COGNITIVE IMPAIRMENT AND DIABETIC CONTROL AMONG ELDERLY TYPE II DIABETES MELLITUS IN HUSM

by

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Khairunnisa Mohd Khathri, November 2016

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LIST OF ABBREVIATIONS

ACCORD	Action to Control Cardiovascular Risk in Diabetes
AD	Alzheimers disease
ADA	American Diabetes Association
CDT	Clock drawing test
CIB	Clock in the box
CPG	Clinical practice guideline
DLB	Lewy body dementia
DKQ	Diabetes knowledge questionnaire
DCCT	Diabetes Control and Complications Trial
ECAQ	Elderly cognitive assessment questionnaire
FTD	Frontotemporal dementia
HbA1c	Glycated hemoglobin
HPLC	high performance liquid chromatography
HUSM	Hospital Universiti Sains Malaysia
IADL	Instrumental activities of daily living
KPP	Klinik Pakar Perubatan

KRK	Klinik Rawatan Keluarga
MLogRx	Multiple logistic regression
MGDS-14	Malay version geriatric depression scale-14
MMSE	Mini mental state examination
MMSE serial- 7	Mini mental state examination serial -7
NGSP	National Glycohemoglobin Standardization Program
NHANES	National Health and Nutrition Examination Survey
NHMS	National Health and Morbidity Survey
POC	Point of care
SLR	Simple logistic regression
SMBG	Self-monitoring of blood glucose
UKPDS	UK Prospective Diabetes Study
VaD	Vascular dementia
WHO	World Health Organisation

Abstrak

Tajuk: Kekurangan fungsi kognitif dan kawalan kencing manis serta perhubungannya dikalangan pesakit kencing manis jenis II warga tua di Hospital Universiti Sains Malaysia

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Pengenalan: Tujuan kajian ini adalah untuk mengenalpasti ‘proportion’ kawalan kencing manis dan kekurangan fungsi kognitif serta perhubungannya dikalangan pesakit kencing manis jenis II warga tua di Hospital Universiti Sains Malaysia. Dengan peningkatan populasi kencing manis di negara kita, pengenalpastian ‘proportion’ dan perhubungannya adalah penting untuk melihat tren penyakit dalam masyarakat kita. Peningkatan warga tua beserta penyakit kencing manis akan meningkatkan bebanan kepada sistem kesihatan negara kita. Dengan ini, kami berharap dengan kajian ini ia akan membantu dalam pengurusan warga tua.

Objektif: Ini adalah kajian rentas untuk mengenalpasti ‘proportion’ kekurangan fungsi kognitif dan kawalan kencing manis serta perhubungannya dikalangan pesakit kencing manis warga tua di HUSM.

Kaedah: Ia melibatkan 403 pesakit kencing manis yang menerima rawatan di Klinik Rawatan Keluarga HUSM, bagi umur 60 tahun dan ke atas. Kajian ini dijalankan dari bulan August 2013 hingga bulan May 2014. Pesakit yang menuhi kriteria akan disaring untuk kemurungan sebelum nama di letak dalam sistematik pilihan rawak 1 dalam 2. Soalan di jawab sendiri oleh pesakit. Soalan tersebut mengandungi sosio-demografik data dan soalan tahap pengetahuan kencing manis. Tahap Hba1c 7 dan kebawah digunakan untuk mengenal pasti tahap pengawalan kencing manis dan pemeriksaan 'mini mental state examination' digunakan utuk mengetahui kekurangan fungsi kognitif.

Keputusan: 'Proportion' kawalan kencing manis berdasarkan Hba1c 7% dan kebawah adalah 25% dan kekurangan fungsi kognitif adalah 4%. Dalam kajian ini didapati tiada perhubungan antara kekurangan fungsi kognitif dan kawalan kencing manis. Purata tahap pengetahuan kencing manis adalah 12.9.

Kesimpulan : Daripada kajian ini, kawalan kencing manis agak baik berbanding kajian lain di Malaysia tetapi masih kurang dari piawaian negara, manakala kekuranagan fungsi kognitif dikalangan pesakit adalah rendah. Ini mungkin menyebabkan tiada hubungan boleh dilihat antara kawalan kencing manis dan kekurangan fungsi kognitif.

Associate Professor Dr Juwita Shaaban: Supervisor

Dr Razlina Abdul Rahman: Co-Supervisor

Associate Professor Dr Azidah Abdul Kadir: Co-Supervisor

Abstract

Title: Cognitive impairment and diabetic control association among elderly Type II diabetes Mellitus in Hospital University Sains Malaysia

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Introduction: This study aims, looked at the proportion of diabetic control and cognitive impairment, and its association among elderly Type II diabetes Mellitus in HUSM. As the elderly population in our country and diabetes keep increasing to determine proportion and its associations is important to see our population disease trend. Increase number of ageing people with diabetes will increase our health care burden, thus hopefully it will help in managing geriatric with diabetes population.

Objective: This is a cross sectional study to determine the proportion of cognitive impairment and diabetes control and their association among elderly diabetes in HUSM

Methods: It's involved 403 patient type 2 DM who attending Klinik Rawatan Keluarga HUSM, age more than 60. This study was conducted from August 2013 until May 2014. Self-administrated questionnaire were given for data collection. Patients were screen for depression then they were put into systematic random sampling 1 in 2. The questionnaires that were used in

this study consist of socio-demographic data, and Malay version Diabetes Knowledge questionnaire. Hba1c 7 and below was used to determine diabetes control and Mini Mental State Examination Malay version was used to asses cognitive impairment.

Result: The proportion of diabetic control in this study based on Hba1c level 7% and below was 25% and 4.0% found to have cognitive impairment. There is no association between cognitive impairment and diabetes control. The mean score of diabetes knowledge questionnaire is 12.9. **Conclusion:** From this study, the diabetes control was quiet good compared to other study in this country, but still below national standard and low proportion of cognitive impairment. There is no association between cognitive impairment and diabetes control may due to low proportion of cognitive impairment.

Associate Professor Dr Juwita Shaaban: Supervisor

Dr Razlina Abdul Rahman: Co-Supervisor

Associate Professor Dr Azidah Abdul Kadir: Co-Supervisor

CHAPTER 1

INTRODUCTION

1.1 Study introduction

Diabetes mellitus is one of the most common chronic disease plaguing Malaysians. Its number and significance continue to increase in line with urbanization that inevitably leads to sedentary lifestyle; discourages physical activity and promotes obesity. Estimates of current and future burden diabetes would incur are important in order to allocate community and health resources, emphasize the role of lifestyle, and design measures to counteract its increasing prevalence (1). The overall prevalence of DM among older persons was 34.4% as compared with 20.8% for adult population aged 30 years and more in Malaysia in 2011(2).

As Malaysia undergoes demographic transition as a result of socio-economic development, improved quality of health care and living standard, life expectancy increases and disease pattern undergoes changes. The inevitable shift in disease pattern is from a spectrum of mainly infectious diseases to a more chronic degenerative and non-communicable disorders(3).

Diabetic control is is achieved when the HbA1c level achieve < 6.5 %, according to Malaysian Clinical Practise Guideline 2009. However the diabetic control target was different if compared to other guidelines. For example American Diabetes Association (ADA) used Hba1C less than 7% while European diabetes policy group used Hba1c less and equal than 6.5%. This target was set up to minimize the complications in diabetic patient. Furthermore, research has shown, Type 2 diabetes can cause mild to moderate deficits in cognitive function (6). A study in a hospital geriatric unit found that a better glycemic control in type 2 diabetes patients results in less cognitive impairment (7).

Cognitive impairment is common among elderly population. Sherina et al reported that cognitive impairment in rural Malaysia was 22.4%. The figure increased to 38% among elderly age more than 85 years and older. In addition the, the older people with diabetes and other chronic illness, the cognitive impairment may become poorer.

Cognitive function involves higher brain functions, that includes memory, perception, executive functions (planning and problem solving) and language (4). Specific cognitive functions such as immediate memory, visuospatial and constructional abilities, attention, and specific executive functions (planning and problem solving) are significantly associated with diabetes control. Specific cognitive abilities, particularly planning and problem solving, play an independent role in diabetes control(5).

This study aims, looked at the proportion of diabetic control and cognitive impairment, and its association among elderly Type II diabetes Mellitus in HUSM. As the elderly population in our country and diabetes keep increasing to determine proportion and its associations is important to see our population disease trend. Increase number of ageing people with diabetes will increase our health care burden, thus hopefully it will help in managing geriatric with diabetes population.

CHAPTER 2:

LITERATURE REVIEW

2.1 The Ageing Population of Malaysia

Ageing is a process of becoming older, whereby operations of the human body are progressively vulnerable to wear and tear. However, it is also subjected to society's definition of old age. In developed world, chronology plays a paramount role. Most developed countries accept the chronological age of 65 as a definition of old. Yet, like many westernized concepts, this does not bode well with the situation in Africa. At the moment, there is no United Nations standard numerical criterion, but the UN's agreed cutoff is 60+ years to refer to the older population.(8)

Globally and in the Western Pacific Region, the proportion of people aged 60 years and over is growing faster than any other age group. The proportion of the population aged 60 years and above is expected to exceed the proportion of the younger population aged 0–14 years in Malaysia by 2049(9). Malaysian population is gradually ageing similar to other nations in the world. The life expectancy of Malaysia has gradually risen from 71.9 and 76.5 years for men and women respectively in 2009 to 72.4 and 77.0 years in 2012, a considerable increase in the absolute and relative numbers of older people in both developed and developing countries(10).

Predisposing factors to cognitive impairment include old age, female gender, no formal education, ethnicity and very poor self-rated health (11). An ageing population influences disease trends and patterns by increasing the incidence of chronic and degenerative conditions. WHO has

identified dementia, including Alzheimer's disease, as a major public health concern for all countries, regardless of income level. Globally, 7.7 million new cases of dementia is estimated annually and the number will increase as the population ages further. About 25%–30% of people aged 85 or older experience some degree of cognitive decline (9). Early signs of dementia are often mistaken for "normal" signs of ageing, which then delays diagnosis and treatment. These conditions can detract an individual from a quality life, and reduce their ability to live independently, with consequences on others, particularly family members and health and social services.

Primary care physicians are the gatekeepers to specialized services and the elderly are frequent users of the primary care facilities. Despite this, majority of patients with dementia remain undetected and therefore missing out on appropriate treatment (12). More than 60% of patients got their first treatment at moderate and severe stages of the illness (13), corresponding to 9-11 years after the onset of first symptoms (14). It is important to have reliable estimates of the proportion of cognitive impairment or dementia as this would enable more accurate provision and planning of optimal care for the affected elderly in the community.

2.2 Diabetes in elderly

Diabetes is an important health condition in ageing population. At least, 20% of patient over 65 years old have diabetes (15). Based on NHMS III, prevalence of diabetes was 11.4% people age more than 60 years old. If we referred to National Diabetic Registry 2013, the mean age for diabetic patient in Malaysia was 59.7 years. It has mean duration for follow up 6.5 years (16). It showed that, most of the patient in Malaysia was elderly.

Management diabetes in elderly is complex. Elderly need to be managed with very individualize therapy to achieve good diabetic control among them (17). Older adult also had several common geriatric syndrome, such as polypharmacy, cognitive impairment, urinary incontinence, injurious fall and persistent pain. In addition older adult with diabetes have higher rates of premature death, functional disabilities, and coexisting illness such as hypertension, coronary heart disease, stroke if compare to non -diabetic patient (15).

2.21 Diabetic control in elderly

Diabetic control among Malaysian generally was poor. Only 11%of patient in private practice in Malaysia reach HbA1c less than 6.5% (18). The number was poor compare to National target now; to reach 30% Hba1c less than 6.5%. However there is limited data on diabetic control among elderly in Malaysia.

In America, among NHANES III participants aged 65 or older, ADA guidelines for glycemic control ($HbA_{1c} < 7\%$) were achieved by 71%, 44%, and 27% of persons using no drug therapy, oral hypoglycemic agents, and insulin, respectively (19). For glycemic target for elderly, for independent elderly optimal target is 7%-7.5%, for functionally dependent the target range is 7.0% - 8.5% (International diabetes federation). However in Malaysian Diabetes Mellitus CPG 2009, there is no specific range but the general target was Hba1c is 6.5% below was used.

If we see Action to Control Cardiovascular Risk in Diabetes (ACCORD), it was terminated early due to the finding of increased mortality in participants randomized to a strategy of very intensive glycemic control with a target A1C of <6%. The mean age for ACCORD study was 60 years old. the UK Prospective Diabetes Study (UKPDS), participants newly diagnosed

with type 2 diabetes were followed for 10 years, and intensive control (median Hba1c 7.0%) was found to be reduced overall microvascular complication (20). It showed that a very strict diabetic control is not suitable for elderly.

2.22 Factor contribute to diabetic control in elderly

Elderly with Type 2 diabetes mellitus display significant excess of cognitive dysfunction, associated with poorer ability in diabetes self-care and greater dependency. Routine cognition screening in older diabetics is highly recommended (21). Evidence showed that an effective self-management training in type 2 diabetes, particularly in the short term, improves glycemic control (22).

Multiple factor that could contribute to diabetic control in elderly such as cognitive impairment. Poor diabetic control may be due to dietary habits because local diet contains high carbohydrates especially sugar, eggs, coconut and its products. Reduced daily physical activities, which also contribute to poor diabetic control. The other contributory factor is lack of knowledge of the disease and its medication. Patient with poor knowledge will complicate their management further(23).

Poor family support may be related to reduced medication adherence and poor diabetic control(24). Educational level was associated with long-term glucose control, and seemed to be related to the incidence of combined morbid events in people with type 2 diabetes (25). Marital status and gender differences should be considered in the delivery of health care services and design of programs to help patients with type 2 diabetes (26).

2.3 Cognitive impairment in elderly

It is estimated that there are 24.3 million people with cognitive dementia worldwide, with 4.6 million new cases each year (12) . The variation of the reported prevalence estimates among nations are mostly in the range that might be explained by methodological difference in case-detection and classification of cognitive impairment used in these studies. Thus it is often difficult to make a direct comparison of prevalence between countries or with other studies.

There are many subtypes of dementia such as Alzheimer disease (AD), vascular dementia, lewy body disease, frontotemporal dementia and mixed dementia(12). Besides that, there is also a term called mild cognitive impairment. Mild Cognitive Impairment (MCI) is widely acknowledged as a transitional state between normal ageing and dementia(27). There is likely a transitional period between normal ageing and the diagnosis of clinically probable very early AD, and this transitional zone has been described using a variety of terms such as mild cognitive impairment (MCI), dementia pro-drome, incipient dementia and isolated memory impairment among others (28). Individuals currently characterized as having MCI progress steadily to greater stages of dementia severity at rates dependent on the level of cognitive impairment at entry and they almost always have the neuropathologic features of AD (29).

Prevalence of diabetes mellitus over the past 40 years has reached an epidemic proportion. Due to its multiple complications, it translates into a huge increase in burden for the healthcare system (1, 30). Malaysia is in the top 10 countries with populations suffering from diabetes mellitus (30). In Malaysia, the diabetes prevalence rate has risen faster than expected, almost doubled over the last decade.

Cognition is the process of thinking, learning and remembering. Cognitive impairment is not uncommon in late age due to either the ageing process or physical or mental disorders(31).

There was is an increase in prevalence cognitive impairment with age, with 1.6 % in the 50-64 age group, 7.5 % in the 65-74 age group, 15.5.% in 75-84% and 32.4% in the 85+ age group (32). In Malaysia, prevalence of cognitive impairment is about 22.4%. The figure increased to 38% for population aged 85 years and older (33).

2.3.1 Diabetes mellitus and cognitive impairment

Type 2 diabetes mellitus is a risk factor for cognitive impairment and dementia. Diabetes could influence cognitive function either directly, that is, through the underlying insulin resistance or increased fluctuations in blood glucose levels, or indirectly, that is, through microangiopathy (e.g., status lacunar is capsula interna) or macroangipathy of the brain, increasing the risk for stroke (34). From autopsies, macroscopic brain infarcts can be seen more commonly in people with diabetes than in people without (35). Diabetes has the capacity to evoke more generalized and widespread microvascular changes in the brain, causing micro infarcts, which possibly lead to generalized atrophy and white-matter changes. The occurrence of micro infarcts and their relation to brain atrophy and cognitive decline in elderly people is an evolving concept in the area of dementia research (36).

The prevalence of dementia in diabetics is approximately twice that of normal population (37). A study in the UK showed that the prevalence of cognitive impairment in elderly diabetics is 29% (21). These older adults with diabetes also have a high incidence of other functional disabilities, including hearing impairment (48%), visual impairment (53%), history of recent falls (33%), fear of falls (44%), and difficulty performing instrumental activities of daily living (IADL) (39%). Older adults with diabetes are at a high risk of undiagnosed cognitive

dysfunction, depression, and functional disabilities. Cognitive dysfunction in this population is associated with poor diabetes control.

2.4 Diabetes control and cognitive impairment

Several study showed diabetic control was associated with cognitive impairment. An increase Hba1c over time in non -diabetic and non –demented elderly patient was associated with cognitive decline (38). Better glycemic control is associated with less cognitive impairment in elderly patients with type 2 diabetes (7). The present study supports the hypothesis that there is an association between diabetes and cognitive dysfunctions.

Although the effect sizes of the diabetes on cognitive functions are low and moderate, it still should be considered important, because the cognitive dysfunctions can affect daily activities (39). Older adults with diabetes have a high risk of undiagnosed cognitive dysfunction, depression, and functional disabilities. Cognitive dysfunction in this population is associated with poor diabetes control (40).

2.5 Diabetes knowledge

Adequate knowledge of diabetes is a key component of diabetes care. The potential benefits of diabetes knowledge include a sense of empowerment and improved quality of life(41). Participation in the combination of education, dietetic consultation and SMBG instruction was associated with the highest knowledge scores (41). It showed that diabetes patient need multidisciplinary approach to increase their diabetes knowledge.

Diabetes knowledge includes blood glucose levels, hba1c, chronic nature (no cure), dietary guidelines, benefits of physical activity, frequency of physical activity, general diabetes long-term, complications, diabetes foot complications, self-monitoring of blood glucose, sick-day management, annual check-ups diabetes medication, hypoglycaemia and sick-day management (42).

Knowledge of patients' actual and target health outcomes seems to be a prerequisite for effective patient involvement in managing chronic diseases, such as diabetes. The goal of diabetes education is the improvement of individual diabetes knowledge. Good self-management is a critical pathway to success (43).

2.6 Assessment of diabetes control

There are multiple aspect need to be considered when setting a target for diabetes control. For the optimal target, the Hba1c level need to be individualized to the need of each patient and their disease factor. The factor that can be involved for optimal Hba1c level is disease duration, life expectancy, important comorbidities, established vascular complication, patient attitude, expected treatment effort, resource and support system (15).

The optimal blood glucose control was different according to different guideline. Malaysian clinical Practice guideline stated, the optimal blood glucose control is to achieve Hba1c less than 6.5% (44). However, according American diabetes Association; lowering Hba1c approximately 7% has been shown to reduce microvascular complications of diabetes and if implemented soon after the diagnosis of diabetes, it associated with long term reduction in macrovascular disease. In patient who are lower risk to get hypoglycemia, more stringent Hba1c

can be reach (<6.5%). Less stringent Hba1c goal appropriate for the patient with multiple comorbidities (15).

In International diabetes federation, for independent elderly optimal target is 7%-7.5%, for functionally dependent the target range is 7.0% - 8.5% .

Hba1c measurement should be performed using by the NGSP and standardized or traceable to the Diabetes Control and Complications Trial (DCCT) reference assay. Although point of care (POC) Hba1c assay s may be NGSP certified, proficiency testing is not mandated to do this testing. So, use of POC assay for diagnostic purpose may be problematic and is not recommended (15).

It has several advantage to fasting plasma glucose such as greater convenience (no fasting required), greater pre-analytical stability, less day to day perturbation for example acute stress and illness. The disadvantage greater cost, limited availability, different reading for younger age, race/ ethnicity. The reading might be disturbs in patient with haemaglobinopathies, anemia and pregnancy (15).

2.7 Assessment of cognitive impairment

Screening tests that detect the presence of cognitive impairment are available but they are not able to distinguish the causes. No test has been shown to have excellent discriminatory value in random community samples. Their use as screening tests for unselected populations is likely to result in more false positives than true positive cases. The Mini Mental State Examination (MMSE) is a 30-point assessment tool used to screen cognitive function. It was initially developed as a screening test to distinguish ‘organic’ from ‘non-organic’ (e.g. schizophrenia) cognitive disorders. More recently, it has become a common method of screening for, and

monitoring the progression of, dementia and delirium (45). The MMSE score ranges from 0 to 30 points, with higher number indicates better performance. The MMSE consists of questions designed to assess patient's mental status in the following 7 categories:

– Orientation in time (5 points): year, season, date, day, month

– Orientation in space (5 points): country, city, street (or building), floor and location

– Short term memory (3 points): repetition of 3 words (concrete and frequent words)

– Counting backwards (5 points): subtraction of seven serially

– Episodic memory (3 points): delayed recall of 3 previously repeated words

– Language (8 points)

– Constructional praxis: copy of overlapping pentagons (1 point)(46)

When it comes to Malaysia, a more customized and validated Malay- Mini Mental State Examination is used to screen cognitive function of Bahasa Malaysia-speaking patients. There are three versions used: M-MMSE-7(serial 7), M-MMSE-3 (serial 3) and M-MMSE-S (spell 'dunia' backwards). For males and females with higher educational background, a cutoff score ≤21 for M-MMSE-7 was set; for M-MMSE-3, a value of ≤18, and for MMMSE-S, ≤ 17 value was set. In view of the significantly different cut-off scores, it is crucial that these scales are not used interchangeably to avoid inaccuracies in the diagnosis of dementia in the population (47). It should be used as a cognitive test for dementia among Malaysian patients.

2.8 Assessment of diabetes knowledge

The first tools, the diabetes knowledge test (DKT), was developed and validated in the mid-1980s by the Michigan Diabetes Research and Training Centre to address the need for a

valid and reliable diabetes specific knowledge instrument that could be used by diabetes educators and researchers(48). The questionnaire was not updated for the latest version.

The other type of questionnaire is DKN (Diabetes knowledge). DKN was not been updated and they no longer reflect current guidelines and standards of care (e.g. they refer to urine sugar testing which is no longer recommended) and, like the DKT, they contain many questions regarding insulin therapy which did not fit our criteria for a generic tool that is applicable to all people with type 1 or 2 diabetes.

The third identified validated knowledge questionnaire, the ADK (audit of diabetes knowledge) now, was developed and tested in the UK (49). It consists of 23-item sets with a total of 104 questions/ items which makes it a more comprehensive, thus a more onerous and resource intensive tool for application in a clinical setting, and hence did not meet our criteria for a brief tool.

There is one validated Diabetes Knowledge Questionnaire for the Indigenous Population in Malaysia (orang asli) (50). But it was only suitable among Orang Asli population.

Thus, the latest DKQ 2011 (diabetes knowledge questionnaire) was translated and validated in Malay version for our research (42)

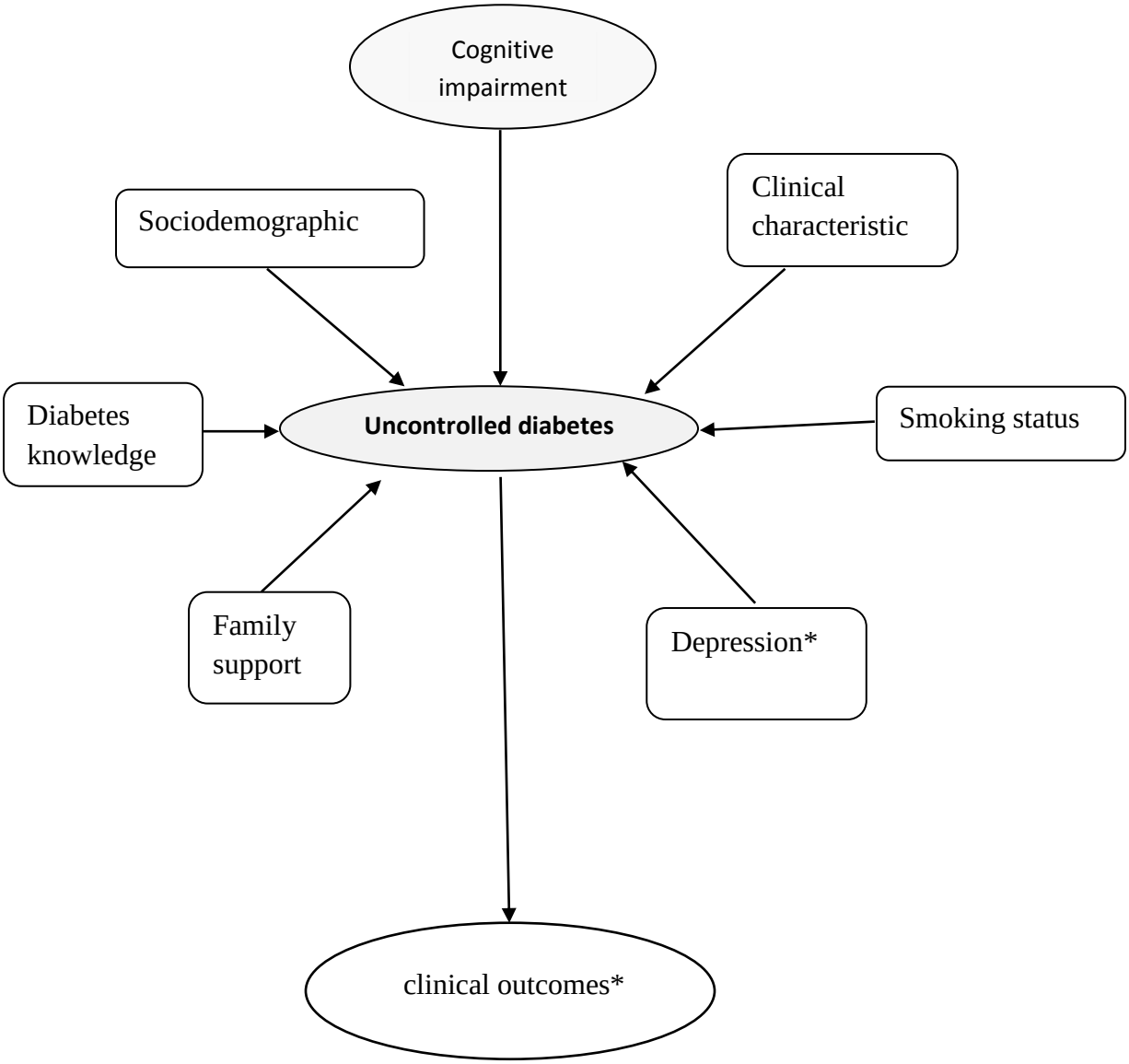
2.9 Rationale of study

Diabetes control is important for elderly with cognitive impairment. It reflects diabetes control of patients. Elderly diabetes with cognitive impairment is associated with a poor ability to diabetes self-care and greater dependency to others.

Malaysia will be an aged nation in 15 years' time (in 2030) when our elderly population aged 60 years and above will contribute to 15% of our total population. Ageing causes a major

acceleration in healthcare cost with some major challenges. Thus this study about older population will help our country to prepare for older generation.

Thus, the determination of cognitive impairment and diabetes control in elderly diabetes is important. Furthermore, describing diabetes knowledge in this research will help multidisciplinary approach to teach them diabetes control. This research thereby is hoped to be able to help improve the Malaysian health care system with regards to diabetes management in geriatric patient.



*Not included in the study

2.8 Figure 1: Conceptual framework

CHAPTER 3:

OBJECTIVES AND RESEARCH HYPOTHESES

3.1 General Objective

To determine the proportion of diabetes control, cognitive impairment and their association among elderly Type II diabetes Mellitus in HUSM

3.2 Specific Objectives

1. To determine the proportion of diabetes control among elderly Type II diabetes Mellitus in HUSM
2. To determine the proportion of cognitive impairment among elderly Type II diabetes Mellitus in HUSM
3. To determine the association between cognitive impairment and diabetes control among elderly Type II diabetes Mellitus in HUSM
4. To describe the diabetes knowledge among elderly Type II diabetes Mellitus in HUSM

3.3 Research questions and hypothesis

Is there any association between diabetes control and cognitive impairment among elderly Type II diabetes Mellitus in HUSM?

H1: There is significant association between diabetes control and cognitive impairment among elderly Type II diabetes Mellitus in HUSM

3.4 Definitions of operational terms

i. Cognitive impairment is the score 21 or below using Malay version MMSE (47)

ii. Diabetes control is Hba1c $\leq$ 7 % (17)

iii. Diabetes knowledge is a knowledge regarding diabetes, nature of the disease, how to manage it and diabetes complication.

CHAPTER 4

METHODOLOGY

4.1 Study Design

It is a cross sectional study.

4.1.1 Study duration

From August 2013 until May 2014

4.1.2 Study area

This study was conducted in Klinik Rawatan Keluarga and Klinik Pakar Perubatan Hospital Universiti Sains Malaysia (HUSM). Situated in the east coast of Peninsular Malaysia, HUSM is one of many teaching hospitals in Malaysia. There are two tertiary or referral centers in Kelantan, namely the HUSM and Hospital Kota Bharu (HKB). Klinik Rawatan Keluarga (KRK) HUSM is under Family Medicine Department and it provides services for all disciplines at primary care level. Meanwhile, Klinik Pakar Perubatan(KPP) is under Medical Department.

4.2 Study population and sample

4.2.1 Reference population

Diabetes mellitus patients in Kota Bharu, Kelantan

4.2.2 Source of population

Diabetes patients attending diabetes clinics at Klinik Rawatan Keluarga and Klinik Pakar Perubatan HUSM

4.2.3 Inclusion criteria

i. Diabetes type II with age equal or more than 60 years.

Exclusion criteria

i. Ongoing infection, cirrhosis, end stage renal failure, head injury, delirium, depression, psychosis, diagnosed dementia, cerebrovascular accident and psychiatric problem (other causing reduce cognitive function was exclude in this study to see only diabetes cause reduce cognitive function)

ii. Illiterate

iii. Deaf and blind

4.2.4 Sampling method

The sample size (n) was 403. There were an average 100 to 150 elderly diabetes patients attending KRK or KPP, HUSM in a week. Five patients who fulfilled the inclusion and exclusion criteria were selected each day during the 5 day clinics. The patient who are agree will be screen for depression with mgds-14. Patient who score 8 and below will be excluded from study. After they are screen from depression, their name put into name list.

A systematic random sampling in the ratio of 1:2, based the list, was carried out at the Diabetes clinics of Klinik Rawatan Keluarga and Klinik Perubatan Keluarga HUSM. The patient age 60 that fulfil inclusions and exclusion criteria was selected will be given questionnaire. The questionnaire was self-administered.

4.2.4 Sample size

The sample size was calculated based on data available and type of outcome that we expect.

For objective 1

Sample size calculation to determine proportion diabetes control among elderly Type II diabetes Mellitus in a tertiary center was done using single proportion formula.

$n = (z/\Delta)^2 \times p (1-p)$

$z = 1.96$

Detectable difference (Δ) = 0.05

P= Proportion diabetes control among Type II diabetes elderly Malaysians showed (21.8%) good glycemic control ($HbA_1c < 7\%$)(2).

The minimum sample size was 263 and after considering 20% non-response rate the calculated sample size was 315.

For objective 2

Sample size calculation to determine proportion of cognitive impairment in elderly diabetes mellitus patient in HUSM was done using single proportion formula.

$n = (z/\Delta)^2 \times p (1-p)$

z = 1.96

Detectable difference (Δ) = 0.05

P= proportion elderly cognitive impairment elderly diabetes in Wales UK was 29%(21)

The minimum sample size was 316 and after considering 20% non-response rate the calculated sample size was 379.

For objective 3

To determine the association between cognitive impairment and diabetes control among elderly Type II diabetes Mellitus in a tertiary centre. The sample size calculated using 2 proportion by power sample software.

P1: proportion of exposure (cognitive impairment) among cases (uncontrolled diabetes) in elderly= 0.21 (51)

Po: proportion of exposure (cognitive impairment) among control (controlled diabetes) in elderly= 0.4 (51)

Power: 0.8

Alpha: 0.05

m = ratio of control (normal cognitive) to case (cognitive impairment)) patients = 5 (51)

number of sample per group

Sample size is 336 subjects. Total = 403 (including 20% non-response rate).

For objective 4

To describe the diabetes knowledge among elderly Type II diabetes Mellitus in a tertiary centre; no sample size required

The biggest sample size is from objective 3. So the sample size for this study is 403.

4.3 Research tool

Patients were screen for depression with Malay version Geriatric Depression Scale (MGDS 14) before giving questionnaire. There were 3 sections in the questionnaire

1. Case Report Form (CRF)
2. Malay version Mini Mental State Examination
3. Malay version diabetes knowledge questionnaire (DKQ)

4.3.1 Case Report Form (CRF)

The Case Report Form provides age, gender, socio demographic characteristics (9 items), familial factors (5 items) and medical history (6 items). It also includes Hba1c

4.3.2 Diabetes control

The diabetes control was asses by Hba1c. The result was review was trace by computer in the clinic. All the blood investigations was taken less than 6 month period. The blood samples were analysed for quantitative glycated hemoglobin concentration using the BioRad HPLC D10 hemoglobin A1c programme on BioRad HPLC D10 analyser. The method used for estimation in HUSM was BioRad HPLC D10.

4.3.3 Mini Mental State Examination (Malay version)

The Validated Malay Version of Mini Mental State is used to measure cognitive impairment (47). This study used the validated Malay version of MMSE as screening instrument for subjects who are literate. There are many types of tools found suitable for screening of patients at risk of cognitive impairment but the Mini Mental State Examination (MMSE) has been recommended for its widespread acceptance and use. Although there are currently many questionnaires that can effectively measure the extent of cognitive impairment, a simple, easy-to-use survey that has good screening ability is especially important in a busy primary care clinics.

The MMSE is a structured interview designed for a bedside screening of cognitive impairment as well as in various community settings including primary care, general medical outpatient and inpatient clinics. The MMSE test was subscaled to identify 6 cognitive abilities namely orientation, attention, calculation, registration, recall, language and construction. These 6 categories will contribute to the 19 questions and give a maximum score of 30 points and a minimum score of 0. The original English version of MMSE has been used worldwide. It has also been translated and validated in various languages. In the study done by Folstein *et al* (1975), the cut-off score was 23 with the sensitivity of 100 % and specificity of 44 %. In Malaysia, MMSE has been translated into Bahasa Malaysia and validated so as to be used in the local setting (47).

M-MMSE study was done on 300 subjects (24.3% with dementia vs 75.5% controls) using the 3 versions: M-MMSE-7(serial 7), M-MMSE-3 (serial 3) and M-MMSE-S (spell‘dunia’ backwards). It was found that the optimal cut-off scores varied with each version and education level. However in this study M- MMSE-7 refers to serial 7 due to standardized the finding and

most of the patient having higher educational level. It was easier for interviewers to make an assessment of the patient using M-MMSE-7. The cut-off score was set at 21 and below for both male and female. Satisfactory levels of sensitivity and specificity were obtained which were 88.5 % and 75.3 % respectively with positive predictive value and negative predictive value of 53.7% and 95.5% respectively when a cut-off point of 21 and below was adopted to screen out suspected dementia cases. The validated Malay version of MMSE fulfilled the above criteria. It can be used effectively to evaluate the extent of cognitive impairment with satisfactory reliability, sensitivity, and distinctness.

4.3.4 Malaysian Geriatric Depression Scale (MGDS -14)

Even though obvious depression has been excluded from study, some patient may have underlying mild depression or not yet being diagnose and it can mistake cognitive impairment. Malaysian Geriatric depression scale was used to differentiate cognitive impairment from depression. For depression patients, MGDS -14 was used to exclude false positive cognitive impairment. The M-GDS-14 is based on the Geriatric Depression Scale (GDS). The GDS has been recommended by the Royal College of Physicians, British Geriatric Society and the Royal College of General Practitioners as a suitable scale to screen for depression. It has been extensively validated in both 15- and 30-item formats. It can be a self-rating scale as well as questions in an interview.

Teh *et al* (52) had translated and validated the 15-item scale, living out item 9, due to its non-discriminatory value against clinical diagnosis of depression, making it a 14-item scale instead of 15. The validated 14-item Malay version of Geriatric Depression Scale (M-GDS-14) was used in the study. It is a self-rating questionnaire carried out with the help of a trained