

**MENTAL AND PHYSICAL HEALTH-RELATED QUALITY OF LIFE
AND THEIR ASSOCIATED FACTORS AMONG ERECTILE
DYSFUNCTION PATIENTS IN THE NORTHEAST OF PENINSULAR
MALAYSIA**

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**DISSERTATION SUBMITTED IN PARTIAL
FULFILMENT OF THE REQUIREMENTS FOR THE
DEGREE OF MASTER OF MEDICINE
(FAMILY MEDICINE)**



UNIVERSITI SAINS MALAYSIA

2022

ACKNOWLEDGEMENTS

First and foremost, Alhamdulillah, praises to Allah for His showers of blessing throughout the years of this research completion. I am very thankful to my respected main supervisor, Professor Dr Shaiful Bahari binti Ismail, and co-supervisors, Associate Professor Dr Norhayati binti Mohd Noor and Dr Noraini binti Mohamad from Department of Family Medicine, Universiti Sains Malaysia, for their priceless advice, continuous encouragement, and patience during my academic journey. I also would like to express my heartfelt appreciation to Dr Rahiza binti Abdul Rahman from Klinik Kesihatan Ketereh for her support and assistance during my thesis writing under her supervision.

Life is a journey, with problems to solve, lessons to learn, but most of all, experiences to enjoy. It had been a very tough academic years for me. I definitely unable to make it without the prayers and support from my dearest wife , Najwa binti Shamsuddin@Mohamed Shukri, my mother Hajjah Karimah binti Yusof and my beloved children Ahmad Rayyan Rizqi, Ahmad Ilman Rifqi, and Rania Zahraa. I am overwhelmed in all humbleness and gratefulness to acknowledge my depth to family members, lecturers, colleagues, and friends. Thank you.

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LIST OF ABBREVIATIONS

BMI	Body mass index
BP	Blood pressure
CI	Confidence interval
DM	Diabetes mellitus
ED	Erectile dysfunction
HPT	Hypertension
IIEF	International index of erectile function
JEPem	Jawatankuasa Etika Penyelidikan Manusia
MOH	Ministry of Health
MREC	Medical Research & Ethics Committee
OR	Odds ratio
QOL	Quality of life
SLR	Simple linear regression
GLR	General linear regression
SF-12	12-item short form survey
USM	Universiti Sains Malaysia

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ABSTRAK

Latar Belakang:

Disfungsi ereksi adalah suatu masalah perubatan biasa di kalangan lelaki dan boleh menjejaskan kualiti hidup pesakit yang mengalami penyakit ini. Kajian ini dibuat bertujuan untuk menentukan faktor yang berkaitan dengan kualiti hidup dan kaitannya dengan fungsi seksual dalam kalangan pesakit disfungsi ereksi. Ia menggunakan reka bentuk kajian keratan rentas di kalangan pesakit disfungsi ereksi di klinik kesihatan lelaki di sebuah hospital tertiar di timur laut Semenanjung Malaysia.

Kaedah:

Kajian ini merupakan kajian keratan rentas yang dijalankan kepada seratus dua puluh lapan (128) pesakit disfungsi ereksi di klinik kesihatan lelaki Hospital Universiti Sains Malaysia (HUSM). Persampelan mudah telah digunakan dalam pemilihan peserta yang layak. Borang laporan kes mengumpul maklum balas daripada rekod perubatan dan dua soal selidik yang diurus sendiri, iaitu soal selidik 12-Item Short Form Survey dan International Index for Erectile Function. Analisis deskriptif, analisis pengesahan regresi linear mudah dan berganda telah dilakukan menggunakan SPSS versi 26

Kesimpulan:

Umur dan keterukan disfungsi erektil dikaitkan dengan kualiti hidup yang berkaitan dengan kesihatan mental. Etnik dan keterukan disfungsi erektil dikaitkan dengan kualiti hidup berkaitan kesihatan fizikal. Strategi penjagaan kesihatan untuk pengesanan dan rawatan

awal disfungsi erektil harus merangkumi diagnosis awal penyakit-penyakit lain dan sedia ada, serta meningkatkan kualiti hidup yang berkaitan dengan kesihatan.

Kata kunci: disfungsi ereksi, kualiti hidup, 12-Item Short Form Survey, International Index for Erectile Function, kesihatan lelaki.

ABSTRACT

Introduction:

Erectile dysfunction is a common medical problem and affects the quality of life in the patients who suffered this illness. This study aimed to determine the associated factors for quality of life and its association with sexual function among erectile dysfunction patients. It applied a cross-sectional design among erectile dysfunction patients in a men's health clinic in a tertiary hospital in northeast of Peninsular Malaysia

Methodology:

The number of participants recruited was 128. Convenient sampling was applied in the selection of eligible participants. The case report form collected responses from medical records and two self-administered questionnaires, namely the 12-Item Short Form Survey and International Index for Erectile Function questionnaire. Descriptive analysis, simple and multiple linear regression confirmatory analyses were performed using SPSS version 26.

Conclusion:

Age and severity of erectile dysfunction were associated with mental health-related quality of life. Ethnicity and severity of erectile dysfunction were associated with physical health-related quality of life. A healthcare strategy for erectile dysfunction detection and treatment should include early diagnosis of underlying and concomitant disorders, as well as improved patient health and health-related quality of life.

Keywords: erectile dysfunction, quality of life, 12-Item Short Form Survey, International Index for Erectile Function, men's health.

CHAPTER 1: INTRODUCTION

Study Background

Quality of life (QOL) is defined as individuals' perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns (WHO, 1997). QOL questionnaire can be used to measure cross-sectional differences in QOL between patients that able to detect important changes even if those changes are small (Guyatt *et al.*, 1993). QOL is proven to be a good marker of functional status and well-being of a patient who endured treatment for various medical conditions (Stewart *et al.*, 1989). QOL has become an important factor in the evaluation of treatment and assessment of medical diseases (Wagner *et al.*, 2000). Factors such as religion, environment, financial, and health status are important determinants of a person's QOL (Tian-hui *et al.*, 2005).

There are many studies that have been carried out to measure the QOL by using various tools in diseases, such as, cancer, musculoskeletal disease, cardiovascular disease, and psychiatric disorders (Garratt *et al.*, 2002). For erectile dysfunction (ED), the study QOL in the patients who suffered this illness have been published mainly in United States and European populations (Penson *et al.*, 2003)(Litwin *et al.*, 1998). However, there is no study found for QOL in ED patients in Malaysian population, specifically in Kelantan.

Erectile dysfunction is a common medical problem affecting many men worldwide that leading to fear, loss of image and self-confidence and depression. The multifactorial nature of ED, comprising both organic and psychologic aspects, may often require a

multidisciplinary approach to its assessment and treatment. The number of patients with this disease and their severity are increased with age. At primary care setting, ED was common among men aged 40 years and above (Ab Rahman *et al.*, 2011). Apart from age, the other important risk factors of ED include diabetes, hypertension, diuretics and oral hypoglycaemic agents (Koh, 2013). Nowadays, most of the medical treatments for ED are focussing on improving QOL of patients (Althof, 2002).

Literature Review

Measuring the QOL has gained great significance in the study of the health status of populations and in the evaluation of both the quality of clinical and health care in general and the efficacy health interventions (Sánchez-Cruz, 2003). In ED patients, health-related quality of life in mental domain noted to have more severe impairment compared to physical domain (Litwin *et al.*, 1998).

There are many factors associated with QOL in ED patients, which relates to sociodemographic aspects as well as comorbidities. A study that assess quality of life in ED patients on tadalafil or sildenafil citrate showed that ED has a negative impact on all domains of QOL (Attia *et al.*, 2013). It is noted that age factor is associated with QOL, where men with ED younger than 65 years was found to have poorer QOL (Guest and Das Gupta, 2002). The comorbid illnesses, such as, hypertension and other cardiovascular disease also showed poorer QOL outcome in ED patients (Guest and Das Gupta, 2002). Other study stated that the most common factor related to ED is type 2 diabetes mellitus, which was associated with poorer quality of life, as measured with generic and diabetes-specific instruments (De Berardis *et al.*, 2002). In diabetic patients specifically, ED

management may often involve a multidisciplinary approach where psychosexual counselling and specialist urologist advice is required in addition to the skills and expertise of the diabetologist (Basu and Ryder, 2004). Furthermore, it is revealed that the mood, overall sexual function, satisfaction in relationships, and overall QOL in both men and their partners improved following treatment of ED (Rosen *et al.*, 2004). Obesity also was found to have poor impact in ED patients. One study concluded that lifestyle changes were associated with improvement in sexual function in about one third of obese men with ED (Esposito *et al.*, 2004).

Various tools are used to measure the quality of life, among which are 12-Item Short Form Survey (SF-12), EuroQol 5-dimension (EQ5D) questionnaire, the World Health Organization Quality of Life Instruments (WHOQOL-BREF), International Quality of Life Assessment (IQOLA), Short Form 36 (SF-36) Health Survey, and the University of Washington Quality of Life instrument (UW QOL). In a study which assess the growth of QOL measures and the availability of measures across specialties, the most widely used QOL tool is SF-36 (Garratt *et al.*, 2002). It is because SF-36 is a concise validated, self-administered, 36-item questionnaire which addresses eight important domains of quality of life including physical function, bodily pain, vitality, role-physical, general health perceptions, emotional well-being, social function, and role-emotional (Litwin *et al.*, 1998). Meanwhile, other good QOL measurement tool is WHOQOL-BREF which consisted of four domains which are physical health, psychological, social relationship, and environment (WHO, 1996). On the other hand, SF-12 is a newer tool which is comprised of Physical Component Summary Score (PCS) and Mental Health Component Summary

Score (MCS) identical to SF-36 that indicate the same magnitude of ill-health and degree of change overtime (Jenkinson *et al.*, 1997). SF-12 becoming more popular in clinical trials and routine outcome assessment due to its brevity and psychometric performance (Brazier and Roberts, 2004).

Study Justification

One study has estimated that 322 million men will have ED in 2025 based on the prevalence of ED in 1995 of 152 million and the largest projected increases will be in developing countries, i.e. Africa, Asia and South America (Aytaç *et al.*, 1999). A random survey of 351 men aged more than 50 years old in Malaysia showed that 70% had ED based on the International Index for Erectile Function (IIEF) questionnaire (Khoo *et al.*, 2008). This indicates that ED is highly prevalent among men and QOL has become an important health status indicator in determining the general well-being among ED patients.

The QOL of patients with erectile function may be impaired by non-modifiable factors, such as, age, race, and ethnicity and modifiable factors, such as, comorbidities, BMI, and lifestyle. These were based on a few studies done abroad where one of them stated that QOL in ED patient is poorer in those with comorbid illnesses and improves with age (Guest and Das Gupta, 2002). There is no study on QOL in ED patients in Malaysian population. Therefore, the study QOL and its associated factors among ED patients in Universiti Sains Malaysia will become an important indicator of functional status and well-being as part of the management for ED patients.

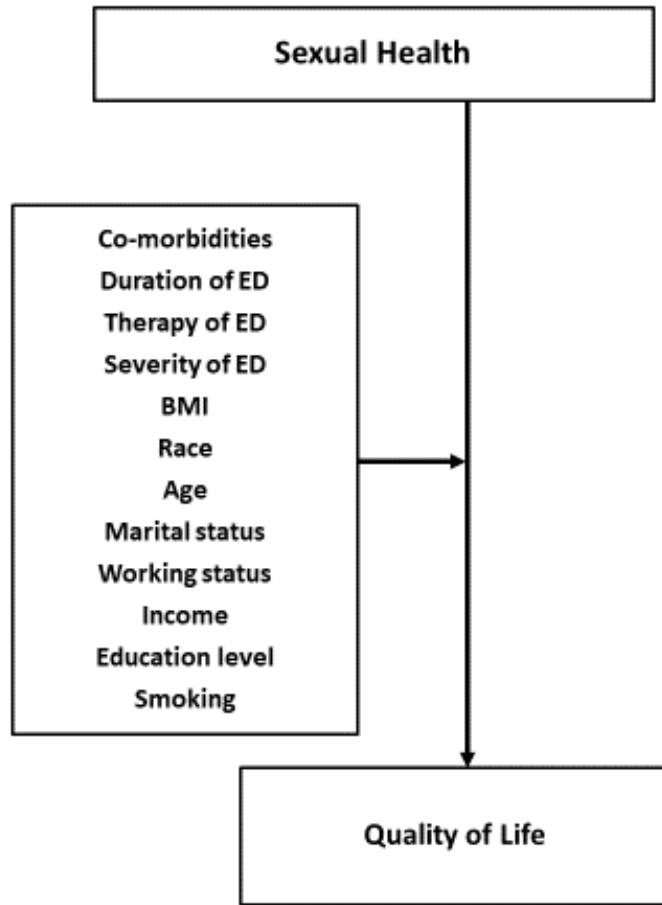


Figure 1. Conceptual Framework

Objectives and Research Hypotheses

General objective:

To determine the mental and physical health-related quality of life and their associated factors among erectile dysfunction patients attending men's health clinic, USM Hospital.

Specific objectives:

1. To determine the level of quality of life among erectile dysfunction patients.

2. To identify the sociodemographic and clinical associated factors for quality of life among erectile dysfunction patients.

3. To determine the quality of life, its associated factors and association with mental health among erectile dysfunction patients attending men's health clinic in USM Hospital.

Research Hypotheses

1. Sociodemographic (race, age, marital status, work status, income, education level and smoking) and clinical (BMI, hypertension, diabetes, and dyslipidaemia, ED duration, ED therapy, ED severity) factors are significantly associated with quality of life among ED patients in USM Hospital.
2. There is a significant association between mental health and sexual function among ED patients in USM Hospital.

CHAPTER 2: METHODOLOGY

Operational definitions

Mental health is defined as a state of well-being in which every individual realizes his or her own potential, can cope with the normal stresses of life, can work productively and fruitfully, and is able to make a contribution to her or his community (WHO, 2014). The assessment for mental health is based on mental component score (MCS) of SF-12.

Sexual health is defined as a state of physical, emotional, mental and social well-being in relation to sexuality; it is not merely the absence of disease, dysfunction or infirmity which requires a positive and respectful approach to sexuality and sexual relationships, as well as the possibility of having pleasurable and safe sexual experiences, free of coercion, discrimination and violence (WHO, 2002). In this study, sexual function is based on the International Index for Erectile Function (IIEF) score.

Erectile dysfunction is defined as the persistent or recurrent inability, for at least three months duration, to achieve and/or maintain an erection sufficient for satisfactory sexual performance (CPG on Erectile Dysfunction, 2000), which in this study, is based on clinical signs and symptoms.

Study design: Cross sectional study

Reference population: ED patients attending men's health clinic at USM Hospital

Source population: ED patients attending men's health clinic at USM Hospital from July 2017 to October 2018

Study population:

Inclusion criteria

- i. Aged >18 years old

Exclusion criteria

- i. Diagnosed mental illness
- ii. Illiterate

Sample Size Calculation

For Objective 1, the sample size calculation to determine the level of quality of life is based on single mean formula.

$$n = \left[\frac{Z_{\alpha/2} \cdot \sigma}{\Delta} \right]^2$$

n = minimum required sample size

Z = value of standard normal distribution = 1.96

Δ = estimated difference from population mean = 3

σ = standard deviation of QOL among ED patients = 9.41 (Penson *et al.*, 2003)

The minimum calculated sample size was 38 and after considering 10% non-response rate, the sample was 42.

For objective 2, the sample size calculation to identify the associated factors (sociodemographic and clinical) for quality of life was done using Power and Sample Size Calculation software (Dupont and Plummer, 1997). The outcome variable was quality of life score. Hence, calculation for linear regression should be done for independent numerical variables and calculation for comparing two means should be done for independent categorical variables. There is very limited information available for sample size calculation of linear regression and therefore, the sample size is calculated based on comparing two means.

$$\alpha = 0.05$$

$$\text{power} = 0.8$$

$$\sigma = \text{within group standard deviation of QOL in diabetic} = 11.48 \text{ (Penson } et al., 2003)$$

$$\delta = \text{expected detectable difference in population mean} = 6$$

$$m = \text{ratio of control to cases} = 1$$

The minimum calculated sample size was 116 and after considering 10% non-response rate, the sample was 128.

For objective 3, calculation for linear regression was done to determine the quality of life, its associated factors and association with mental health. However, there was inadequate information to make the calculations possible. Therefore, the biggest sample size was from objective 2 for the variable comorbidity of diabetes ($n = 128$) and was taken as the study sample size.

Sampling Method

Convenient sampling was applied due to the limited number of ED patients. All ED patients fulfilling the inclusion and without the exclusion criteria were eligible for this study.

Research Tools

The information were obtained from medical records that include (i) sociodemographic and (ii) medical characteristics. Information also obtained through case report form that will obtain responses for (iii) quality of life based on 12-Item Short Form Survey (SF-12) and (iv) sexual function based on IIEF-5 questionnaire. Anthropometry for body mass index was measured.

Sociodemographic characteristics: this includes race, age, marital status, work status, income, education level, and smoking status. ***Medical characteristics:*** this includes BMI, hypertension, diabetes, dyslipidaemia, duration of ED, therapy of ED, and severity of ED.

Quality of life: The SF-12 comprises 12 questions covering eight subscales: physical function (PF), role limitations due to physical health (RP), bodily pain (BP), general health perceptions (GH), vitality (VT), social functioning (SF), role limitations due to emotional problems (RE) and mental health (MH). PF assesses limitations in physical activities caused by health problems. RP assesses problems with daily activities caused by physical health. BP measures the extent of pain. GH measures perception of health based on physical limitations, emotional limitations and well-being. VT measures perception of

fatigue or energy. SF measures limitations in social activities caused by physical or emotional problems. RE assesses problems with activities because of emotional problems. MH measures psychological well-being and distress. The questionnaire assesses overall physical and mental function using summary scales of PCS scores and MCS scores (Ware *et al.*, 1996).

The Malay version of the SF-12v2® questionnaire was validated among 108 mothers who had caesarean sections during a one-month postpartum follow-up at the obstetrics and gynaecology clinic in a tertiary teaching hospital. The internal consistency reliability for the SF-12 PCS and the SF-12 MCS were 0.749 and 0.701, respectively. Spearman correlations of individual items and the SF-12 component summary scores showed that the PF, RP, BP and GH items correlated more highly with the PCS scores, whereas the VT, SF, RE and MH items correlated more highly with the MCS scores, leading to good convergent validity. The confirmatory factor solution showed that the two factor constructs, each with six items, had acceptable factor loadings, satisfactory absolutes and parsimonious fitness (RMSEA = 0.1, $\chi^2/df = 2.4$) (Norhayati and Aniza, 2014). The permission to use the SF-12v2® questionnaire has been requested from QualityMetric® and currently is in progress.

Sexual function: The IIEF questionnaire developed by Rosen addresses the five domains with 15 items of male sexual function, namely, erectile function, orgasmic function, sexual desire, intercourse satisfaction, and overall satisfaction. It is psychometrically sound, and has been linguistically validated in 10 languages including Malay. This questionnaire is readily self-administered in research or clinical settings. The IIEF demonstrates the

sensitivity and specificity for detecting treatment-related changes in patients with ED. A high degree of internal consistency was observed for every item and for the total scale (Cronbach's alpha values of 0.73 and higher and 0.91, respectively) in the populations studied. Test-retest repeatability correlation coefficients for the five domain scores were highly significant (Rosen *et al.*, 1997).

A simplified version, IIEF-5 showed substantial agreement existed between the predicted and true ED (weighted kappa=0.82). The possible scores for the IIEF-5 range from 5 to 25 which further classified ED into severe (1-7), moderate (8-11), mild to moderate (12-16), mild (17-21) and no abnormality (22-25). The cut-off score of 21 discriminated best between ED and no ED (Rosen *et al.*, 1999). The Malay version IIEF-5 questionnaire was validated among 200 subjects with the Cronbach's alpha values of 0.90 and higher (Lim *et al.*, 2003).

Data Collection

Patients attending outpatient men's clinic, USM Hospital presenting with ED symptoms were assessed for study eligibility. Subjects were briefed regarding the nature of the study. Once agreed, informed consent form was distributed. The medical records were also reviewed for additional sociodemographic and medical information. Underlying comorbidities for diabetes, hypertension and dyslipidaemia based on the prior 3 months record. The case report form that consists of self-administered questionnaire then was distributed. Once completed, the completeness of the questionnaire was checked. Then their BMI was measured by using SECA beam scale.

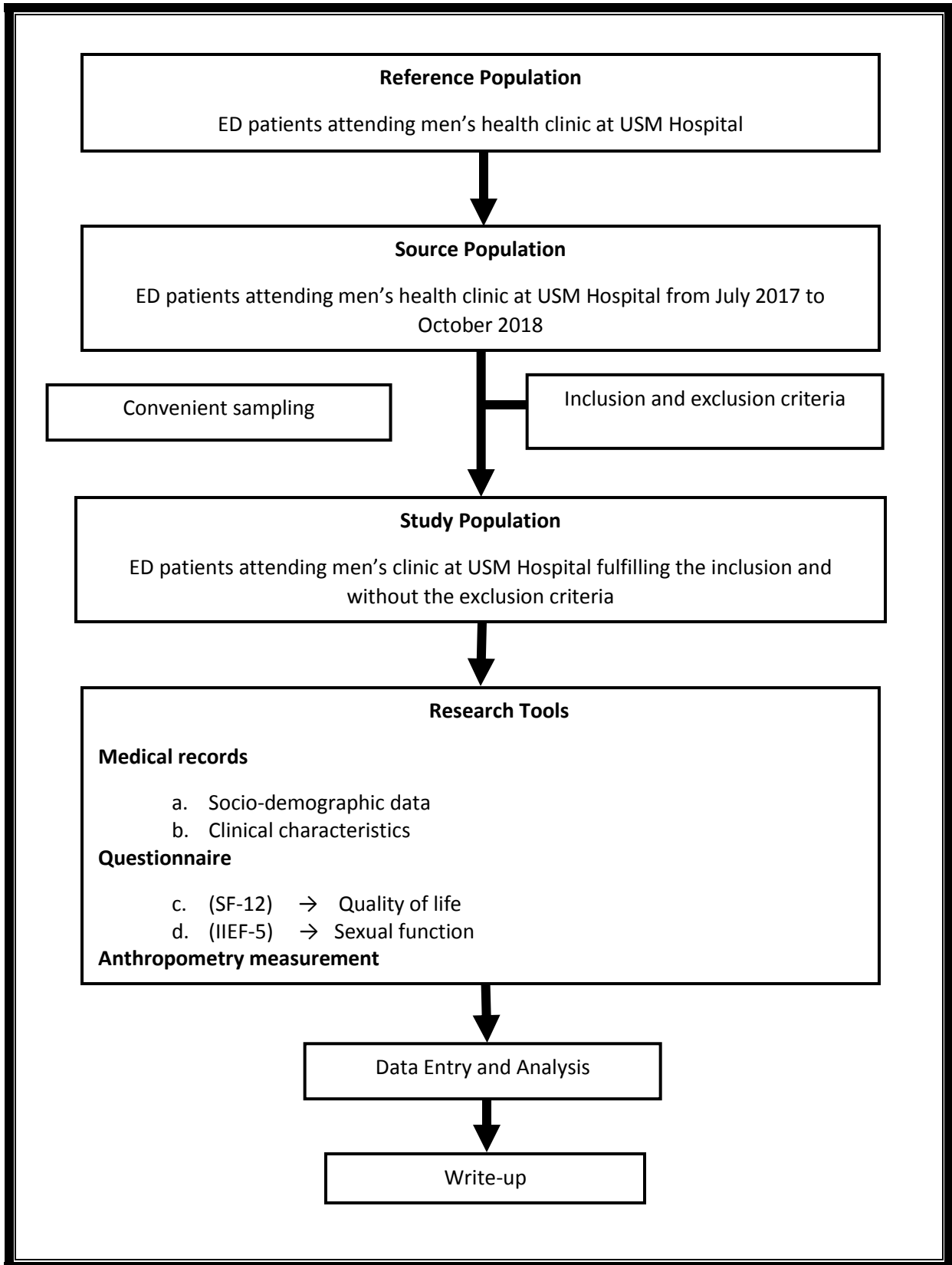


Figure 2. Flow chart of the study

Data Entry & Statistical Analysis

Analyses were done by using SPSS for windows version 24. Objective 1 is to determine the level of quality of life among ED patients. Descriptive analysis was performed.

Objective 2 is to identify the associated factors for quality of life. Simple and multiple linear regression exploratory analyses was performed. The SF-12 questionnaire assesses the physical and mental function-related QOL separately based on physical component summary (PCS) and mental component summary (MCS) scores, respectively. These analyses were done separately. First, the dependent variable for PCS score was analysed. The independent variables are race, age, work status, income, education level, and smoking status, IIEF-5 score, ED duration, ED therapy, BMI, HPT, DM, and dyslipidemia. Then, the dependent variable for MCS score was analysed along with the similar independent variables.

Objective 3 is to determine the quality of life, its associated factors and association with mental health. The dependent variable is MCS score of SF-12. The fixed factor is IIEF-5 score while adjusting for comorbidities (DM, HPT, dyslipidaemia). Simple and multiple linear regression confirmatory analyses were performed.

The procedure of General Linear Regression analysis

General Linear Regression is a statistical analysis to examine the relationship between one numerical dependent variable and more than one independent variables. The goal is to develop a best fitting, simple (parsimonious), biologically sound and easy model to

estimate the beta. General Linear Regression is a special name given when the independent variables for Multiple Linear Regression consists of mixed numerical and categorical variables.

The distribution and frequencies were examined. All continuous variables were expressed as mean (SD) or median (IQR) depending on the data distribution. Categorical data were presented as frequency and percentage. Categories with small sample size were noted and meaningful combination of categories was done when indicated.

Simple Linear Regression (SLR) was done on all independent variables at univariable level. The analysis was continued with General Linear Regression (GLR). Variable selection was done to get the 'preliminary main effect' model by automatic backward and forward stepwise procedure. A model with the significant variables chosen from those two procedures was reconfirmed. 'Preliminary main effect' model was obtained from the confirmed model. However, for confirmatory analysis, the process for variable selection is not required.

Interaction and multicollinearity were checked in fine modelling. All possible 2-way-interaction terms of the independent variables in the preliminary main effect model were done. Multicollinearity was checked for the variables in the preliminary main effect model and also for all the other variables excluded to ensure that they were not excluded due to multicollinearity problem with other variables. Serious multicollinearity problem is present

if the variance inflation factor (VIF) is equal to or more than ten. Now the ‘Preliminary final model’ was obtained.

Model assessment was done by checking the linearity assumptions (overall model linearity and linearity of each independent numerical variable), equal variance assumption, normality assumption and outliers by using standardized residual plots. Residual plots include scatter plots and histogram of residuals. In scatter plot (residuals versus predicted), if the standardized residuals were randomly scattered along the zero line (predicted value), the model is considered fit and overall linearity assumption met. If the standardized residuals were dispersed equally at any point of predicted value, equal variance assumption was considered satisfied. In histogram, if the distribution of standardized residuals was normally distributed, the normality assumption was met. In scatter plot (residuals versus independent numerical variable), if the standardized residuals were randomly scattered along the zero line, the variable functional form was appropriate.

Dummy table

Table 1. Characteristics of erectile dysfunction patients

	mean	(SD ^a)	n(%)
<u>Socio-demographic characteristics</u>			
Age (years)			
Personal income (RM)			
Education Level			
Primary/secondary school			
Degree/ Master/ PhD level			
Employment status			
Employed			

Unemployed

Race

Malay

Non-Malay

Marital status

Married

Non-married

Smoking status

Smoker

Non-smoker

Medical Characteristics

BMI (kg/m²)

Diabetes Mellitus

Yes

No

Hypertension

Yes

No

Dyslipidemia

Yes

No

Duration of ED (months)

Therapy of ED

Yes

No

Severity of ED
(IIEF5 score)

^aStandard Deviation

Table 2. Associated factors of quality of life among erectile dysfunction patients

Variables	SLR ^a			GLR ^b		
	b ^c (95% CI ^d)	t stat ^e	P value	Adj. b ^f (95% CI ^d)	t stat ^e	P value
<u>Socio-demographic</u>						

characteristics

Age (years)

Personal income (RM)

Education Level

Primary/secondary

Degree/ Master/ PhD

Employment status

Employed

Unemployed

Race

Malay

Non-Malay

Marital status

Married

Non-married

Smoking status

Smoker

Non-smoker

Medical Characteristics

BMI (kg/m²)

Diabetes Mellitus

Yes

No

Hypertension

Yes

No

Dyslipidemia

Yes

No

Duration of ED (months)

Therapy of ED

Yes

No

Severity of ED

(IIEF5 score)

^a Simple Linear Regression

- ^b General Linear Regression
- ^c Crude regression coefficient
- ^d Confidence Interval
- ^e *t* statistic
- ^f Adjusted regression coefficient

Table 3. Association between mental health and sexual function

Variables	SLR ^a			GLR ^b		
	b ^c (95% CI ^d)	t stat ^e	P value	Adj. b ^f (95% CI ^d)	t stat ^e	P value
Sexual function (IIEF5) score						

- ^a Simple Linear Regression
- ^b General Linear Regression
- ^c Crude regression coefficient
- ^d Confidence Interval
- ^e *t* statistic
- ^f Adjusted regression coefficient. Adjusted for DM, HPT, dyslipidaemia

Ethical Approval

Ethical approval was obtained from Research and Ethics Committee of Medical Science, Health Campus, Universiti Sains Malaysia (JEPeM). The approval letter from JEPeM was included in the appendices. The permission for the use of Malay version IIEF-5 was obtained from the author (Lim *et al.*, 2003). The permission for the use of SF-12v2[®] questionnaire was obtained from QualityMetric[®]. Confidentiality of the data will be strictly maintained unless required by law. All forms are anonymous and only the researcher and supervisors can access the data.

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CHAPTER 3: MANUSCRIPT

MENTAL AND PHYSICAL HEALTH-RELATED QUALITY OF LIFE AND THEIR ASSOCIATED FACTORS AMONG ERECTILE DYSFUNCTION PATIENTS IN THE NORTHEAST OF PENINSULAR MALAYSIA

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Abstract

Erectile dysfunction is a common medical problem and affects the quality of life in the patients who suffered this illness. This study aimed to determine the mental and physical health-related quality of life and their associated factors among erectile dysfunction patients. It applied a cross-sectional design among Erectile dysfunction patients in a men's health clinic in a tertiary hospital in northeast of Peninsular Malaysia. Convenient sampling was applied in the selection of eligible participants. The case report form collected responses from medical records and two self-administered questionnaires, namely the 12-Item Short Form Survey and International Index for Erectile Function questionnaire. Descriptive analysis, simple and multiple linear regression confirmatory analyses were performed using SPSS version 26. The number of participants recruited was 128. Age and severity of erectile dysfunction were associated with mental health-related quality of life. Ethnicity and severity of erectile dysfunction were associated with physical health-related quality of life. A healthcare strategy for erectile dysfunction detection and treatment should include early diagnosis of underlying and concomitant disorders, as well as improved patient health and health-related quality of life.

Keywords: erectile dysfunction, quality of life, 12-Item Short Form Survey, International Index for Erectile Function, men's health

Introduction

Quality of life (QoL) is defined as individuals' perception of their position in life in the context of the culture and value systems in which they live and concerning their goals, expectations, standards, and concerns (WHO, 1997). QoL questionnaire can be used to measure cross-sectional differences in QoL between patients that can detect important changes even if those changes are small (Guyatt *et al.*, 1993). QoL is proven to be a good marker of the functional status and well-being of a patient who endured treatment for various medical conditions (Stewart *et al.*, 1989). QoL has become an important factor in the evaluation of treatment and assessment of medical diseases (Wagner *et al.*, 2000).

Factors such as religion, environment, financial, and health status are important determinants of a person's QoL (Tian-hui *et al.*, 2005).

Many studies have been carried out to measure the QoL by using various tools in diseases, such as cancer, musculoskeletal disease, cardiovascular disease, and psychiatric disorders (Garratt *et al.*, 2002). For erectile dysfunction (ED), the study QoL in the patients who suffered this illness has been published mainly in the United States and European populations (Penson *et al.*, 2003). It is estimated that 322 million men will have ED in 2025 based on the prevalence of ED in 1995 of 152 million and the largest projected increases will be in developing countries, i.e. Africa, Asia, and South America (Ayta *et al.*, 1999). A random survey of 351 men aged more than 50 years old in Malaysia showed that 70% had ED based on the International Index for Erectile Function (IIEF) questionnaire (Khoo *et al.*, 2008). This indicates that ED is highly prevalent among men and QoL has become an important health status indicator in determining the general well-being among ED patients.

Erectile dysfunction is a common medical problem affecting many men worldwide that leads to fear, loss of image and self-confidence, and depression. The number of patients with this disease and their severity increased with age. In primary care settings, ED was common among men aged 40 years and above (Ab Rahman *et al.*, 2011). Other important risk factors of ED include diabetes, hypertension, diuretics, and oral hypoglycaemic agents (Koh, 2013). Nowadays, most of the medical treatments for ED are focused on improving the QoL of patients (Althof, 2002).

There are many factors associated with QoL in ED patients, which relate to sociodemographic aspects such as age (Guest and Das Gupta, 2002), obesity (Esposito *et al.*, 2004) as well as comorbidities (Basu and Ryder, 2004; De Berardis *et al.*, 2002; Guest and Das Gupta, 2002). A study that assessed the QoL in ED patients on tadalafil or sildenafil citrate showed that ED has a negative impact on all domains of QoL (Attia *et al.*, 2013). It is revealed that the mood, overall sexual function, satisfaction in relationships, and overall QoL in both men and their partners improved following treatment of ED (Rosen *et al.*, 2004).

Various tools are used to measure the QoL, among which are the 12-Item Short Form Survey (SF-12), World Health Organization Quality of Life Instruments (WHOQOL-BREF), International Quality of Life Assessment (IQOLA), and Short Form 36 (SF-36) Health Survey. In a study that assesses the growth of QoL measures and the availability of measures across specialties, the most widely used QoL tool is SF-36 (Garratt *et al.*, 2002). It is because SF-36 is a validated, self-administered, 36-item questionnaire that addresses eight important domains of QoL including physical function, bodily pain, vitality, role-physical, general health perceptions, emotional well-being, social function, and role-emotional (Litwin *et al.*, 1998). Meanwhile, another good QoL measurement tool is WHOQOL-BREF which consisted of four domains which are physical health, psychological, social relationship, and environment (WHO, 1996). On the other hand, SF-12 is a newer tool that is comprised of Physical Component Summary Score (PCS) and Mental Health Component Summary Score (MCS) identical to SF-36 that indicate the same magnitude of ill-health and degree of change over time (Jenkinson *et al.*, 1997). SF-12