Prevalence and associated factors of undiagnosed glycaemic disorders in men with erectile dysfunction attending a primary care clinic

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Abstract

Objectives: Undiagnosed glycaemic disorders remain a major health concern as in such cases the opportunity for early interventions that can potentially prevent complications is missed. Erectile dysfunction (ED) has been suggested as a predictor for glycaemic disorders in men. However, data on men with ED having undiagnosed glycaemic disorders is limited, especially in the Malaysian context. This study aimed to identify prevalence and associated factors of undiagnosed glycaemic disorders in men with ED.

Methods: We applied a cross-sectional purposive sampling technique on a group of 114 men with ED without underlying glycaemic disorders. They underwent a 2-h oral glucose tolerance test and the cases were then classified into two groups: normal and undiagnosed.
Introduction

Erectile dysfunction (ED) is defined as the inability to attain and/or maintain penile erection sufficient for satisfactory sexual performance. It has been estimated that ED affected 152 million men worldwide in 1995 and more than twice that number are expected to be affected by 2025, with the largest projected increases in the developing parts of the world including Asia. The latest men’s health report found the prevalence of ED in Asia ranging from 2% to 81.8%. The wide range is due to differences in the method employed by researchers to define ED. Korea and China were found to have the highest prevalence in the Asia-Pacific region whereby the former used self-reported ED while the latter utilised the Sexual Health Inventory for Men scoring system. In Malaysia, it was found that the prevalence of ED ranged from 37.3% to 79.5% and was associated with increasing age, cardiovascular diseases, and depression. Of note, ED is also a common presenting problem to primary care facilities whereby few studies found that the prevalence was about 70% for patients attending such facilities.

The effects of ED are vast involving psychosocial well-being, interpersonal relationships, and quality of life for men and their partners. It was once considered a psychogenic disorder, but now has been found to be associated with a variety of organic causes such as endocrine, vascular, and neurological disorders. The frequent co-existence of ED and diabetes mellitus (DM) may suggest that these conditions share a common pathophysiological pathway such as endothelial dysfunction, autonomic neuropathy, and vascular and hormonal abnormalities. Researchers suggest that the presence of ED may act as a predictor for early detection of DM because it is easily recognisable by patients while DM is often not. This is important because DM is usually diagnosed nine to twelve years after the initial onset; thus, patients commonly present micro- and macrovascular complications (up to 52% and 40%, respectively). Furthermore, a prediabetes state such as impaired fasting glucose (IFG) and impaired glucose tolerance (IGT) were also found to be associated with both micro- and macrovascular complications implying the need to diagnose glycaemic disorders (both prediabetes and DM) early. Therefore, an assessment of erectile function may provide information on previously undiagnosed glycaemic disorders.

Materials and Methods

Background of the place of study

Kajang Health Clinic is a government primary care facility providing outpatient and maternal and child health services. It is situated in Kajang, an urban area with a majority population of the Malay ethnicity, followed by that of Chinese and Indian ethnicities. It is approximately 30 km from Malaysia’s capital city, Kuala Lumpur.

Study design

This was a cross-sectional study conducted from November 2011 to January 2012.

Population and selection criteria

The source population in our study was all men with ED attending Kajang Health Clinic. The inclusion criteria were men at least 18 years old, sexually active, literate in either Malay or English, and not known to have glycaemic disorders. Men who refused to give consent for answering the International Index of Erectile Function-5 (IIEF-5) or for drawing blood were excluded from the study.

Sample size and sampling method

The sample size calculated was 150, based on the prevalence of undiagnosed DM and IFG at 8.4%, obtained from

uncertainty about the factors associated with the prevalence of undiagnosed glycaemic disorders.
the study conducted by Sairam and Kulinskaya, with a 95% confidence interval, absolute precision of 5%, and expected dropout rate of 20%. Conveniencesampling was employed whereby all men attending Kajang Health Clinic fulfilling both inclusion and exclusion criteria were selected to fill out the IIEF-5 questionnaire. Those diagnosed with ED were all invited to participate in our study.

**Study instruments and data collection**

The abridged IIEF-5 form was used to assess the presence of ED and its severity. The IIEF-5 contains five questions and each of the questions has five or six different answer options which carry marks of 0 to 5. Therefore, the total score of all five questions range from 1 to 25. The validated Malay and English versions of IIEF-5 were obtained from Malaysia’s DM clinical practice guideline.18 Foresta et al. recommend that ED per se is not a diagnosis and its aetiology should be included (assessed by clinical, and sometimes laboratory findings) because they think that ED is more of a symptom of underlying diseases rather than a disease in itself. However, such detailed assessment was not feasible in this study due to time and human resource constraints. Hence, we used IIEF-5 as a validated and widely available tool for identifying patients with ED in this study.

A data collection form which consisted of four parts was also used in this study. The first and second part comprised of the patient’s sociodemographic information such as age, ethnicity, marital status, education level, employment, and monthly household income. The patient’s clinical profile, which included amount of physical activity, status of smoking, alcohol intake, comorbidities, concomitant medications, and family history of DM, were obtained in the third part. The final part contained the patient’s IIEF-5 score, body mass index (BMI), and the result of oral glucose tolerance test (OGTT).

Verbal consent was obtained from patients prior to ED screening using the IIEF-5 questionnaire. Patients diagnosed with ED were invited to participate in this study and they were given a patient information sheet and consent form. Patients who consented were recruited into the study. They were asked to fill in the data collection form, assisted by an interviewer. Body weight and height were measured using calibrated weighing scales and a tape measure, respectively, on the same day. Data collection for each participant took approximately 20 min. All participants were subjected to OGTT within two weeks of the initial visit. They were asked to fast overnight for at least 8 h before a fasting venous sample (2 ml) was collected. This was followed by a glucose drink (75 g glucose diluted into 250 ml of warm water) over 5 min whereby another 2 ml of venous blood sample was taken after 2 h. The results of the OGTT were obtained from the clinic’s laboratory and recorded. The participants were categorized into normal, IFG, IGT, or DM categories accordingly. Additionally, patients who had readings in the range indicating DM were asked about symptoms of DM, and the OGTT was repeated if they were asymptomatic to confirm the diagnosis. Otherwise, DM was diagnosed based on the first OGTT results. All participants were informed about the test results during follow-up sessions, two weeks later and those diagnosed with ED and glycaemic disorders were referred for further assessment and management.

**Operational definition**

ED is defined as an IIEF-5 score of 21 and below. The severity can be divided into mild (score 17–21), mild to moderate (score 12–16), moderate (score 8–11), and severe (score 1–7). The term glycaemic disorders used in this study comprised of DM, IGT, and IFG. DM is diagnosed when the following conditions are met:

1) For patients asymptomatic of hyperglycaemia, OGTT done on two separate occasions revealing a fasting plasma glucose (FPG) level of $\geq 7.0$ mmol/L or 2-h plasma glucose (2HPG) level of $\geq 11.1$ mmol/L.

2) For patients with symptoms of hyperglycaemia, a single OGTT result revealing the above FPG or 2HPG level.

IFG and IGT are defined using a single OGTT result whereby the former is diagnosed when the FPG is from 6.1 to 6.9 mmol/L and 2HPG < 7.8 mmol/L, while the latter is diagnosed when the FPG < 6.1 mmol/L and 2HPG is from 7.8 to 11.1 mmol/L.

**Data analysis**

Data were entered and analysed using SPSS version 19.0. Exploratory data analysis with normality plots was conducted for all continuous variables to assess the distribution of data. Data was initially analysed using descriptive statistical methods followed by test of associations between independent variables and undiagnosed glycaemic disorders. Pearson’s chi-squared and Fisher’s exact test were used to check the association between categorical variables, and for continuous data, a t-test was used for normal distribution. Statistically adjustment for potential confounding factors of other covariates was tested using multivariate analysis. All p-values reported were two-sided and p-values less than 0.05 were considered to be statistically significant.

**Results**

A total of 290 men were screened for ED using the self-assessment IIEF-5 questionnaire and 173 men (59.7%) were found to have ED. All of them were invited to participate in the study and only 150 agreed to participate, yielding a response rate of 87%. There were 36 subjects who did not attend the OGTT session and they were excluded from the analysis. The final data set consisted of 114 subjects.

Age of patients living with ED in our study ranged from 27 to 72 years old and their BMI ranged from 17.7 to 44.1 kg/m². Anti-hypertensive and lipid lowering drugs were the two most common medications prescribed to patients, up to 34.2% (39 men) and 23.7% (27 men), respectively. In addition, all patients were married and non-alcoholics. Table 1 presents detailed sociodemographic and clinical profiles of the patients. The majority of patients had mild ED (46.5%, 53
men), followed by mild to moderate ED (42.9%, 49 men). The remaining patients had moderate and severe ED, both with 5.3% (6 men).

The prevalence of undiagnosed glycaemic disorders in men with ED was 41.2% (47 men) whereby 28.1% (32 men) had IGT and 13.1% (15 men) had DM. None were found to have IFG. Significant differences were found in age, BMI, hypertension status, and number of medications used for chronic diseases between the normal and undiagnosed glycaemic disorders groups (Table 2). Independent variables

| Table 1: Description of respondents’ socio-demographic and clinical characteristics. |
|---------------------------------------------------------------|
| Characteristics                                              | n (%)                        |
| *Age (years)                                                 | 48.6 (9.2)                   |
| "BMI (kg/m²)"                                                | 27.2 (5.12)                  |
| Age group (years)                                            |                             |
| 26–35                                                        | 11 (9.7)                     |
| 36–45                                                        | 33 (28.9)                    |
| 46–55                                                        | 43 (37.7)                    |
| 56–65                                                        | 26 (22.8)                    |
| 66–75                                                        | 1 (0.9)                      |

| Ethnicity          |                                 |
|--------------------|---------------------------------|
| Malay              | 82 (71.9)                       |
| Chinese            | 18 (15.8)                       |
| Indian             | 11 (9.7)                        |
| Others             | 3 (2.6)                         |

| Education level    |                                 |
|--------------------|---------------------------------|
| Primary            | 10 (8.8)                        |
| Secondary          | 84 (73.7)                       |
| Tertiary           | 20 (17.5)                       |

| Income group       |                                 |
|--------------------|---------------------------------|
| Low (<RM1500/month)| 53 (46.5)                       |
| Middle (RM1500–3500/month) | 49 (43.0)                     |
| High (>RM3500/month)| 12 (10.5)                      |

| Employment         |                                 |
|--------------------|---------------------------------|
| Unemployed         | 3 (2.6)                         |
| Employed           | 88 (77.2)                       |
| Retired            | 23 (20.2)                       |

| BMI category       |                                 |
|--------------------|---------------------------------|
| Underweight        | 3 (2.6)                         |
| Normal             | 20 (17.6)                       |
| Overweight         | 42 (36.8)                       |
| Obese I            | 39 (34.2)                       |
| Obese II           | 9 (7.9)                         |
| Obese III          | 1 (0.9)                         |

| Physical activities|                                 |
|--------------------|---------------------------------|
| None               | 42 (36.9)                       |
| Once/week          | 26 (22.8)                       |
| >Once/week         | 30 (26.3)                       |
| Daily              | 16 (14.0)                       |

| Smoking            |                                 |
|--------------------|---------------------------------|
| Non-smoker         | 47 (41.2)                       |
| Past smoker        | 26 (22.8)                       |
| Current smoker     | 41 (36.0)                       |

| Comorbidity        |                                 |
|--------------------|---------------------------------|
| Hypertension       | 39 (34.2)                       |
| Dyslipidaemia      | 27 (23.7)                       |
| Bronchial asthma   | 6 (5.3)                         |
| Gouty arthritis    | 5 (4.4)                         |
| Ischaemic heart disease | 3 (2.6)                      |
| Stroke             | 3 (2.6)                         |

| No. of comorbidities|                                 |
|---------------------|---------------------------------|
| Nil                 | 55 (48.2)                       |
| One                 | 35 (30.7)                       |
| Two                 | 18 (15.8)                       |
| At least three      | 6 (5.3)                         |

| No. of medications used|                                 |
|------------------------|---------------------------------|
| None                   | 64 (56.1)                       |
| One                    | 24 (21.1)                       |
| Two                    | 7 (6.1)                         |
| At least three         | 19 (16.7)                       |

| Family history of DM |                                 |
|----------------------|---------------------------------|
| Yes                  | 54 (47.4)                       |
| No                   | 60 (52.6)                       |

*Mean (SD); BMI, body mass index; DM, diabetes mellitus; RM, Ringgit Malaysia.

| Table 2: Characteristics of participants with normal and undiagnosed glycaemic disorders. |
|---------------------------------------------------------------|
| Characteristics                                              | Normal (n = 67) | Undiagnosed glycaemic disorders (n = 47) | p-value |
| *Age (years)                                                 | 46.1 (8.72)     | 51.3 (9.41)                             | 0.003   |
| "BMI (kg/m²)"                                                | 26.3 (4.93)     | 28.5 (5.22)                             | 0.022   |
| *Ethnicity                                                   |                 |                                         |         |
| Malay                                                        | 50 (74.6)       | 32 (68.1)                               | 0.180   |
| Chinese                                                      | 7 (10.4)        | 11 (23.4)                               |         |
| Indian                                                       | 7 (10.4)        | 4 (8.5)                                 |         |
| Others                                                       | 3 (4.6)         | 0 (0.0)                                 |         |
| Income group                                                 |                 |                                         |         |
| Low (<RM1500/month)                                          | 32 (47.8)       | 21 (44.7)                               | 0.962   |
| Middle (RM1500–3500/month)                                   | 28 (41.8)       | 21 (44.7)                               |         |
| High (>RM3500/month)                                         | 7 (10.4)        | 5 (10.6)                                |         |
| Education level                                              |                 |                                         |         |
| Primary                                                      | 5 (7.5)         | 5 (10.6)                                | 0.266   |
| Secondary                                                    | 53 (79.1)       | 31 (66.0)                               |         |
| Tertiary                                                     | 9 (13.4)        | 11 (23.4)                               |         |
| Employment                                                   |                 |                                         |         |
| Unemployed                                                   | 1 (1.5)         | 2 (4.3)                                 | 0.559   |
| Employed                                                     | 54 (80.6)       | 34 (72.3)                               |         |
| Retired                                                      | 12 (17.9)       | 11 (23.4)                               |         |
| Dyslipidaemia                                                |                 |                                         |         |
| Yes                                                          | 14 (20.9)       | 13 (27.7)                               | 0.403   |
| No                                                           | 53 (79.1)       | 34 (72.3)                               |         |
| Hypertension                                                 |                 |                                         |         |
| Yes                                                          | 17 (25.4)       | 22 (46.8)                               | 0.018   |
| No                                                           | 50 (74.6)       | 25 (53.2)                               |         |
| Family history of DM                                         |                 |                                         |         |
| Yes                                                          | 30 (44.8)       | 24 (51.1)                               | 0.508   |
| No                                                           | 37 (55.2)       | 23 (48.9)                               |         |
| Physical activities                                          |                 |                                         |         |
| None                                                         | 20 (29.9)       | 22 (46.8)                               | 0.124   |
| Once/week                                                    | 20 (29.9)       | 6 (12.8)                                |         |
| >Once/week                                                   | 18 (26.9)       | 12 (25.5)                               |         |
| Daily                                                        | 9 (13.3)        | 7 (14.9)                                |         |
| Smoking                                                      |                 |                                         |         |
| Non-smoker                                                   | 29 (43.3)       | 18 (38.3)                               | 0.141   |
| Past smoker                                                  | 11 (16.4)       | 15 (31.9)                               |         |
| Current smoker                                               | 27 (40.3)       | 14 (29.8)                               |         |
| No. of medications used                                      |                 |                                         |         |
| None                                                         | 42 (62.6)       | 22 (46.8)                               | 0.018   |
| One                                                          | 15 (22.4)       | 9 (19.1)                                |         |
| Two                                                          | 5 (7.5)         | 2 (4.3)                                 |         |
| At least three                                               | 5 (7.5)         | 14 (29.8)                               |         |

*Mean (SD); †t-test; ‡Fisher’s exact test; BMI, body mass index; DM, diabetes mellitus; RM, Ringgit Malaysia. p-values were calculated by Pearson’s chi-squared unless mentioned otherwise.
such as age, ethnicity, education level, employment, household income, physical activity, smoking status, hypertension, dyslipidaemia, number of medications, family history of DM, and BMI were included in the model for predicting the occurrence of undiagnosed glycaemic disorders. Age and BMI remained to be significantly associated with undiagnosed glycaemic disorders after adjustment for other confounders (Table 3).

**Discussion**

Screening of patients attending the Kajang Health Clinic with the IIEF-5 questionnaire found that 59.7% of men had ED. This result concurred with a population-based survey conducted in Malaysia that reported a prevalence of 62.1%. However, this was lower in comparison to that in two other studies conducted in the same country, which reported a prevalence of approximately 70%. The difference, as such, is due to the lower mean age of the sample collected in our study (48.2 ± 9.2 years); thus, making a comparison with the other studies inaccurate because advancing age in men is a well-known associated factor for ED.

Our study found that the prevalence of undiagnosed DM in men with ED was 13.1%, and this was comparable to that shown in a similar study conducted by Deutsch and Sherman. In their study, the prevalence was 12.1% with the mean age of included men being 47.2 years. In contrast, the prevalence in this study was approximately three times higher compared to that in the study by Sairam et al. wherein it was 4.7%. This is possibly due to the use of FPG to diagnose DM in their study despite OGTT being the gold standard with higher sensitivity and specificity. FPG alone has been found to miss approximately 30% of previously undiagnosed DM cases. A study carried out in an older population reported that up to 70% of new DM patients were diagnosed solely by elevated 2HPG.

As for undiagnosed IGT in men with ED, our study found a higher prevalence compared to that in the study by Deutsch and Sherman at 28.1% and 6.9%, respectively. The study by the latter may be underpowered in terms of a smaller sample size (58 men with ED) and the usage of the three hour-long OGTT may cause such a difference. Furthermore, FPG is the most common test used for screening of DM, while OGTT will only be performed if the FPG is at the prediabetes level, leaving IGT less likely to be diagnosed. For the same reason, IFG diagnosis will be more likely in the general population via a screening program, reducing this study’s sample pool (men with undiagnosed IFG), as evidenced by no men with ED having been found to have IFG in our study.

The prevalence of undiagnosed glycaemic disorders (DM, IFG, and IGT combined) in this study was 41.2%. This signifies that nearly half of the men with ED in this study were exposed to the risk of developing micro- and macrovascular complications of DM and prediabetes, unknowingly. This finding should alert healthcare providers regarding the importance of DM screening in patients presenting with symptoms of ED. An intensive DM screening program especially in men with ED is warranted to detect and manage glycaemic disorders early, to prevent such complications. We did not compare the prevalence in this study with that in another study due to the difference in defining the outcome variable whereby DM, IFG, and IGT were categorized as undiagnosed glycaemic disorders in this study, compared to undiagnosed DM used in other studies.

Advancing age in men with ED was found to be significantly associated with undiagnosed glycaemic disorders (adjusted OR = 1.10, 95% CI: 1.03, 1.17, p = 0.002). This result concurred with the finding from the Malaysian National Health Morbidity Survey of 2015, which showed an increasing trend in the prevalence of undiagnosed DM with advancing age. The survey reported the prevalence of undiagnosed DM in the general population at 5.5% in the 18–19 years old age group and peaked at 13.6% among people aged 60–64-years-old. This was supported by a study carried out in an urban population in Iran that reported that both diagnosed and undiagnosed glycaemic disorders were associated with age. Age-related reduction in pancreatic islet cell functions and increase of insulin resistance (secondary to increased fat deposition, reduction in muscle mass, and sedentary lifestyle) may explain the higher prevalence of glycaemic disorders in elderly patients, but it is not the reason it remains undiagnosed. In addition, a study carried out by Cheah and Goh in Malaysia found that elderly patients aged 60-69-years-old were more likely to undergo blood glucose screening compared to a younger age group. Thus, it can be inferred that elderly patients were less likely to have undiagnosed glycaemic disorders, which contradicted the findings of the current study. Of note, our study only included 11 men (9.6%) in that age group with the majority of the sample being taken from the 35–55 years age group (66.6%), which made the comparison difficult, and possibly biased. Further evaluation on health-seeking behaviour, particularly diabetes screening, in this age group and population (men with ED) is required to resolve this discrepancy.

Our study also found that increasing BMI was associated with the prevalence of undiagnosed glycaemic disorders (adjusted OR = 1.16, 95% CI: 1.05, 1.29, p = 0.003). This was in concordance with the Tehran Lipid and Glucose Study, which showed that higher BMI was associated with undiagnosed DM in men. Similarly, the Cooperative Health Research in the Region of Augsburg Survey 2000

### Table 3: Associated factors of undiagnosed glycaemic disorders by multiple logistic regression.

| Factors                  | Adjusted odds ratio (95% CI) | p-value |
|--------------------------|------------------------------|---------|
| Age (years)              | 1.10 (1.03, 1.17)            | 0.002   |
| BMI (kg/m²)              | 1.16 (1.05, 1.29)            | 0.003   |
| One medication used      | 0.31 (0.05, 1.77)            | 0.185   |
| Two medications used     | 0.27 (0.02, 3.31)            | 0.306   |
| Three medications used   | 1.24 (0.14, 11.13)           | 0.851   |
| Hypertension             | 1.82 (0.29, 11.42)           | 0.523   |

*Significant if p < 0.050; CI, confidence interval; BMI, body mass index.

* Forward LR Multiple Logistic Regression was applied. Multicollinearity and interaction term were checked and not found. H—L test, classification table, area under ROC are statistical methods.
carried out in Southern Germany also found that participants with undiagnosed diabetes had a higher BMI than normoglycaemic participants. Both studies were carried out in the general population of the respective countries. Insulin resistance, secondary to fat deposition is a known pathophysiology of glycaemic disorders. However, this does not explain the reason for higher BMI resulting in more cases of undiagnosed glycaemic disorders. Chang et al. conducted a focus group discussion and found that obese and overweight patients had self-stigmatization. A literature review by Puhl and Heuer concluded that obesity stigma either from self or others had decreased health care utilization for curative and preventative care. A visit to a primary health clinic is important because it opens up an opportunity for screening and risk assessment. However, the concept of obesity stigma may be a barrier for this study population. Overweight and obese patients may feel less confident, shameful, and perceive being judged when contemplating a clinic visit, thus reducing the opportunity for DM screening.

Malaysia’s clinical practice guidelines for managing DM recommend that screening of DM in asymptomatic adults be conducted starting at 30 years old. In addition, adults with a BMI ≥ 23 kg/m² with additional DM risk factors are also recommended for screening. Despite the low threshold for screening, our study found a worrying proportion of patients with undiagnosed glycaemic disorders. This suggests that men with ED may have a unique health-seeking behaviour preventing them from undergoing screening. Sociology’s theory of ‘hegemonic masculinity’ suggests that men see seeking preventative care and sex-related health issues as weak and vulnerable characteristics. In ageing men, manifestation of masculinity via sexual prowess, physical strength, and career successfulness has dwindled over the years resulting in the opposite health-seeking behaviour as the sole method of showing masculinity. This theory was explained and studied quantitatively by Springer and Mouzon, who found that masculinity idealists were associated with less seeking behaviour for preventative care than that in masculinity moderates.

This study has a few limitations. The cross-sectional study design was unable to show a causal relationship between patients’ characteristics and undiagnosed glycaemic disorders. Additionally, the use of purposive sampling and overrepresentation of Malay ethnicity made the results unsuitable to represent the whole country. Exclusion of illiterate people from this study also reduced the sample pool in terms of representation of other ethnic groups (Chinese and Indian), which caused overrepresentation of one ethnic group.

Conclusion

In conclusion, nearly half of the men with ED in this study had undiagnosed glycaemic disorders. This was associated with increasing age and BMI. These findings should alert healthcare workers to be vigilant in terms of DM screening in patients with ED. Components of sociology, patient, and healthcare system factors should be incorporated in future studies to find the causes of the high number of undiagnosed glycaemic disorders in men with ED.

Conflict of interest

The authors have no conflict of interest to declare.

Ethical approval

Ethical approval was obtained from the National University of Malaysia ethical committee (FF-378-2011) and Medical Research and Ethics Committee (MREC), Ministry of Health Malaysia (NMRR-11-629-9303).

Authors’ contributions

NYL conceived and designed the study, conducted the research, and collected and organised the data. MRAR and SMH conceived and designed the study. NYL and TSH analysed and interpreted the data. NYL and TSH wrote the initial and final drafts of the manuscript. All authors have critically reviewed and approved the final draft and are responsible for the content and similarity index of the manuscript.

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