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Female Urinary Incontinence: A Study Protocol Using the Malay QUID in Selangor, Malaysia

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Abstract

Background: Female urinary incontinence (UI) is a common complaint that is perhaps under reported in Malaysian women. Despite several studies conducted in various healthcare settings to document the prevalence, risk factors and quality of life, there continues to be a wide disparity in the results.

Objective: This study has been designed to document the prevalence, types of UI and some of the risk factors of female UI in Selangor, including the impact of UI on the sufferer's and family member's quality of life.

Methods/design: The study employs a mixed method approach. It is a cross-sectional, household study conducted in the state of Selangor, Malaysia, followed by a phenomenology study on a small sample of women. The research instrument used was the Monash Malaysia Women Health Questionnaire (MMWHQ), which consisted of four internationally validated questionnaires; 6-items Questionnaire for Urinary Incontinence Diagnosis (QUID), 17-items Menopause Quality of Life Questionnaire (MENQOL), 20-item Pelvic Floor Distress Inventory (PFDI-20) and 22-items Psychological General Wellbeing Index (PGWBI). Written permission to use and translate these validated, international questionnaires was obtained from the respective researchers. Additional questions on health assessment, reproductive health, behavioral lifestyle and socio-economic status were also included in the MMWHQ to provide a holistic health perspective of Malaysian women undertaking this study. Descriptive statistics were applied to document the prevalence and types of UI using the QUID criteria while binary and multinomial logistic regression were used to determine the predictive factors for UI and type of UI, respectively.

Discussion: This survey is anticipated to determine the estimated prevalence, risk factors and quality of life of community dwellers rather than women visiting healthcare settings. This is the first community based survey on UI ever to be conducted in Selangor, Malaysia.

Keywords: Female urinary incontinence; QUID; Prevalence; Risk factors, QOL; MMWHQ

Introduction

Urinary incontinence (UI) is a common problem that might be under reported in Malaysian women. The reported prevalence is wide and varied and there is very little on the risk factors or its impact on the quality of life of the Malaysian women [1-3].

UI is frequently referred to as a "silent epidemic" but there is a lack of documented evidence on how the Malaysian women with UI experience this phenomena and what impact it has on the quality of life of the individual, spouse or care giver. Earlier studies have reported that there might be ethnic differences in women reporting their urinary symptoms and the various types of UI they are inflicted with [4-8].

The wide and varied reported prevalence might be due to the differences in the questionnaire design or terminologies used to document the prevalence and risk factors in Malaysian women. No study has been done in Malaysia that uses the 2002 ICS (International Continent Society) terminology in their questionnaire. Further studies are therefore necessary, using the appropriate terminologies and standardized translated versions of the English language Monash Malaysian Women Health questionnaire (MMWHQ) [9].

In this regard, the MMWHQ in Malay [10], Mandarin [11] and Tamil [12] languages had been prepared to document the prevalence of UI, together with the identification of the potential risk factors, or exacerbating factors in Malaysian women in Selangor. In this study, the terminology used in the questionnaire is based on the ICS 2002 guidelines. Additional risk factors predisposing women to UI have been noted in recent studies [13-16]. Younger aged women, overweight or obese women and sedentary lifestyle have been associated with UI but no such study has been conducted in Malaysian women. Difference

in treatment seeking behavior has also been reported between women from developing and developed countries as well as women from higher and lower income categories. [17-21].

But this has not been explored in detail in Malaysian women. Crosscultural differences in the attitude and perception by women with UI exist but no phenomenology study has been undertaken in Malaysian women.

Even though maternal mortality reduction has been impressive in Malaysia, it has reached a plateau in recent years. There are still unmet needs and issues surrounding the women's health, for instance UI in Malaysian women. Majority of Malaysian women with UI do not voice their suffering and avoid seeking any form of treatment. The phenomenology study is intended to provide an insight into the Malaysian women's experience of the phenomena and the perspective of the individual, her spouse or care giver to the experience.

A population based study using a standardized instrument in English, Malay, Mandarin and Tamil version will help document accurately the prevalence and current risk factors associated with UI. The evidence documented will contribute towards the Malaysian body of knowledge in urological clinical practice. Appropriate guidelines to the Ministry of Health will enable health professionals to manage women with UI with greater sensitivity. This may increase the level of compliance to the management of UI.

Objectives

This study has been designed to document the prevalence, types of UI and some of the risk factors of female UI in Selangor, including the impact of UI on the sufferer's and family member's QOL.

Study Methodology

This is a cross-sectional, population based, observational study using a triangulation approach or mixed method and applying both quantitative (survey) and qualitative (in-depth interviews) research methods. It was conducted in the state of Selangor, Malaysia. The target group was Malaysian women who were citizens and had lived in Selangor for one or more years.

A cross sectional, observational pilot study was conducted between 2010 and 2011 with a sample size of 111. For the qualitative study pilot study, only two women out of all women diagnosed with UI, were invited to participate in the in-depth interviews. The main study was undertaken from 2012 to 2015.

Study population

In 2008, the population of Malaysia was estimated to be at 27,728,700 [22]. Malaysia is a multi-ethnic country consisting of Malays, Chinese, Indians and Others. There is a significant migrant population, with an estimated 1,907,800 non-Malaysian citizens living in Malaysia.

The population profile is relatively young, with 8,876,200 (32%) below 15 years old, 17,620,200 (63.5%) in the 15-64 age group, and 1,232,300 (4.4%) aged 65 years and above. Selangor has a population of around 5.46 million; the state's ethnic composition consists of Malays 57.1%, Malaysian Chinese 28.6%, Malaysian Indians 13.3%, and other ethnic groups 0.8% as shown in Figure 1 [22].

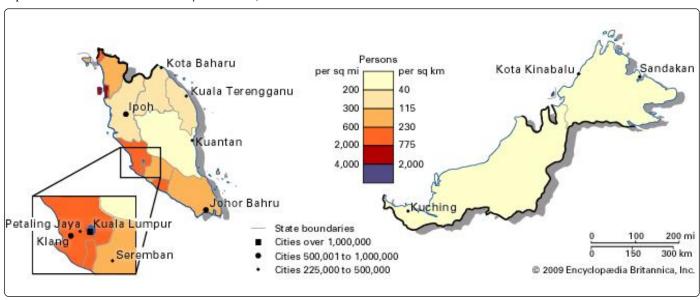


Figure 1: Map of Malaysia showing the state of Selangor as an urban settlement [22].

Location of the study

The state of Selangor was chosen due to limitations of resources and convenience as well as it is the most economically developed state in the whole of Malaysia.

The state in Figure 2 is divided into nine administrative districts [23].

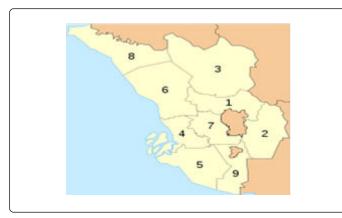


Figure 2: Nine administrative districts of Selangor [23]. These districts have been numbered as follows: 1. Gombak, 2. Hulu Langat, 3. Hulu Selangor, 4. Klang and Port Klang 5. Kuala Langat, 6. Kuala Selangor, 7. Petaling, 8. Sabak Bernam, 9. Sepang

Sample size

Crude estimate

n=minimum required sample

 $(Z\alpha)=1.96$

[95% -Confidence Interval (CI), p=0.05 significant value]

q=(1 - P) (P in decimal)

d / Δ =precision 5% (absolute precision of 5%)

P=expected prevalence

The prevalence of UI has been documented as 14.5% (n=351) Malaysian women [24].

Using Pocock's formula:

$$n = \frac{Z\alpha^2 P(1-P)}{d^2} = \frac{1.96^2 \times 0.145 \times (0.855)}{(0.05)^2}$$
$$= \frac{1.96 \times 1.96 \times 0.145 \times 0.855}{0.0025} = 190.5 = 191 \text{ respondents}$$

Dropout rate: 20% of 191=38 included=191+38=229 (main project) (Minimum sample size)

Pilot test for questionnaire's validity and reliability=100 women

Inclusion criteria

- Women aged ≥ 18 years
- Women who never had any pregnancies or children
- Women who have been pregnant more than two years ago and have children
- Women with controlled diabetes, heart diseases, high blood pressure
- Women with menopausal symptoms
- Living in Selangor for at least one year
- Consented to participate
- Able to comprehend either Malay or English language MMWHQ

Exclusion criteria

- · Pregnant women
- Women who had an abortion within the last one year
- Women who had a baby in the past two years
- Any of the following conditions in the last 3 months:
- 1. Uncontrolled diabetes
- 2. Acute mental illness
- 3. Kidney disease
- 4. Uncontrolled heart disease
- 5. Uncontrolled blood pressure or has a pace maker
- Women who had any other acute major illness
- Recent operation on their reproductive tract organs
- Currently on cancer treatment
- Bed ridden

Qualitative study-in-depth interviews

Study design: Phenomenology study

Sampling: Purposive/judgement sampling based on the sampling criteria. Women with episodes of UI, their spouses or care givers were included for interviews.

Sample size: Saturation could be achieved after 10-12 interviews [25].

Phenomenology is both a philosophy and a methodology that can be used to give insightful account of the relationship between UI and health related quality of life (HRQOL) in the woman who experiences it, her spouse or care taker. It is a critical reflection on the conscious experience. Language is the central medium for transmitting meaning and the main instrument of data collection is the interview [26].

Women identified with UI (stress: SUI, urge: UUI or mixed: MUI) during the survey were invited to participate in the qualitative study after the completion of a brief questionnaire, namely Incontinence Impact Questionnaire (IIQ) [27], to determine the level of impact UI had on them, their partner or immediate family member's QOL. The respondent and partners/family members were invited to participate in in-depth interviews to explore their attitude and openness towards UI. In addition to identify the gaps in knowledge, which are having the most adverse effect on health seeking behavior in women, and to examine the impact of female UI, on their QOL and partner relationship. Phenomenology theory will be used to interpret the interview data.

Recruitment process

The Department of Statistics Malaysia's staff were approached to determine the number of households required to interview 500 women within Selangor. With the assumption that each household has at least one eligible respondent for the study, 32 enumeration blocks (EBs) (3.5 per district) were randomly selected out of 15,786 EBs. All 16 living quarters (households) in each selected EB were included in the survey.

The staff of the Department of Statistics of Malaysia had also provided the researchers with marked maps of specific streets, roads, residential blocks and housing estates within the enumeration blocks to recruit women. The simple random sampling method used had reduced the human bias in the selection of respondents. It not only provided each woman an equal opportunity (probability) to be selected

to participate in the study but also provided the researcher with a sample that was considered to be greatly representative of the population of Selangor.

Flyers with brief information sheet about the research project were placed into their letterboxes informing them of the research project. All women in the household fulfilling the inclusion and exclusion criteria would be approached. Follow up home visits during the same week were made by the researcher to explain to the women about the research project and to find out if the women within the households were willing to participate in the project.

Upon receiving a written consent to participate, the volunteers are briefly interviewed to find out if they have met the inclusion criteria. If a selected household resident declined to participate in the health assessment but is willing to answer the questionnaire, then the missing data was also included into the database. But if the participant declines to participate after voluntarily agreeing to do so, then she is replaced by another from the same district by using random sampling. Altogether, 3.5 enumeration blocks were selected, with 56 respondents from each district.

Mixed method sampling techniques

In this study, multiple probability sampling techniques were used because probability samples were aimed to achieve representativeness, which is the degree to which the sample accurately represents the entire population [28]. The first stage was to identify various locations in the state of Selangor to recruit participants within the population so that there was an even distribution of respondents from all 9 districts of Selangor.

The second stage was to get a random sample whereby fifty-six women (unit of interest) from each enumerator block of the locations were visited to recruit volunteers. The third step was to ensure that the volunteers met the inclusion criteria before they were able to participate in this study.

Research instrument

The research instrument, the English version MMWHQ [9] which was developed specifically for this study. In addition to the English language MMWHQ, it was also developed in the Malay language MMWHQ [10], and later into the Mandarin language [11] and finally into the Tamil language [12]. MMWHQ consisted of four internationally validated questionnaires, i.e. Questionnaire for Urinary Incontinence Diagnosis (QUID) [29], The Menopause Quality of Life Questionnaire (MENQOL) [30], 20-item Pelvic Floor Distress Inventory (PFDI-20) [31] and Psychological General Wellbeing Index (PGWBI) [32].

Additional questions on health assessment, reproductive health, behavioral lifestyle and socio-economic status were also included in the questionnaire [9-12], to provide a holistic health perspective of Malaysian women undertaking this study. Written permission to use and translate these validated, international questionnaires was obtained from the respective researchers.

In the case of the PGWBI questionnaire, a MAPI user agreement and translation agreement forms were signed between the researcher and MAPI Research Institute, France [33]. All validated international questionnaires were translated into Malay, Mandarin and Tamil language and was done based on the MAPI Research Institute Trust guidelines by Acquadro et al. [34].

It included the following steps: forward translation, backward translation, a review by clinicians, cognitive debriefing, and international harmonization (if more than one language was involved), proof reading, and finally a written report. The researchers coordinated the full linguistic validation process with a team consisting of a bilingual Malay clinician, a Malay language teacher, including three Malay professional women.

An Australian study by Botlero et al. [35] had used QUID designed by Bradley et al. [29]. The QUID research instrument is described as a short, valid and responsive instrument that could serve as a diagnostic tool to determine the types of UI. No standardized research instrument to measure the prevalence of UI has been used in Malaysia, nor has a population based study on UI been conducted in the female Malaysian

Therefore, this six-item questionnaire (QUID) was intended to be used to determine the prevalence and incidence of UI in the Malaysian women more accurately. In addition, using a standardized tool that has been used in different populations could provide for a better comparison of the prevalence and incidence in Malaysia.

The Menopause Quality of Life Questionnaire (MENQOL) [30] is a multidimensional, reliable validated condition-specific QOL instrument and is considered appropriate for use in Malaysian women. Furthermore, there is now a growing belief that complaints associated with pelvic floor distress (PFD) symptoms appear a lot earlier in life than previously thought and progressively worsen with age in some women [36] and there is also a negative impact of PFD on the QOL of women with UI.

Hence, the questionnaire pelvic floor distress inventory (PFDI-20) [31] was included in this study. In order to better understand and manage QOL of women with UI, Botlero et al. [37] used Dupuy's Psychological General Wellbeing Index (PGWBI) [32] in their Australian study. It covers five domains namely; depression, anxiety, tension/stress, health and general wellbeing and was considered an appropriate instrument to be used by Malaysian women in assessing their QOL.

Study procedure

The MMWHQ contains detailed questions about the women's health status particularly, reproductive health, urinary function, menopausal symptoms and psychological wellbeing. The study also involves general health assessment. The health assessment requires the researcher to take body measurements of height weight, hip waist ratio, blood pressure and a finger prick blood sample for the measurement of blood glucose level. Malay language or the English language versions were made available to the participants.

This survey will be able to determine the prevalence and risk factors, which contribute towards developing UI. Some women with UI were approached to participate in in-depth interviews to examine the effect of UI on the QOL of sufferer and the immediate family.

Data collection

Data were collected from participants during the second home visit after they had been provided with both verbal and written information in Malay language. Upon request, English, Mandarin and Tamil language information was provided. Informed consent was obtained prior to their participation. Upon receiving the consent from the participants, an appointment was made for the researcher to visit the respondents again at home in order to administer the Malay language MMWHQ. Each booklet consists of questions with semi-structured responses. Women, who were literate and preferred to self-administer the questionnaire, would either mark a cross in the box provided or where necessary, wrote an answer in the space provided. If there were any questions the respondent found sensitive and reluctant to answer, they are free to refuse to answer the question. Answering the questionnaire would take approximately 45 minutes to an hour.

In cases of women who were not literate, the questionnaire was completed during a face-to-face interview whereby the questions were read out to the respondent by the researcher and the answers ticked according to the response. Some of the questions asked were personal and if the respondent was not feeling comfortable with them, they were not required to respond to the question. If a respondent experienced any distress from the interview, she was free to withdraw from the interview. The participants were also free to withdraw at any time during the interview with no consequences. Questions not answered were entered in the database as missing data. The researcher conducting the health assessment, that comprises of measuring the height, weight, body composition analysis [38] (Figure 3 and 4).



Figure 3: Body composition body analyzer SC-330 Tanita [38] and SECA stand meter.



Figure 4: Glucometer, blood pressure apparatus, measuring tape, urine dipstick test.

A flow chart of the data collection is displayed in Figure 5.

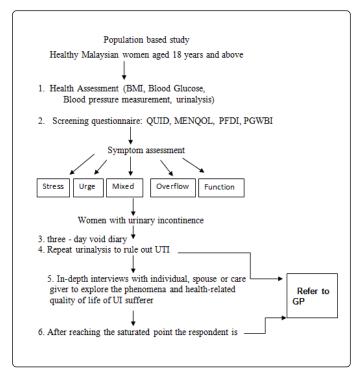


Figure 5: A flowchart on data collection.

Data management

The answered questionnaire was coded to ensure confidentiality and privacy. All respondents were provided with the researcher's work contact number and email address in case they had any queries. The researcher assured the respondents that their names and personal details would not be written on the questionnaire, except for a code number. The respondents' names will not be disclosed to anyone else either. Their participation and interview responses will be kept private and confidential unless there is a serious concern for their safety.

The answers to the researchers' questions will be combined with answers given by other women so that no one will know or identify the respondent. Participants were told that the storage of these forms will adhere to the University regulations and be kept at Monash University in a locked cupboard/filing cabinet for a minimum of 5 years. After five years, all data in hard copy will be disposed and data in soft copy will be deleted from the university computer. A report of the study might be submitted for publication, but individual participants will not be unidentifiable in such a report.

Statistical analysis

Factor analysis and reliability tests were performed using SPSS (PASW version 20). Exploratory Factor Analysis (EFA) [39] was applied to the questionnaire. First, the Keiser-Meyer-Olkin (KMO) test for sampling adequacy and Bartlett's test for sphericity was done to ensure that the EFA [39,40] was adequate for principal component analysis (PCA).

Extraction and rotation using Vairmax method was used for the PCA to note the Eigenvalue, scree plot and component matrix. Cronbach's α was also determined for reliability [41] of the extracted factors. Confirmatory Factor Analysis (CFA) [42] was performed using SPSS AMOS version 20 [43] to report on the theoretical relationships between the observed and unobserved variables including if the hypothesized model was a good fit to the observed data.

Descriptive results namely, mean, mode, standard deviation, frequency and percentage were used to describe the demographic characteristics of the respondents, prevalence of UI symptoms, specific risk factors associated with women with UI who are of normal weight, overweight and obese. Binary and multinomial logistic regression was used to investigate the relationship between risk factors and UI and types of UI. A 'p' value less than 0.05 was taken as a level of significant.

Qualitative study

NVivo 9 software [44] was used to analyze the transcripts, which explores the attitude to UI and the use of support strategies in different ethnic groups, identifying the gaps in knowledge that are having the most adverse effect on health seeking behavior in incontinent women and partners/family. Identify their coping strategies and examine the impact of female UI, urgency and frequency on the QOL, partner relationship and family dynamics.

Limitation of study

In this cross-sectional observational study, a survey questionnaire was administered and in-depth interviews undertaken by respondents who were diagnosed with UI. They were expected to maintain a 3-day void diary too. Since no uro-dynamic assessment was performed, the use of a questionnaire was considered a limitation of this study.

Ethical Consideration

This study was a low risk research project.

Ethical approval from the Medical Research and Ethics Committee (MREC), Ministry of Health Malaysia (Project NMRR-11-149-8830) and Monash University Human Research Ethics Committee (MUHREC) Certificate of Approval (Project no. CF10/1725-2010000963) was obtained.

Finance and Resource Use

Monash University Malaysia Seed Grant was obtained from the cardio-metabolic research cluster in 2008 and 2009, respectively, to fund the pilot study. The Ministry of Science, Technology and Innovation (MOSTI) e-Science Fund, Project no: 06-02-10-SF0103 funded the main project.

Disclosure of Interests

All authors are collaborative researchers in this project.

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Dissemination of Results and Publication Policy

The possible benefits of this study will include additional knowledge on the prevalence, risk factors, treatment seeking behavior and the impact of UI on the QOL life of Malaysian women and their families. The STROBE Statement, a check list of 22-items [45,46], was considered essential for good reporting of observational studies such as this study.

The information published will support evidence-based practice among medical and health professionals including early detection of overactive bladder and UI symptoms amongst women. Publishing in an online journal will widen the dissemination of the information to a wider audience.

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