucose autooxidation and polyol pathway activation. AGE: Advance Glycation End product(Ibrahim, 2017)

Peripheral diabetic neuropathy affects sensory, motor and autonomic system nerves. Progressive loss of sensory neuropathy will cause diabetic patient loss of protective sensation of foot, causing the foot easy to get injured or ulceration.

Nerve conduction testing is an effective way to identify peripheral diabetic neuropathy because its rate of detection peripheral diabetic neuropathy is high(Kamei *et al.*, 2005).However, nerve conduction testing is expensive and time consuming, therefore not

suitable as a screening tool to detect peripheral diabetic neuropathy in outpatient setting(Perkins and Brill, 2003).

Currently, Semmes Weinstein monofilament test is a useful screening tool to detect diabetic peripheral neuropathy worldwide and a systemic review concluded that monofilament can achieve sensitivity of 90% or above(Feng *et al.*, 2009) provided to do in a correct method. A systemic review revealed that optimum effect of monofilament test can achieve by using 5.07/10 g monofilament to check the plantar aspects of the great toe, third, and fifth metatarsal head. Patient is classified as at risk if unable to detect one or more sites. Monofilament will be placed perpendicularly each site of foot until monofilament buckles and hold for 2 seconds. Area of callus will be avoided. Respondents need to close their eye. Respondents will respond “yes” if they can feel it or “no” if they cannot feel it when the monofilament applied at the particular site(Ibrahim, 2017)

2.6 Peripheral Vascular Disease

In United State, the 1999-2000 National Health and Nutrition Examination Survey (NHANES) revealed that the prevalence of peripheral arterial disease was 4.5% within the general population but increased to 9.5% in diabetic population(Selvin and Erlinger, 2004).

Computer Tomography Angiography(CTA) or Magnetic Resonance Angiography(MRA) are vital tools for vascular assessment. However, these methods are time consuming and costly, therefore not used as routine screening tool for peripheral arterial disease(Rofsky and Adelman, 2000).

Ankle Brachial Index (ABI) is used a as screening tool to detect peripheral arterial disease(Ibrahim, 2017). A study reported ABI has a sensitivity of 95%, and specificity of 99%(Atlas, 2015). ABI is an easy, simple and high reproducible method to diagnose peripheral

arterial disease(Boulton *et al.*, 2008). ABI is obtained by dividing the higher of the ankle pressure (higher of dorsalis pedis or posterior tibialis) by higher brachial systolic pressures. Ankle pressure (dorsalis pedis or posterior tibial artery) is measured by using handheld doppler. ABI > 0.9 is normal. Peripheral arterial disease is defined when ABI ≤ 0.9. ABI ≥ 1.30 means vascular calcification and arterial elasticity is impaired(Ibrahim, 2017).

2.7 Diabetic Wound Classification

Wagner Classification for diabetic wound was introduced by Wagner in 1981(Lavery *et al.*, 1996). This classification is based on wound depth. There are 6 grades in Wagner classification.

Wagner Classification	
Grade	Lesion
0	Intact skin
1	Superficial Ulcer
2	Deep ulcer to tendon, bone, joint
3	Deep ulcer with abscess or Osteomyelitis
4	Forefoot gangrene
5	Whole foot gangrene

2.8 Foot care knowledge and practise among diabetes:

Education is one of the effective methods to prevent diabetic foot ulcer, thus able to prevent amputation (Singh *et al.*, 2005). Patient education can improve short term knowledge(Singh *et al.*, 2005). However, with just foot care knowledge alone, without practising foot care, it is not sufficient to prevent diabetic foot ulcer. Good foot care knowledge and practice are effective in preventing diabetic foot complication(Muhammad-Lutfi *et al.*, 2014).

In Pakistan, a study reported only 29.3% diabetic patients had good knowledge of foot care and 14% diabetic patients had good practice of foot care, which revealed a serious condition(Hasnain and Sheikh, 2009). A study done in Sri Lanka showed that patients with diabetic foot ulcer had satisfactory foot care knowledge, but their foot care practices were unsatisfactory(Jeewanta, 2011). In India, a study comparing foot care knowledge and practice between diabetic patient with or without diabetic foot ulcer revealed that both components are poor in diabetic foot ulcer group(Chellan *et al.*, 2012). This study conducted in oversea countries which may differ to local population. However, till date, no local study was done comparing foot care knowledge and practice between diabetic patient.

Currently, there are limited local study to determine the knowledge and practice among diabetic patient, especially in Kelantan. In Terengganu, a study showed that patients who admitted for diabetic foot complication had poor foot care knowledge and practice(Muhammad-Lutfi *et al.*, 2014). Another study done in UKM Medical Centre, assessing foot care knowledge and practice among diabetic elderly, revealed that most patients had good foot care knowledge (90.1%), but a few patients had a good foot care practice (6.2%)(Hussein SZ, 2018).

3. JUSTIFICATION OFSTUDY:

Diabetic foot ulcer is a global disease causing significant morbidity and mortality to diabetic patient, especially complication of amputation. Diabetic foot ulcer also causes heavy economic burden to diabetic patient, as well as health related quality of life being affected. To prevent foot ulcers and its complication, patient foot care awareness should be translated to proper practice foot care (Al Zahrani and Qadi, 2011).

The association of foot care knowledge or practices with diabetic foot ulcer remain ambiguous. In India, a study found out that diabetic patient with poor foot care knowledge and

practise have high incidence of diabetic foot ulcer(Chellan *et al.*, 2012).A study done in Poland revealed that was no significant difference of knowledge level between the diabetic population at high risk of developing foot ulcer and low risk of developing foot ulcer group, but foot care practice in the high-risk group was better than the low risk group(Pollock *et al.*, 2004). Till date, no local study has done to show the influence of foot care knowledge or practice on diabetic foot ulcer. By conducting this study able to provide local evidence of association between foot care knowledge level or practise with diabetic foot ulcer incidence. This information will be a vital step to enhance the efforts given by our health care system to prevent diabetic foot ulcer, and in future planning for intervention.

In Terengganu, a study showed that patients who admitted for diabetic foot complication had poor foot care knowledge and practice(Muhammad-Lutfi *et al.*, 2014). This study only focuses on foot care knowledge and practice level of patient with diabetic foot ulcer, did not study the relationship between foot care knowledge or practice level with diabetic foot ulcer.

We choose cross section study design because diabetic foot ulcer is a chronic disease which needs a long follow-up period. All the studied risk factors are objective e.g. laboratory measurement, knowledge & practise level is the current situation, hence minimum recall bias will be found.

4. RESEARCH QUESTION

1. Is the percentage of poor foot care knowledge between Type 2 diabetes mellitus patients (T2DM) with and without diabetic foot ulcer (DFU)?

Ho: There is no difference in percentage of poor foot care knowledge between type 2 diabetes mellitus patients with and without diabetic foot ulcer

2. Is there any association between foot care knowledge and diabetic foot ulcer?

Ho: There is no association between foot care knowledge and diabetic foot ulcer

3. Is there any association between foot care practice and diabetic foot ulcer?

Ho: There is no association between foot care practice and diabetic foot ulcer

5. OBJECTIVES

5.1 General:

1. To determine the association of foot care knowledge & practice on diabetic foot ulcer among T2DM

5.2 Specific:

1. To determine the percentage of good foot care knowledge among T2DM patients
2. To determine association between foot care knowledge and diabetic foot ulcer
3. To determine association between foot care practice and diabetic foot ulcer

6. CONCEPTUALFRAMEWORK

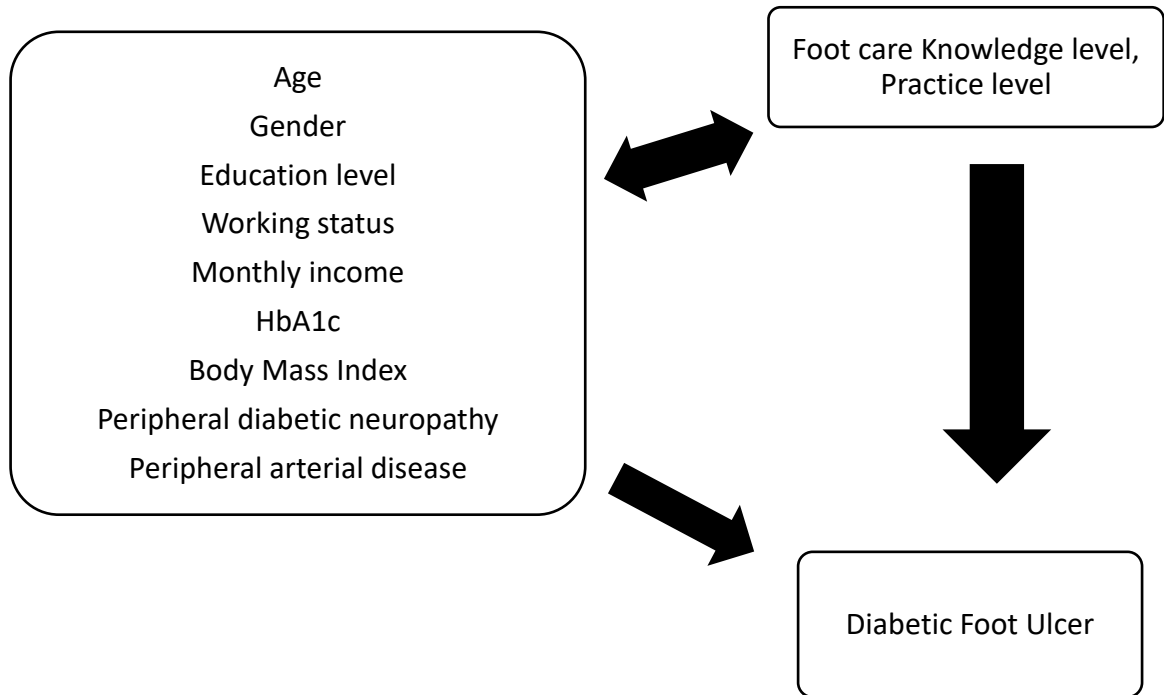


Figure 2. Conceptual framework of interactions between foot care knowledge or practise score with diabetic foot ulcer, and the interactions risk factors with foot care knowledge or practise score.

7. RESEARCH DESIGN

This is a **cross sectional study** conducted in Hospital Universiti Sains Malaysia from March to September 2019

8. STUDY AREA

The study will be conducted in Hospital University Sains Malaysia (HUSM) because HUSM is a local referral center in the Kelantan for diabetic mellitus and diabetic foot management

Patient in control group recruited from

- Diabetic Clinic, Hospital USM
- Staff Clinic, Hospital USM

- Medical ward, Hospital USM

Patient in case group recruited from

- Orthopaedic Clinic, Hospital USM
- Medical ward and Orthopaedic ward, Hospital USM

9. STUDY POPULATION

Reference population is Type 2 diabetes mellitus patients in Kelantan.

10. SUBJECT CRITERIA

10.1 Control Group:

Inclusion Criteria:

1. Age \geq 18 years old
2. No ulcer in either foot
3. No previous history diabetic foot ulcer

Exclusive Criteria:

1. Patient with psychologic disorder or psychiatric illness that unable to give consent
2. Patient who is pregnant
3. Patient with other causes of neuropathy, such as thyroid disease, malignancy or alcohol neuropathy
4. Patient with major foot amputations, such as below knee amputation or above knee amputation
5. Patient who is too sick to participate

10.2 Case Group:

Inclusion Criteria:

1. Age \geq 18 years old
2. Patient must be without diabetic foot ulcer

Exclusive Criteria:

1. Patient with psychologic disorder or psychiatric illness that unable to give consent
2. Patient who is pregnant
3. Patient with other causes of neuropathy, such as thyroid disease, malignancy or alcohol neuropathy
4. Patient with bilateral foot amputations, such as below knee amputation or above knee amputation
5. Patient who is too sick to participant
6. Bilateral foot ulcer

11. SAMPLE SIZE ESTIMATION

For Objective 1

The sample size was calculated using the proportion formula, $n = (z)^2 p (1-p)/e^2$

Variables	z	p	E	n	n+10%	Reference
Poor knowledge	1.96	0.31	0.10	83	93	(Hasnain and Sheikh, 2009)

z= z score, 1.96

p= estimated prevalence or proportion

e=range of confidence interval, 0.10

For Objective 2&3

The sample size was calculated using the PS Power and Sample Size Software, Version 3.0 (D and D, 1990).

Variables	α	β	m	P0	P1	n	n+10%	(n+10%)x3	Reference
Poor knowledge	0.05	0.8	2	0.31	0.6	33	36	108	(Hasnain and Sheikh, 2009)
Poor practice	0.05	0.8	2	0.32	0.6	36	39	117	(Hasnain and Sheikh, 2009)

α = Type I error probability for a two-sided test, probability of falsely reject the null hypothesis.

Power (1- β) = Probability of correctly rejecting the null hypothesis.

m = ratio of control to case patients.

P0 = probability of exposure in controls.

P1 = probability of exposure in cases.

n = number of patients

We are planning a study of independent cases and controls with 2 control(s) per case. Prior data indicate that the probability of exposure among controls is 0.42. If the true probability of exposure among cases is 0.7, we will need to study 36 case patients and 72 control patients to be able to reject the null hypothesis that the exposure rates for case and controls are equal with probability (power) 0.8. The Type I error probability associated with this test of this null hypothesis is 0.05. We will use an uncorrected chi-squared statistic to evaluate this null hypothesis. Based on above estimation, by considering 10% of non-response rate, optimum sample size required for case = 39 subjects in case patients, and for control = (39*2) = 78 subjects in control patients.

The largest sample size in this estimation is 117 patients, consist of 39 T2DM patients with diabetic foot ulcer and 72 T2DM patients without diabetic foot ulcer

12. SAMPLING METHOD AND SUBJECT RECRUITMENT

Convenient sampling method (a nonprobability sampling method) will be applied in the study because there is no complete list of T2DM patients in HUSM available for sampling. Patient who fulfilled the control group's inclusion and exclusion criteria will be recruited from diabetic clinic, staff clinic and medical ward HUSM. Patient who fulfilled the case group's inclusion and exclusion criteria of the will be recruited from orthopaedic clinic, medical ward and orthopaedic ward HUSM. Both control and case group will be recruited from March to September 2019.

13. Research tool

13.1 This study was conducted by using a self-administered questionnaire from the researcher which contained three sections

i. Sociodemographic questionnaire:

This questionnaire will document respondent's socio-demographic background such as age, gender, race, working status, level of education, total monthly income

ii. Foot care knowledge questionnaire

Foot care knowledge questionnaire was designed by Hasnain *et al*, which is a set of 15 'yes', or 'no' questions on foot care knowledge. It covered foot care knowledge in the areas of foot washing techniques, skin and nail care and foot wear care. Each correct answer carried one point and zero point for a wrong answer. All the points were then added up. The questionnaire was translated Bahasa Malaysia and was tested and validated in 2013 (Muhammad-Lutfi *et al.*, 2014).

iii. Foot care practise questionnaire

Foot care practise questionnaire was designed by Diabetic Resource Centre of Nova Scotia, Canada. The questionnaire consists of 11 ‘yes’ or ‘no’ questions on foot care practise and another question on foot wear, respondent is given 6 choice of foot wear to choose that is practising by respondent. Foot wear question will assess which foot wear are commonly practising among diabetic patient in Kelantan. The questionnaire was translated Bahasa Malaysia and was tested and validated in 2011(Jamani, 2012)

13.2 Diabetic Foot examination proforma

Clinical examination will be performed as per pro forma. The clinical examination includes body mass index, glycaemic control (HbA1c), monofilament test record and ankle brachial index (ABI). The procedures in performing monofilament test to determine the status of peripheral diabetic neuropathy (yes/no) and ABI to determine peripheral arterial disease (yes/no) are explained as in the section of operational definition.

14. OPERATIONAL DEFINITION

14.1 Education level:

Education level is defined as respondent’s highest formal education

14.2 Employment status

Occupational status of the respondents at the time of interview whether employed or unemployed

14.3 Total Monthly Income