QUALITY OF LIFE AMONG PATIENTS WITH URETERIC STENTS AND ITS ASSOCIATED SYMPTOMS IN UROLOGY CLINIC, HOSPITAL UNIVERSITI SAINS MALAYSIA

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LIST OF ABBREVIATIONS

DJS	-	Double J Stenting
ESWL	-	Extracorporeal Shock Wave Lithotripsy
HREC	-	Human Research Ethics Committee
HRQOL	-	Health Related Quality Of Life
HUSM	-	Hospital Universiti Sains Malaysia
LUTS	-	Lower Urinary Tract Symptoms
MANCOVA	-	Multivariate Analysis of Covariance
PNL	-	Percutaneous Nephrolithotomy
QOL	-	Quality Of Life
RPG	-	Retrograde Pyelogram
SD	-	Standard Deviation
SPSS	-	Statistical Package For Social Science
URS	-	Ureteroscopy
USSQ	-	Ureteric Stent Symptoms Questionnaire
UTI	-	Urinary Tract Infection
VAS	-	Visual Analogue Scale
WHO	-	World Health Organization
WHOQOL	-	World Health Organization Quality Of Life

KUALITI KEHIDUPAN DIKALANGAN PESAKIT DENGAN SELITAN STEN DAN PERKAITAN GEJALA DI KLINIK UROLOGI, HOSPITAL UNIVERSITI SAINS MALAYSIA

ABSTRAK

Selitan sten ureteral adalah salah satu prosedur urologi yang paling umum dalam endourologi terkini, dan sering dikaitkan dengan kesan ke atas kualiti hidup (QOL).Objektif kajian ini adalah untuk menilai kualiti hidup (QOL) di kalangan pesakit dengan sten ureteral dan gejala yang berkaitan dengan sten ureteral di Hospital Universiti Sains Malaysia (Hospital USM). Satu kajian rentas sejumlah 82 pesakit dewasa dengan selitan sten ureteral telah dijemput untuk menyertai kajian ini dengan menggunakan soal selidik gejala sten ureteral (USSQ) dengan sampel pemilihan yang bertujuan. Majoriti daripada peserta adalah Melayu (95.1%) dan min umur adalah 53.88 (SD 12.64). Hasil kajian menunjukkan terdapat perbezaan yang signifikan dalam skor min USSQ antara jantina ($p = 0.001$), status perkahwinan ($p = 0.003$), tahap pendidikan ($p = 0.003$) dan bilangan pertukaran sten ($p = 0.001$) berdasarkan kepada masa perubahan sten apabila umur adalah terkawal. Gejala kencing dan rasa sakit yang menjejaskan prestasi kerja dan keseluruhan kesihatan adalah masalah utama yang berkaitan dengan sten. 98.7% pesakit melaporkan gangguan gejala kencing termasuk gejala penyimpanan, inkontinens, dan hematuria; manakala 32% daripada pesakit mengalami kesakitan yang berkaitan sten menjejaskan aktiviti harian. Daripada 82 pesakit, 29.3% melaporkan terdapat aktiviti seksual dan di kalangan pesakit-pesakit ini, 9 (37.5%) adalah disebabkan oleh masalah yang berkaitan dengan sten. Min hari prestasi kerja yang terjejas iaitu pesakit berehat di atas katil sepanjang hari itu ialah 5.5 hari. Hal ini dapat dirumuskan bahawa selitan sten ureteral dikaitkan dengan pelbagai gejala saluran kencing dan kesakitan; dan memberi kesan yang signifikan kepada kualiti kesihatan yang berkaitan dengan kehidupan. Usaha bersepadu dengan segera oleh pihak perawatan kesihatan professional dan pihak berkuasa Kementerian Kesihatan Malaysia untuk mendidik pesakit yang mengalami kesakitan sten yang berkaitan dan gejala kencing yang teruk serta meningkatkan tingkahlaku untuk kepentingan keperluan kesihatan mereka.

QUALITY OF LIFE AMONG PATIENTS WITH URETERIC STENTS AND ITS ASSOCIATED SYMPTOMS IN UROLOGY CLINIC, HOSPITAL UNIVERSITI SAINS MALAYSIA

ABSTRACT

Placement of indwelling ureteric stents is one of the most common urological procedures in current endourology, and often is associated with effect on quality of life (QOL). The objective of this study was to evaluate the QOL among patients with ureteral stents and the symptoms associated with ureteral stents in Hospital Universiti Sains Malaysia (Hospital USM). A cross sectional study of 82 adult patients with indwelling ureteral stents were invited to participate in this study using a self-administered urinary stent symptoms questionnaire (USSQ) sampled by purposive sampling. Majority of the participants were Malay (95.1%) and mean age was 53.88 (SD 12.64). Results revealed a significant difference in mean USSQ score between gender ($p = 0.001$), marital status ($p = 0.003$), educational level ($p = 0.003$) and number of stent change ($p = 0.001$) based on time of stent changes when age is controlled. Urinary symptoms and pain that affected work performance and general health were important stent related problems. Of the patients, 98.7% reported bothersome urinary symptoms that included storage symptoms, incontinence, and hematuria; while 32% of patients experienced stent related pain affecting daily activities. Of the 82 patients, 29.3% reported no sexual life and among these patients, 9 (37.5%) was due to the problem associated with stents. Mean days of work performance affected where patients keep in bed most of the day were 5.5 days. It can be concluded that indwelling ureteral stents are associated with a range of urinary tract symptoms and pain; and have a significant impact on health related quality of life. The urgent concerted effort by healthcare professionals and the Ministry of Health Malaysia authorities to educate patients experienced stent related pain and severe urinary symptoms and to improve their health seeking behavior is needed.

QUALITY OF LIFE AMONG PATIENTS WITH URETERIC STENTS AND ITS ASSOCIATED SYMPTOMS IN UROLOGY CLINIC, HOSPITAL UNIVERSITI SAINS MALAYSIA

CHAPTER 1

INTRODUCTION

1.1 Introduction

Placement of a ureteral stent is one of the most common procedures in urology normally used to relief obstruction of the upper urinary tract (Giannarini et al., 2010). In the last two decades, ureteral stents have become the most prevalent means for upper tract urinary drainage. A number of researchers have reported that ureteric stent placement increases postoperative patient morbidity and negatively affects quality of life (QOL) (Giannarini et al., 2010; Scarneciu, Lupu, Pricop, & Scarneciu, 2015). Previous survey such as that conducted by Scarneciu et al. (2015) showed that the presence of ureteral stent can cause varying degrees of discomfort to patients and reported the prevalence of symptoms associated with ureteral stents and their impact on QOL. Despite its clinical success in relieving obstruction of the upper urinary tract, the insertion of ureteral stent has a number of problems in use. Patients with ureteric stents represent an ideal group for the investigation of QOL, considering this postoperative procedure have an impact on QOL (Danny et al., 2011). However, little is known about QOL of patients with indwelling ureteric stents and its associated symptoms in our local context.

1.2 Background of the Study

Previous studies have shown that ureteric stent result significant morbidity and QOL in many patients (Giannarini et al., 2010; Scarneciu, Lupu, Pricop, & Scarneciu, 2015).

Additionally, randomized controlled trial study by Davenport, Vivekanandan, Collins, Melotti, et al. (2011) comparing symptoms and QOL after sent insertion among 98 patients have reported that ureteral stents continues to have a significant detrimental effect on patient QOL. The past decade has seen increasingly rapid advances in the field of endourology and ureteroscopy (URS) and high prevalence rate placement of indwelling ureteral stents (Giannarini et al., 2010; Scarneciu, Lupu, Pricop, & Scarneciu, 2015; Joshi et al. 2004).

Several studies have indicated that patients with urinary stones represent an ideal group for the investigation of QOL, considering features of this disease such as its high prevalence, peak incidence in a socially active population, severe symptoms and high recurrence rate (Scarneciu, Lupu, Pricop, & Scarneciu, 2015; Danny et al., 2011; American Urological Association Foundation, 2010; Giannarini et al., 2010; Joshi et al. 2004).

1.3 Problem Statement

Urinary calculus disease in human is a universal problem. Evidence shows that the prevalence and incidence of urinary stone disease has been increasing continually in the past decades (Danny et al., 2011; American Urological Association Foundation, 2010; Romero, 2010). Studies report that the prevalence varies in different parts of the world and the reason for this variable presentation is the influence of several factors which are assumed to contribute to the formation of stone in the urine (Danny et al., 2011; Leornado, 2010; Trinchieri, 2008). In Asia the figure is 1–5%, 5–9% in Europe, 3% in North America and 20% in Saudi Arabia (Venkatramana et al., 2010).

Here in Kelantan, a state located at the northern east of peninsular Malaysia, the incidence of urinary stone in the kidney and ureter, and other parts of the urinary tract is

a common problem encountered in clinical practice. From January 2010 to June 2015, the prevalence of urinary stone disease is 498 patients in Hospital Universiti Sains Malaysia (Hospital USM), Kelantan (Medical Record Hospital USM, 2015). Figure 1.1 illustrates the prevalence of patient with ureteric stents in Hospital USM from January 2010 to June 2015 (Medical Record Hospital, USM, 2015).

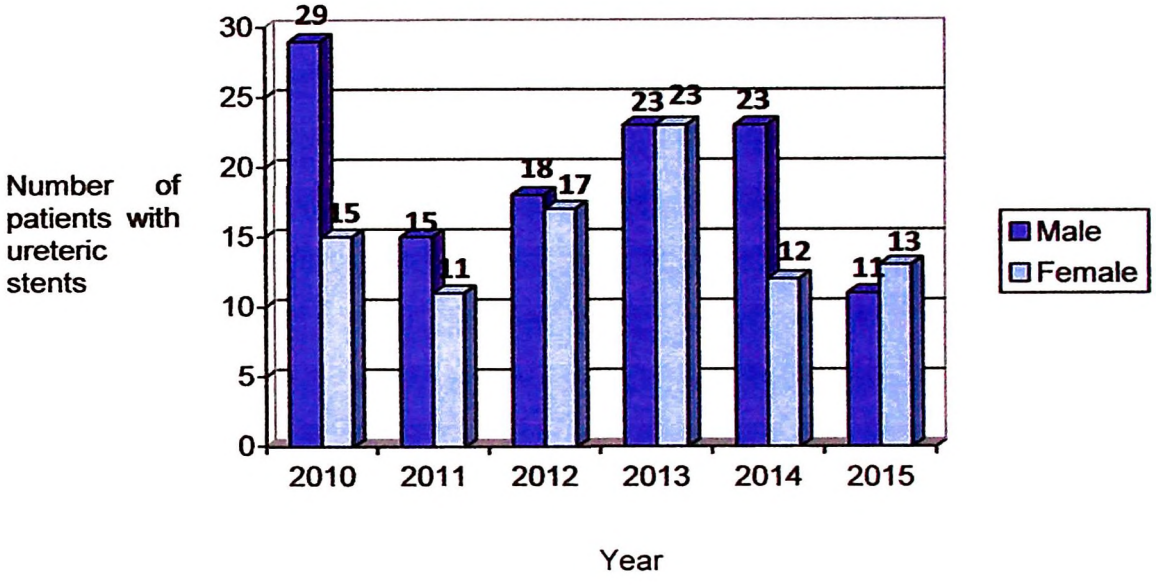

Figure 1.1 Prevalence of Ureteric Stent in Patient from January 2010-June 2015 in Numbers

(Source: Medical Record Hospital USM, 2015)

A study done in Romania had shown a significant increase in the incidence of numerous side effects and impaired quality of life in patient with ureteral stents (Scarneciu et al., 2015), which also corresponds with findings from other studies (Danny et al., 2011; Leibovici et al., 2005). The research to date has tended to focus on developed countries rather than developing countries. Although extensive research has been carried out in the developed countries, only one single study exists which look into urinary stones in Malaysia, its incidence and management by Sreenevasan (1990) while

another study compare extracorporeal shock wave lithotripsy (ESWL) and URS for treatment of proximal ureteric calculi by Izamin, Aniza, Rizal and AlJunid, 2009). What is not year clear is the impact on QOL of indwelling ureteric stents among patients in Malaysia. This suggests a gap in this body of knowledge to motivate the researcher to conduct this study.

In this study, we used a comprehensive, reliable and psychometrically valid multidimensional instrument, the Ureteric Stent Symptoms Questionnaire (USSQ) to evaluate the QOL in patients with ureteral stents. A revised version of Wilson and Cleary's model for health-related quality of life (HRQOL) was used to guide the study. Biological functions, symptoms, functional status, and general health perceptions were examined to determine their potential impact on overall quality of life (refer to Figure 2.2).

1.4. Research Questions

Generating research questions through problems in the sense of identifying and challenging the assumptions underlying existing theories, appears to be a central ingredient in the development of more interesting and influential theories within management and nursing studies (Alversson & Sandberg, 2011). According to Alversson and Sandberg, this was essential to address the gap in the literature that need to be fulfilled and act as a guide to generate objectives for this study. This research questions seeks to address the following questions:

a) What are the USSQ symptom Domains and quality of life (QOL) in patients with ureteral stents?

b) Is there any difference in mean values of symptoms and QOL between gender, marital status, educational level, employment status, number of stent changes, site of ureteric stent with regard to time after controlling the influence of age?

1.5 Research Objectives

The scope of the investigator's research was determined by what the investigator wants to achieve (investigator's objectives) and the types of decisions it needs to help the investigator make (Polit & Beck, 2011).

1.5.1 General Objective

To evaluate the quality of life (QOL) among patients with ureteral stents and the symptoms associated with ureteral stents in Hospital Universiti Sains Malaysia (Hospital USM)

1.5.2 Specific Objectives

a) To determine the QOL in patients with ureteric stents and the associated symptoms using the Ureteric Stent Symptom Questionnaire (USSQ)

b) To determine the significance mean values of symptoms and QOL between the selected demographic variables (e.g gender, marital status, educational level, employment status, and number of stent changes, and site of ureteric stent).

c) To determine the association between socio-demographic characteristics of patient with ureteric stent with regard to time of stent changes and urinary index symptom characteristics and QOL

1.6 Research Hypotheses

Hypothesis 1 : There is a significance difference in mean values of symptoms and QOL between gender, marital status, educational level, employment status, number of stent changes, site of ureteric stent with regard to time, after controlling the influence of age. (H_A)

There is no significance difference in mean values of symptoms and QOL between gender, marital status, educational level, employment status, number of stent changes, site of ureteric stent with regard to time, after controlling the influence of age (H_O)

Hypothesis 2 : There is a significance association between socio-demographic characteristics of patient with ureteric stent with regard to time of stent changes and urinary index symptom characteristics and QOL. (H_A)

There is no significance association between socio-demographic characteristics of patient with ureteric stent with regard to time of stent changes and urinary index symptom characteristics and QOL. (H_O)

1.7 Significance of the Study

Previous studies have reported that ureteric stents has become a part of urological treatment options (Al-Marhoon, Shareef, & Venkiteswaran, 2012). The complications

of short-term or long-term use of indwelling stents has been a controversial and much disputed subject in regards to patient's QOL and varied in patients (Al-Marhoon et al., 2012). This study provides an important opportunity to advance the understanding of QOL among patients with ureteral stents. Additionally, this study makes a major contribution to local research and offers some important insights into this issue of the symptoms associated with ureteral stents and its impact on QOL. This is exemplified in the work of Danny et al. (2011) that patients with indwelling ureteric stents represent an ideal group for the investigation of QOL, considering high prevalence of ureteric stones in contemporary society (Danny et al., 2011). Therefore, the findings should make an important contribution to the field of urology and add to the body of knowledge by exploring the QOL among patients with ureteral stents and the symptoms associated with ureteral stents in Hospital USM

1.8 Definitions of Operational Terms

QOL - WHO defines quality of life (QOL) as an individual 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. It is a broad ranging concept affected in a complex way by the person's physical health, psychological state, level of independence, social relationships, personal beliefs and their relationship to salient features of their environment (Faisal, 2011; Oort, 2005; WHOQOL, 1998). In this study, QOL refers to the patient's perception of their position in life in the context of ureteric stent symptoms questionnaire (USSQ).

Ureteric stent - Ureteral stent is used to relieve ureteral obstruction, promote ureteral healing following surgery, and to assist with ureteral identification during pelvic surgery. Ureteral stent placement is associated with some degree of morbidity in the majority of patients that ranges from generalized urinary discomfort to urinary tract infection or obstruction. Much of the morbidity is related to the biocompatibility of the materials used to fashion the stent and, to some extent, their design; unfortunately, the ideal stent has yet to be discovered (Nakada & Patel, 2015).

CHAPTER 2

LITERATURE REVIEW

2.1 Introduction to the Chapter

This chapter provides a review of literatures on quality of life (QOL) among patients with indwelling ureteric stent as a whole. In also includes the impact of stenting on QOL, QOL and concept of QOL and the conceptual framework guiding this study.

2.2 Prevalence of Ureteric Stones

Epidemiological surveys have been previously reviewed showing that in economically developed countries the prevalence rate ranged between 4% and 20% (Trinchieri, 2008). The prevalence of urinary calculi is estimated to be 1–5% worldwide. It is the third most commonly encountered cases in urology clinics after urinary tract infection and prostate diseases (Danny et al., 2011). Not only it is one of the most costly urological diseases in terms of treatment, but also has a high recurrence rate of approximately 50%, which has a negative impact on the quality of life of the patient and in turn on the health care system (Danny et al., 2011). Ureteral stone is among the most painful and prevalent among urologic disorders. The figures are increasing in both developed and developing countries due to environmental and dietary changes (American Urological Association Foundation, 2010). Lifetime prevalence of ureteric calculus is relatively high, occurring in approximately 12% of men and 7% of women (Bickle, 2015; Pearle, Calhoun, & Curhan, 2005). The risk is increased with a past history of ureteric calculi or with positive family history. Most patients present aged between 30 and

60 years of age (Bickle, 2015; Tamm, Silverman, & Shuman, 2003) , with peak incidence between 35-45 years old. Initial calculus presentation occurring past 50 years of age is uncommon (Bickle, 2015). The epidemiology of urolithiasis differs according to geographical area in term of prevalence and incidence, age and sex distribution, stone composition and stone location. Such differences have been explained in terms of race, diet and climate factors. Furthermore changing socio-economic conditions have generated changes in the prevalence, incidence and distribution for age, sex and type of urolithiasis in terms of both the site and the chemical-physical composition of the calculi (Trinchieri, 1996, 2008).

According to Bach et al., (2012), different treatment options would depend on the diagnosis of kidney or ureteral stones. They further explain that factors that influence the decision include symptoms, stone characteristics, medical history, treatments available at hospital and the expertise of doctor, personal preferences and values; and pointed out that not all stones require treatment. Kidney or ureteral stones should be treated if they cause symptoms. There are three common ways to remove stones: shock-wave lithotripsy (SWL), ureteroscopy (URS), and percutaneous nephrolithotomy (PNL). They further pointed out that which active treatment option is best for patient depends on many aspects. The most important factor is the symptoms the stone causes. Based on whether the stone is in the kidney or the ureter, the doctor may recommend different treatment options to manage urinary stone (Bach et al., 2012).

2.3 The Role of Ureteral Stents

A ureteral stent is a thin, flexible tube threaded into the ureter to help urine drain from the kidney to the bladder or to an external collection system. Urine is

normally carried from the kidneys to the bladder via a pair of long, narrow tubes called ureters (each kidney is connected to one ureter). A ureter may become obstructed as a result of a number of conditions including kidney stones, tumors, blood clots, postsurgical swelling, or infection. Placement of ureteral stent is to restore the flow of urine to the bladder. Ureteral stents may be used in patients with active kidney infection or with diseased bladders (e.g., as a result of cancer or radiation therapy). Alternatively, ureteral stents may be used during or after urinary tract surgical procedures to provide a mold around which healing can occur, to divert the urinary flow away from areas of leakage, to manipulate kidney stones or prevent stone migration prior to treatment, or to make the ureters more easily identifiable during difficult surgical procedures. The stent may remain in place on a short-term (days to weeks) or long-term (weeks to months) basis.

2.4 Quality of Life (QOL)

The World Health Organization (WHO) defines Quality of life as "an individual's 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. It is a broad ranging concept affected in a complex way by the person's physical health, psychological state, personal beliefs, social relationships and their relationship to salient features of their environment" (Faisal, 2011). The satisfaction, which is subjective and may fluctuate multidimensional factors that include everything from physical health, psychological state, level of independence, family, education, wealth, religious beliefs, a sense of optimism, local services and transport, employment, social relationships, housing and the environment, cultural perspectives, values,

personal expectations and goals of what we want from life, not just the absence of disease but the presence of physical, mental and social well-being. As explained by Barcaccia et al. (2013), it is the individual level of acceptance of current condition, and ability to regulate negative thoughts and emotions about that condition (Barcaccia, Esposito, Matarese, Bertolaso, & Marinis, 2013).

QOL is multidimensional and includes psychosocial, physical and emotional status as well as patient autonomy, and is applicable to a wide variety of medical conditions (American Urological Association Foundation, 2010). QOL is a new view of health from a bio-psycho-social perspective that emerged as a perceived need to balance and supplement the success of modern medicine to improve the QOL in the case of serious, chronic, debilitating or fatal diseases (Alshowkan, Curtis, & White, 2012; Basu, 2004). Over the last 30 years, several definitions of QOL have been provided and most of them were based on a theoretical orientation and ranged in scope from a focus on psychological issues such as feelings of well being and satisfaction with issues related to standards of living such as perceived health, housing, finances, and employment (Alshowkan et al., 2012; Awad & Voruganti, 2000).

According to the American Urological Association Foundation, QOL is an estimate of leading a life free of impairment, disability or handicap (American Urological Association Foundation, 2010). Patients with urinary stones represent an ideal group for the investigation of QOL, considering features of this disease such as its high prevalence, peak incidence in a socially active population, severe symptoms and high recurrence rate.

2.5 Quality of Life in Patients with Ureteral Stents

Ureteral stones are usually stones from the kidney that have moved into the ureter. The pain is caused by the stone passing down the ureter and is so severe and the patient becomes very restless and uncomfortable (American Urological Association Foundation, 2010). Patients presenting with pain are more likely to have stones located in the ureter (Danny et al., 2011).

Ureteral stones disease is among the most painful and prevalent among urologic disorders that can substantially impact health-related quality of life (HRQOL) particularly in patients with a history of recurrent stones. Patient's age, the presence of stone in the distal part of the ureter, stent, together with low back pain were found to significantly influence the QOL of ureteral stone patients in the present study (Danny et al., 2011). They further explained that although there is ample literature describing QOL in patients with other urologic disorders, a few studies have assessed QOL in stone patients after a surgical intervention, despite the documented high rate of life-time recurrence.

Chronic blockage of a ureter affects approximately five individuals out of every 1,000; acute blockage affects one out of every 1,000. Bilateral obstruction (blockage to both ureters) is more rare; chronic blockage affects one individual per 1,000 people, and acute blockage affects five per 10,000 (Wright & Sherk, 2015).

Discomfort can vary from one patient to another in an idiosyncratic manner, but is believed to affect over 80% of patients (Miyaoka & Monga, 2009). Conversely, a low incidence of 19.6% of stent-related complications (Miyaoka & Monga, 2009).

Several studies in literature describe the symptoms related to ureteral stents and their respective estimated incidence: irrigative voiding symptoms including frequency (50-60%), urgency (57-60%), dysuria (40%), incomplete emptying (76%), flank (19-32%) and suprapubic pain (30%), incontinence, and hematuria (25%) are included. Frequency is attributed to a mechanical stimulus that comes from the bladder coil (Haleblian, Kijvikain, de la, & Preminger, 2008; Miyaoka & Monga, 2009). They further explained that along with urgency, it affects a significant proportion of patients (60%).

Daytime frequency distinguished by the lack of coexisting nocturia suggests that mechanical stimulation relates to physical activities and/or awareness of this stimulation during the day, which would not be significant during the night. Objective assessment through frequency volume charts corroborates this theory.

Stent displacement with physical activity may also impact stent discomfort. In Miyaoka and Monga's (2009) small study of 6 patients, they noted up to 2.5 cm of movement of the renal coil or bladder coil and associated bowing in the proximal ureter with alteration in patient position. Urgency is thought to be a direct result from the presence of the stent, which may also unmask or exacerbate pre-existing subclinical detrusor over activity (Miyaoka & Monga, 2009).

Dysuria is usually experienced at the end of voiding. It has been proposed that dysuria is secondary to trigonal irritation by the distal end of the stent when it crosses the midline or forms an incomplete loop (Miyaoka & Monga, 2009). In a similar way, a recent published randomized clinical trial confirmed that urgency and dysuria were more common with longer stents and negatively impacted the patients' quality of life (Miyaoka & Monga, 2009).

Flank pain is most likely a result of urine reflux towards the kidney that leads to an excessive rise in intra-pelvic pressure that ultimately translates into pain (Miyaoka & Monga, 2009). It is usually mild to moderate and is not influenced by the position of the proximal coil either in the upper calyx or in the renal pelvis (Miyaoka & Monga, 2009). Suprapubic pain can result from local bladder irritation by the distal coil or as a secondary sign of associated complication such as encrustation or infection (Miyaoka & Monga, 2009).

Globally, it is evident that the presence of Double J Stenting (DJS) cause varying degrees of discomfort to patients. Analysis of data revealed differences but statistically insignificant between the 4 types of stent used. None of the materials proved to be superior in terms of secondary manifestations of this foreign body in the urinary tract.

Urinary frequency and urgency are symptoms directly caused by mechanical factor. The majority of patients complain of these symptoms increased significantly during the day, highlighting the dependency of physical activity. Bladder muscle over activity is clearly enhanced by the presence of DJS. The urinary frequency and urgency were present in statistical significant percentage 7 days after the stent placement.

Dysuria seems to be more common when using stents with excessive length. According to Scarneciu et al. (2015), dysuria were experienced at 7 days after stent installation and remain after its removal. They indicated that suprapubic pain is associated with direct irritation of the bladder mucosa. However, it can be exacerbated in the case of secondary infection or stones in the distal volute (Scarneciu et al., 2015).

2.6 Conceptual Framework: Wilson and Cleary Model of Health Related QOL

Conceptual framework is a model that describes, explains or predicts the nature of the directional relationships between elements or dimensions of QOL (Ilic, Milic, & Arandelovic, 2010). A conceptual framework lays out the key factors, constructs, or variables, and presumes relationships among them (Jabareen, 2009). In this study, the revised Wilson and Cleary health related QOL model was used as conceptual framework to guide this study (Figure 2.1)

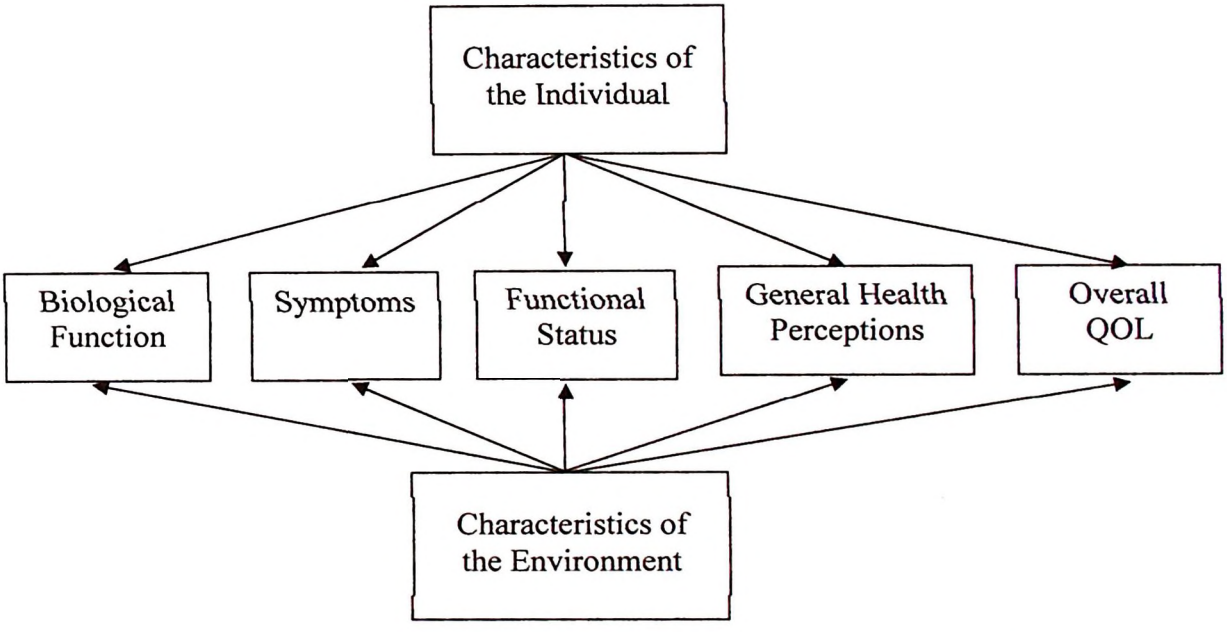

Figure 2.1 Revised Wilson and Cleary's Model of Health-Related Quality of Life

Figure 2.1 illustrates the revised Wilson and Cleary's Model of Health-Related Quality of Life guiding this study. In this model, there are five types measurement of patient outcomes that will be the primary focus: Biological functions, symptoms, functional status, general health perceptions and overall

quality of life. Above all, the characteristics of the individual and the environment influence these components (Ferrans et al., 2005).

The demographic, developmental, psychological, and biological factors that influence health outcomes are categorized under characteristics of individual. Gender, age, marital status, ethnicity are the factors that commonly related to incidence of illness thus these factors can give a direction to the health care providers to target which group that are in high risk for developing such disease that link to the factors as stated above (Ferrans et al., 2005).

Wilson and Cleary (1995) defines symptoms as "a patient's perception of an abnormal physical, emotional, or cognitive state". It can be categorized as psychological, physical or psychosocial. The interactions between both individual and environment factors will influence the experience, evaluation and interpretation of the symptoms.

Functional status can be defined as the ability to perform tasks in multiple domains such as physical functions, social functions, role functions, and psychological function. Since the functional status can be viewed in various perspectives, the traditional models described the functional status as disability, focused on the loss function that affects the daily life (Ferrans et al., 2005).

Wilson and Cleary (1995) defined the general health perceptions in two categories: a) it is the integration of all components that come earlier in this model, and b) they are subjective in nature. For an overall evaluation of certain aspects of health, this component is important. The final component in this model is the overall quality of life that has been defined as the subjective well being related to how happy or satisfied someone is with life as a whole (Ferrans et al., 2005).

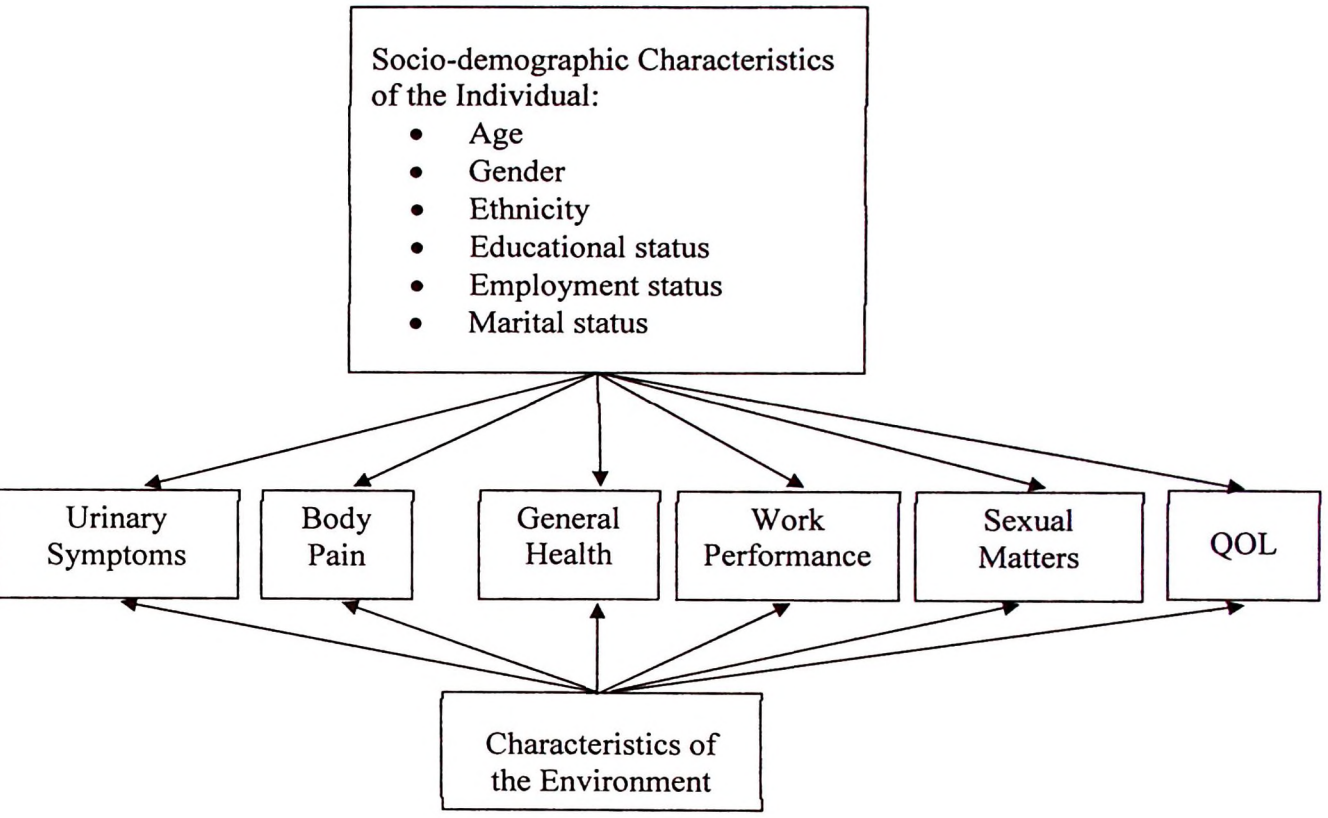

Figure 2.2 Schematic Diagram of HRQOL Adopted in this Study

CHAPTER 3

METHODOLOGY & METHODS

3.1 Introduction to the Chapter

This chapter outlines the research methodology and methods used in this study aiming to evaluate the quality of life (QOL) among patients with ureteral stents and the symptoms associated with ureteral stents in Hospital Universiti Sains Malaysia (Hospital USM).

3.2 Research Design

Research design is a master plan for a research project which escalates the control over factors that could interfere with the validity of the study finding (Grove, Burns, & Gray, 2013). The research design was a cross-sectional study using a structured, self-administered questionnaire. The rationale for this research design was it can be captures a population in a single point in time and can help to remove assumptions (Polit & Beck, 2014).

3.3 Study Population and Setting

The study population was patients with indwelling ureteric stents and came for follow-up at the Urology Clinic, Hospital USM. Hospital USM was chosen as the study setting, the environment within which this study was run due to the reason it being a referral, teaching hospital where most patients with urinary stones were referred.

3.4 Sampling Plan

The sampling plan describes the strategies that was utilized by the researcher to obtain a sample for a study. It is developed to enhance representativeness, reduce systematic bias, and minimizes the sampling errors (Grove et al., 2013).

3.4.1 Sample

When conducting a research study, certain inclusion and exclusion criteria were considered in selecting an eligible sample from the population at the Urology Clinic, Hospital USM.

Inclusion Criteria

Subjects are eligible for inclusion in this study if they:

- Are patients with ureteric stent aged 18 and above
- Attend the Urology Clinic in Hospital USM for follow- up
- Were able to understand, speak and write in English or Bahasa Malaysia

Exclusion Criteria

Subjects are excluded from this study if they:

- Declined participation in this study

3.4.2 Sampling Design

Sampling was guided by the designed sampling criteria and a sampling frame. In this research study, a purposive sampling was used to recruit the sample.

3.4.3 Sampling Size Determination

In this study, sample size was estimated based on Joshi et al., (2003) of the Ureteric Stents Symptoms Questionnaire (USSQ) validation study. Calculation was done using the simple mean formula:

$$n = \left(\frac{1.96 \times \delta}{\Delta} \right)^2$$

Whereby,

n = sample size

z = The standard normal deviation of 1.96 corresponding to 95% confidence interval (CI)

δ = Standard deviation (SD)

Δ= Effect size

Substituting,

$$n = \left(\frac{1.96 \times 2.2}{0.5} \right)^2$$

Sample size calculated is 74 participants.

By considering the dropout rate as 10%, the adjusted n is as follows:

$$n = \frac{\text{n calculated}}{1 - \text{dropout rate}}$$

$$n = \frac{74}{1 - 0.1}$$

$$= 82$$

For the purposes of this study, the highest numbers of sample size of 82 participants were recruited as representative sample size.

3.5 Variables

Variables are characteristics or attributes of a person or object that varies within the population under study (Polit & Beck, 2011). Variables are therefore those attributes that are measured or manipulated in a study. The variables used in this study are independent and dependent variables.