

**TEMPORARY VASCULAR ACCESS
COMPLICATIONS AND ITS IMPACT ON QUALITY
OF LIFE AMONG HEMODIALYSIS PATIENTS**

by

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LIST OF ABBREVIATIONS

AKI	Acute Kidney Injury
AVF	Arteriovenous Fistula
CABSI	Catheter Associated Blood Stream Infection
TVA	Central Venous Catheters
CKD	Chronic Kidney Disease
ESRF	End Stage Renal Disease
GFR	Glomerulus Filtration Rate
HD	Hemodialysis
Hospital USM	Hospital Universiti Sains Malaysia
QOL	Quality Of Life
SD	Standard Deviation
TVA	Temporary Venous Access
WHO	World Health Organization

TEMPORARY VASCULAR ACCESS COMPLICATIONS AND ITS IMPACT ON QUALITY OF LIFE AMONG HEMODIALYSIS PATIENTS

ABSTRACT

Temporary venous access (TVA) is commonly used for patients with chronic renal failure when the vascular access is immature or dysfunction and patients who need for acute hemodialysis (HD) treatment. The objective of this study is to determine the occurrence of TVA complication, the types and its impact on quality of life among HD patients. A cross-sectional survey was conducted within two months period on 52 patients HD patients with TVA who underwent hemodialysis treatment in Hemodialysis Unit at Hospital USM. Altogether, there were 19 males and 33 female respondents involved in this study with median age of 50 years that were selected through convenient sampling method. Most of respondent had internal jugular catheter (78.8%) and the used of TVA in situ was within four to six months. All patients had experienced TVA complication that caused removal of the catheter. Complications of the catheter were catheter associated bloodstream infection 38.5%, catheter thrombosis 36.5% and catheter insufficient blood flow 25%. However, all these complication had no impact on respondents' quality of life. The occurrence of TVA complication among HD patients in this study was 100%.Further study on larger sample size is required to ratify these findings.

KOMPLIKASI VASKULAR AKSES SEMENTARA DAN KESANNYA KE ATAS KUALITI HIDUP DALAM KALANGAN PESAKIT HEMODIALISIS

ABSTRAK

Akses vena sementara (TVA) biasanya digunakan untuk pesakit yang mengalami kegagalan buah pinggang kronik dimana akses vaskular masih tidak matang atau kehilangan fungsi dan pesakit yang memerlukan rawatan hemodialisis dengan segera. Objektif kajian ini adalah untuk menentukan berlakunya komplikasi TVA, jenis dan kesannya terhadap kualiti hidup pesakit dalam kalangan pesakit hemodialisis. Satu kajian rentas telah dijalankan dalam tempoh dua bulan pada 52 pesakit hemodialisis dengan TVA yang menjalani rawatan hemodialisis di Unit Hemodialisis di Hospital USM. Secara keseluruhan, terdapat 19 orang responden lelaki dan 33 orang responden wanita terlibat dalam kajian ini dengan umur median 50 tahun yang telah dipilih melalui kaedah persampelan mudah. Kebanyakan responden menggunakan kateter dalam leher (78.8%) dan penggunaan TVA adalah diantara empat hingga ke enam bulan. Semua pesakit mengalami komplikasi yang menyebabkan pembuangan kateter. Komplikasi kateter yang berlaku ialah jangkitan kateter berkait dengan aliran darah 38.5%, kateter thrombosis 36.5% dan aliran darah dalam kateter tidak mencukupi 25%. Walaubagaimanapun. Semua komplikasi ini tidak memberi kesan terhadap kualiti hidup pesakit. Komplikasi kateter yang berlaku dalam kalangan pesakit hemodialisis dengan TVA adalah 100%. Kajian yang lebih lanjut perlu dilakukan dengan meningkatkan saiz sampel kajian.

CHAPTER 1 INTRODUCTION

1.1 Background of the Study

The Kidney Disease: Improving Global Outcomes (2013) classified kidney diseases into Acute Kidney Injury (AKI) and Chronic Kidney Disease (CKD). The AKI was defined as rapid loss of the capability of the kidney to excrete waste, concentrate urine, preserve electrolyte and maintain fluid balance in the body (Schrier, Wang, Poole, & Mitra, 2004). Most patients with mild to moderate acute kidney injury are asymptomatic and are identified on laboratory testing but patients with severe cases, however, may be symptomatic and present with listlessness, confusion, fatigue, anorexia, nausea, vomiting, weight gain, or edema and patients can also present with oliguria (urine output less than 400 mL per day), anuria (urine output less than 100 mL per day), or normal volumes of urine (Rahman, Shad, & Smith, 2012).

On the other hand, the CKD was defined as the abnormalities of kidney structure or function that present more than three months with implication on health (The Kidney Disease: Improving Global Outcomes, 2013). The CKD can also be identified based on glomerulus filtration Rate (GFR) (more than 30 mg/mmol) and albuminuria rate (less than 15) (The Kidney Disease: Improving Global Outcomes, 2013). In CKD, the kidneys do not usually fail entirely at once. Instead, the problem may slowly progresses over a period of years and depends on the causes. The CKD is measured in five stages. The focus of this study however, is on stage 5, which also known as end stage renal disease (ESRD) (The Kidney Disease: Improving Global Outcomes, 2013).

Patients who are diagnosed with ESRD would generally require life-extending treatment, which also known as renal replacement therapy to regain some of the kidney functions. This includes hemodialysis (HD), peritoneal dialysis (PD) and renal transplant. This study however focuses on HD. This dialysis treatment plays a very important role as part of the main treatment and acts as lifetime appliance for those patients who are not suitable for

kidney transplantation or who are waiting for transplantation (Division of Nephrology, Hypertension and General Internal Medicine, 2011).

According to Astle (2004), HD is a treatment for kidney failure that uses a machine to send the patient's blood through a filter, called a dialyzer, outside the body. It involves the process of diffusion and ultrafiltration to remove excessive fluid and waste products of the body that normally excreted by the kidneys (Astle, 2004). This procedure takes about 4 hours and patient need to dialyze three times per week.

In Malaysia, it has been reported that in 2012, there were 5121 new HD cases representing the rate of 175 per million populations as shown in Tables 1.1 (Lim, Goh, & Ong, 2013). This number has increased from 23,924 in 2011 to 26,067 in 2012. While Table 1.2 shows the statistics of HD patients from 2003 to 2012.

Table 1.1: The number and flow of HD patients in 2003-2012

Year	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012
New HD patients	2259	2610	2830	3227	3552	4030	4359	4704	5316	5121
Died	1017	1164	1334	1643	1756	1915	2275	2664	2881	2719
Transplanted	107	145	101	96	72	91	97	90	87	65
Lost to Follow-up	10	15	15	39	18	18	42	56	102	136
Dialysing at 31 st December	9339	10708	12166	13740	15505	17587	19620	21618	23924	26067

Source: 20th Report of Malaysian Dialysis and Transplant Registry, 2013.

Table 1.2: The rate of HD per million populations 2003-2012

Year	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012
Acceptance rate	89	101	107	122	131	146	156	167	186	175
Prevalence rate	369	413	459	512	570	639	703	765	838	889

Source: 20th Report of Malaysian Dialysis and Transplant Registry, 2013.

According to Astle (2004), HD requires the use of a patent, long-term, functional vascular access, and a means through which to dialyze the patient's blood. The access is a surgically created vein used to remove and return blood during HD. A vascular access allows large amount of blood to flow continuously during HD in order to filter as much blood as possible during treatment. About 500 ml of blood flows through the machine every minute (Astle, 2004). The vascular access should be in place before the first HD treatment.

The arteriovenous (AV) fistula however, frequently requires two to three months to develop and mature, before the patient can use it for HD. If the disease has progresses quickly and requires HD treatment, the patient may not have time to wait for the AV fistula. Thus, catheter will be inserted as a temporary venous access (TVA) for patient so that HD can be started right away (Maleta, Bozidar, Mesaros, & Racki, 2012). The TVA can be used for several weeks or months until the AV fistula matured (Clark & Barsuk, 2014).

The advantages of TVA is that they are easier to be inserted (even by the bedside) through various sites for almost any patient. Furthermore, it usage is commonly associated with the lack of hemodynamic compromise (Lai & Andrew, 2011). Also, TVA insertion does not require "tunnelization" and thus, fast access to the circulatory system can be provided (Lai & Andrew, 2011). The TVA however, is varying in length and thus, the selection must depending on the puncture site and availability of a central vessel (Lai & Andrew, 2011). Besides for patient who requires acute HD, the TV also sometimes indicated for Stage 5 CKD patients, who are on regular dialysis. This is particularly for those with inadequate function of AV fistula or AV graft due to stenosis or thrombosis, (Maleta, Bozidar, Mesaros, & Racki, 2012).

The device use for TVA is called venous catheter, which is a tube inserted into a large vein either in the neck (internal jugular vein), chest (subclavian vein), or leg near the groin (femoral vein), as route for short-term HD (National Kidney Foundation, 2006). Of these routes, internal jugular vein is the most commonly preferred method because of the large vein with a lower risk of pneumothorax compared to the subclavian and inadvertent arterial puncture as well as it can be easily controlled with manual compression (Jha, Sunil Kumar, Bokil, & Galante, 2013). The right internal jugular vein is better than the left side as it is

larger and straighter (Figure 1.1). Also, it is more convenient for the right-handed practitioner and thus, can avoid the possibility of thoracic duct injuries.

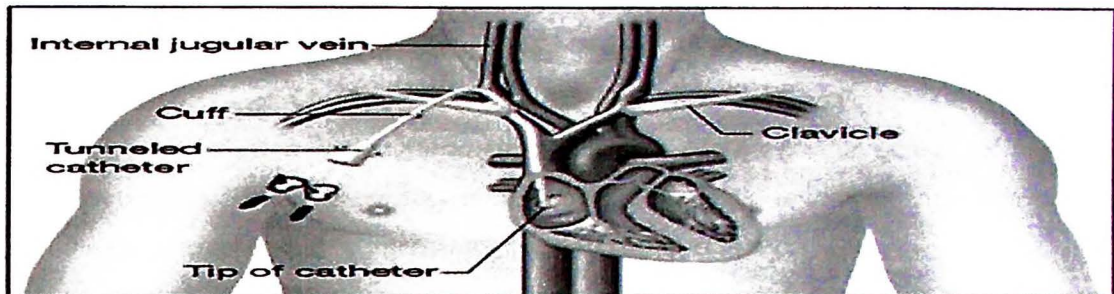


Figure 1.1: The central venous catheter insertion at the internal jugular vein. (Source: The Kidney Foundation of Canada, 2010).

According to Key and Duffy (2009), the subclavian route often preferred for long term central access as it is generally more comfortable for patients, can be easily tunneled and has a lower risk of infection and other long term complications. This route is best avoided in patients requiring long term renal replacement as there is a significant risk of venous stenosis which causes problems for existing or future arteriovenous fistulae moreover it is also best to avoid in patients with abnormal clotting or bleeding diatheses as the vessels are inaccessible to direct pressure after inadvertent arterial puncture because serious immediate complications such as pneumothorax (Key & Duffy, 2009) .

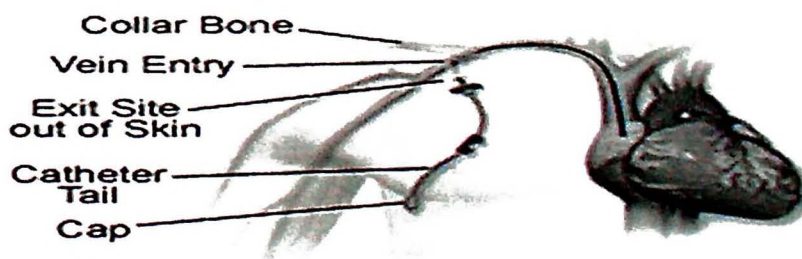


Figure 1.2: The central venous catheter insertion at the subclavian vein. (Source: Key & Duffy, 2009)

The femoral vein is commonly used in urgent situations because of the large diameter that allows large volumes of blood to be dialyzed and infused, particularly for immediate hemodialysis (Sydney Children's Hospitals Network, 2015) such as ventilated and sedated patients as excessive movement can cause kinking of the catheter and mechanical complications (Sydney Children's Hospitals Network, 2015). However, this route has a higher risk of infection in long-term usage because of the greater degree of bacterial colonization found in the groin (Key and Duffy (2009). There is also an increased risk of thromboembolic compared to internal jugular and subclavian routes.

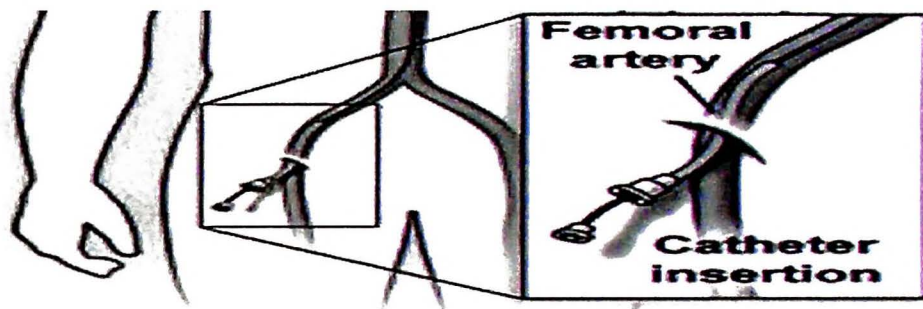


Figure 1.3: The central venous catheter insertion at the femoral vein. (Source: The Kidney Foundation of Canada, 2010).

The catheter used for TVA is made from polyurethane and thus, it is easier to introduce along the guide wire so that the catheter will follow the anatomy of the vein which reduces the risk of vessel damage (Frankel (2006). This is because polyurethane is a material that is stiff at room temperature but soft at body temperature. Compared to other catheters, it is more resistant to bending in the vessel (Frankle, 2006).

Although TVA is important for HD, its usage however, may cause some complications that relate to the dysfunction of the catheter. This includes thrombosis and infection, which can lead to catheter-associated blood stream infection (CABSI) (Tan, Zanariah, Lim, & Balan, 2007). There are two types of complications related to TVA or HD; early or late complications. Early complications include pneumothorax, pleural or mediastinal hematoma, air embolism, thoracic tract injury, damage to nervous structures within the neck and thoracic region, puncture of the cardiac cavities, or cardiac arrest. Whereas late complications such as thrombotic complications, vascular stenosis and catheter-related

bacteremia (Lai & Andrew, 2011). The National Kidney Foundation (2006) recommended that the TVA should remain in place for no longer than five days in the femoral vein and 21 days in the internal jugular and subclavian veins. This is because prolonged duration of catheter usage will increase the risk of infection that later on reduced patient's quality of life.

The common microorganism responsible for such infection is *Staphylococcus Aureus* (Esmanhoto, *et al.*, 2013). Grothe, *et al.* (2010) added to this that the infection also progressed rapidly and become severe with high mortality rate. Some of the impacts on patient's quality of life include patient's loss freedom, dependent on caregivers, marital, family and social life disruptions and reduced or loss of financial income. Patient's also experience drastic psychological, socioeconomic and environmental changes soon after the catheter are inserted and thus, diminished their quality of life (Sathvik, Parthasarathi, Narahari, & Gurudev, 2008).

1.2 Problem Statements

In a study by Isrrate, Mota, & Cana-Ruiu (2009) on 80 HD patients who had received HD for 13.5 hours per week for three sessions, they indicated that the main complications of TVA are thrombosis and infection that require removal of the catheter. Of these two complications however, infection remains the major cause of catheter dysfunction (Isrrate, Mota, & Cana-Ruiu, 2009). The other less common complications are arterial puncture, major bleeding, and systemic sepsis (Savary, Somlo, & Nwanosike, 2005). Most of these studies were conducted in the Western countries. This kind of study however, is scant in Malaysia.

Soon after the catheter is inserted for immediate HD, the patient's quality of life will begin to be disrupted. This is due to the risk of sepsis brought along by the TVA (Napalkov, *et al.*, 2013). Its application would also cause an uncomfortable condition because the insertion site is easily visible to others (jugular vein). While is the catheter is compatible to human body, it is however, is still a foreign body and thus, would some or rather would cause some complications as well as altered patients' social life and reduce their self-esteem

(Micco, et al., 2009). This psychosocial condition due to the use of TVA however, had never been examined in other studies.

At this stage, the researchers managed to find only two published studies conducted in Malaysia relating to venous catheter. One of the studies focused mainly on catheter infection (Tan, Zanariah, Lim, & Balan, 2007). The other study also focused on on infection and antibiotic therapy (Abdul, et al., 2014). However, to the researcher's concern so far, study focusing on both venous catheter complication and its impact on patients' quality of life is still lacking (Wasse, Kutner, Zhang, & Huang, 2007). With this light, the researcher is inspired to conduct this study on HD patients with TVA.

In order to understand the complication of TVA and its impact on patient's quality of life, the Ferrans' model was chosen as the conceptual framework for this study.

1.3 Research Objectives

1.3.1 General Objectives

To assess the complication of TVA and its impact of TVA on patients' quality of life

1.3.2 Specific Objectives

1. To assess the occurrence of TVA complication among HD patients
2. To identify the types of TVA complication that commonly experienced by HD patients.
3. To determine the association between selected HD patients' demographic data (age, sex, years of HD treatment, family income and level of education) and the occurrence of TVA complication.
4. To identify the association between TVA complication and its impact on HD patients' quality of life.

1.4 Research Questions

1. Is TVA complication common among HD patients in Hospital USM?
2. What are the types of TVA complication that commonly experience by HD patients?
3. Is there any impact of TVA complication on HD patient's quality of life?
4. Is there any association between selected HD patients' demographic data (age, sex, and years of HD treatment, Body Mass Index, family income and level of education) and the type of TVA complication?
5. Is there any association between TVA complication and its impact on HD patients' quality of life?

1.5 Hypothesis

1. H_01 = There is no significant association between selected socio-demographic characteristics and the occurrence of TVA complication.
 $H_A 1$ = There is a significant association between selected demographic characteristics and the occurrence of TVA complication.
2. H_02 = There is no association between TVA complication and patients' quality of life
 $H_A 2$ = There is a significant association between TVA complication and patients' quality of life.

1.6 Definition of Terms (Conceptual/Operational)

- | | |
|---------------------------|---|
| Complication | - A morbid process or event occurring during a disease that is not an essential part of the disease, although it may result from it or from independent causes (Napalkov et al., 2013). |
| Quality of Life | - The WHO has defined Quality of Life as individuals' perceptions 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 (WHOQOL Group, 1997). |
| Temporary Vascular Access | - Temporary vascular access is defined as access to the bloodstream by means of a large vein catheter for maximum period of 6 months to make adequate hemodialysis treatment possible (Weijmer, 2004). |
| Hemodialysis Patients | - Patients who was diagnosed with CKD stage 5 or ESRD and requires HD treatment using a machine that filters wastes, salts and fluid from blood because the kidneys are no longer healthy enough to do this work adequately (Frankel, 2006). |

1.7 Significance of the Study

The finding of this study provides a new knowledge about the occurrence of TVA, the types of complication and its' on HD patient's quality of life. It also provides some useful information for HD nurses to help them plan patient's care in advance in the prevention TVA complications and eventually helps to increase patients' quality of life. Furthermore, the findings of this study can be used as a base line data for further research in this area.

CHAPTER 2 LITERATURE REVIEW

2.1 Introduction

This chapter reviewing the current literature related to Temporary Venous Access (TVA) complications. It also presents information on HD patients with TVA includes the prevalence and the types of TVA complications. Besides that, the impact of utilizing TVA on patients' quality of life will also be discussed in this chapter. All these information are included in this study to help improve the current knowledge in this area of care.

2.2 The prevalence of TVA complication

Prevalence is an epidemiological measure used to determine how commonly a disease or condition occurs in a population. It is also used how much of a particular disease or condition is there in a population at a particular point in time (Indrayan, 2013). Lincoln (2012) reported that the prevalence of infection with the use of TVA is nine times higher than arteriovenous fistula and five times higher than arteriovenous graft. The main reasons for the infection is nasal colonization of staphylococcus, other infections, being older and having diabetes (Lincoln, 2011). Xue, *et al.* (2013) reported that based on incident dialysis access type, catheter patients had a infection event rate of 1.27/1000 catheter-days, which was higher than that of patients receiving dialysis through an AVF or AVG and overall 13.3% patients had at least one positive blood culture result during treatment. HD treatment through TVA would worsen certain chronic conditions such as diabetic mellitus and hypertension (Bakris, et al., 2010).

2.3 Common types of complications of TVA

Studies have reported several kinds of TVA complication. This includes infection, sepsis, hemorrhage, pneumothorax, air embolism, arterial or nerve laceration, cardiac perforation, arrhythmia, loss of guidewire, catheter malposition, extravasation, infiltration, edema, refractory bleeding, catheter breakage, catheter blockage, and thrombophlebitis (Ozakin, *et al.*, 2014). A study has reported that complications have occurred in terms of thrombotic

problems, low blood flow, occurrence of infection. The prospective study took 36 months period to complete which includes 31 patients that on hemodialysis treatment and infection was found in 10 patients while thrombotic complications were observed in 27 cases regardless of catheter type (Kukavica, Resic, & Sahovic, 2009)

2.3.1 Catheter associated infection

Catheter related infections, which is the most common TVA complication and irresponsible for significant morbidity and mortality among HD patients. Infection occurs most commonly by migration of skin organisms along the external surface of the catheter from the exit site wound or via the lumen of the catheter due to breakdown in aseptic technique by health care staff (Bagul, Brook, Kaushik, & Nicholson, 2007). The infection can be classified into three groups; exit site infection, tunnel infections, or catheter-related bacteremia (CRB) (Haddad, Cleef, & Agarwal, 2012). According to Beathard and Urbanes (2008), exit-site infection is localized to the exit site and does not extend beyond the cuff. It can be treated with antimicrobials and usually does not require catheter exchange or creation of a new exit site infected.

2.3.2 Thrombosis

Although standard definitions are not available, most clinicians refer to venous thrombosis involving the vein(s) in which the catheter dwells as catheter related thrombosis (Lee & Kamphuisen, 2012). Ozkan and Usuloy (2011) state that thrombosis is a common complication of TVA. Thus, anticoagulant is instilled into both catheter lumens after each dialysis session in an effort to prevent interdialytic catheter thrombosis. Heparin is the predominant anticoagulant lock solution used in HD units but the use of a lower heparin concentration may mitigate the potential risk of serious hemorrhagic complications arising from heparin leaking into the systemic circulation (Maya, Smith, & Allon, 2010).

2.3.3 Pneumothorax

Delayed pneumothorax is a recognized complication of subclavian catheterization. In this case, pleura of the lung is inadvertently perforated most commonly during the insertion of catheter through subclavian veins (Pazos, Inan, Robert, & Walder, 2009). It should be

reminded that the failure of the first attempt for catheter insertion can increase the risk of pneumothorax (Girgin, Arici, Turker, Otlar, Hotaman, & Kutlay, 2010). The sign and symptom of pneumothorax includes shortness of breath, decreased oxygen saturations and chest movements may be abnormal usually confirmed by chest x-ray (Maya, Smith, & Allon, 2010).

2.3.4 Air Embolism

Air embolism occurs when air that entered venous circulation get into the systemic arterial circulation. If the catheter is open to room air, the negative intra thoracic pressure created by breathing inwards draws air into the vein resulting in air embolism because air may then travel through the heart and enter the pulmonary circulation (Ozkan & Ulusoy, 2011). In this condition, the patient will present symptoms of end-artery obstruction includes cyanosis, tachypnoea, coughing, tachycardia, hypotension, loss of consciousness and cardiopulmonary arrest (Zong, 2014).

2.4 The Impact TVA on HD Patient's Quality Of Life

Quality of life is defined as an individual's total well-being, including all aspect of life; physical, emotional, social, mental financial and spiritual as reported in previous studies (Lin, 2013). A few studies had looked into the impact of TVA on quality of life on the physical, social, psychology and financial aspects (Morales & Castillo, 2009; Hayes et al. 2012; Mazairac, et al., 2011; Peng et al. 2013; Hemmati et al. (2011); Stolic et al. (2008; Turkmen et al. 2012; Organ and MacDonald, 2014). The impact is further explained in the following sections.

2.4.1 Physical impact

Morales and Castillo (2009) emphasizes that, patients with TVA must protect the catheter from getting wet. This makes them unable to do usual activities swimming and they could not practice any exercises, play active games or dancing to avoid excessive movement as well as sweating since this would affect the the catheter dressingof causes catheter displacement. This situation would cause them to feel frustration, boring and anguish, particularly in the male patients (Morales & Castillo, 2009). According to Hayes et al.

(2012), although the use of TVA offer needle free dialysis but patient must always be aware of the risk of catheter malfunction with poor blood flow and catheter related infection. Thus, they have to take extra careful whenever they are moving or doing vigorous activity.

2.4.2 Social impact

The restriction in physical activity would also restrict the patients' social activity imposed by catheter and this is a significant loss for them (Morales & Castillo, 2009). A study by Mazairac et al. (2011) on 570 HD patients from 24 different centers reported that the patients needs to undergo frequent and long visit to receive the treatment. They had also to visit the clinic for medical guidance and support. All these doings had affected their quality of life as they had very limited time to socialize and perform routine jobs (Mazairac, et al., 2011). In terms of gender differences, Peng, et al. (2013) indicated that women on dialysis treatment had more depression related symptom and poor self reported quality of life but improved survival compared to man. This is because of their family role as mother and wife that requires more time and attention for the family.

2.4.3 Psychological impact

The impact of TVA on the aspect of psychological is in relation to the process to accept the presence of the catheter in their body part (Hemmati, et al., 2011). According to Hemmati et al. (2011), with regards to age, the adolescents felt great shame and sadness with the catheter attached to their body compared to older adults. They need more time to accept it as a part of their body, which is important to maintain their health. This is proven in the study when they found that one of the issues raised by HD patients with TVA is how to live with it. The patients claimed that they have to restrict their activities just to ensure the catheter functioning but at the same time altered their social life. Some of patient (62.8%) also claimed the TVA makes them feel uncomfortable.

Similarly, Stolic et al. (2008) also reported that the TVA had altered the patients' comfort level since there is a foreign object at the site of insertion (Stolic, et al., 2008). In Turkmen et al. (2012), the impact of TVA on quality of life and sleep quality was measured among 247

HD patients with TVA. The result indicated that sleep disturbance is one of the common impact of TVA. This includes delayed sleep onset, frequent awakening, anxious and daytime sleepiness. Therefore, they concluded that the patients were exposed to high risk of depression that eventually lead to low quality of life. The depression level in this study was assessed by using the Beck Depression Inventory (Turkmen et al.,2012).

2.4.4 Financial impact

Besides physical, social and physiological aspects, impact on financial was also indicated among HD patient with TVA. In a study by Organ and MacDonald (2014), it was reported that a patient has to drive three times a week to receive their HD at the hospital or get someone to drive them. Most of the patients who drove themselves reported daily costs increased by year. This situation worsens for those who had to take a taxi as they had to pay large amount of money per month out of pocket for transportation (Organ & MacDonald, 2014). While most of HD patients were among pensioners, obviously, this is a burden to them as they to spend more just for transportation .

2.5 Tools to measure patients' quality of life

The World Health Organization (WHO) developed two instruments used to measure quality of life which are the WHOQOL-100 and the World Health Organization Quality of Life – BREF (WHOQOL-BREF) that can be used in various cultural settings. It allows comparison of results between different populations and countries and had been utilized in medical practice, research, audit, and in policy making (WHOQOL Group, 1997). Both the WHOQOL-100 and the WHOQOL-BREF instrument have shown good discriminate and content validity, and test-retest reliability.

The WHOQOL-BREF is the new version of the WHOQOL-100. It has 26 items contains two items from the Overall Quality of Life and General Health, and one item from each of the remaining 24 facets included in the WHOQOL-100. Recent analysis of the WHOQOL-100 structure has suggested the possibility of merging domains 1 and 3, and also merging domains 2 and 6, thereby creating four domains of quality of life. In current approach to set the scoring of the WHOQOL-BREF, these domains have been merged therefore, four

major domains are assessed: physical, psychological, social relationships and environment (WHOQOL Group, 1997).

2.6 Conceptual / Theoretical Framework

This study uses the Ferrans' Conceptual Model of Quality of Life (Ferrans's,1996) to help the researcher's understand the population's behavior under study. Based on an individualistic ideology, Ferran's (1996) defined quality of life as a person's sense of well-being that stems from satisfaction and dissatisfaction with the areas of life that is important to him or her. According to this theory, quality of life is considered as a unique experience of individual related to their own values. Each person is the eligible judge of his or her quality of life because the individual differs in what he or she values. This quality of life model consists of four domains, which are 1) health and functioning domain, 2) psychological or spiritual domain, 3) social and economic domain, and 4) family domain (Figure 2.1).

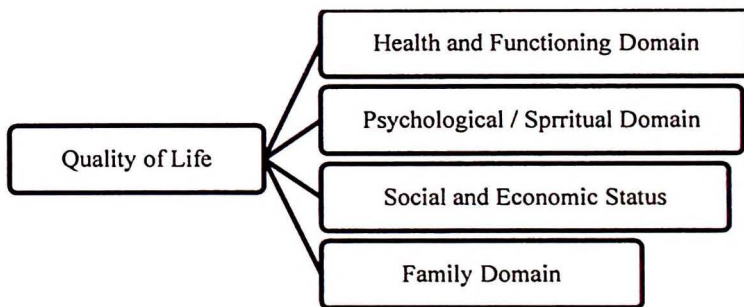


Figure 2.1: The Ferrans'Conceptual Model of Quality of Life (Ferrans, 1996)

The health and functioning domain consists of 14 elements. The elements include usefulness to others, physical independence, ability to meet family responsibilities, own health, pain, energy (fatigue), stress or worries, control over own life, leisure time activities, potential for happy old age or retirement, ability to travel on vacations, potential for a long life, sex life and health care (Ferrans,1996).

The psychological or spiritual domain consists of seven elements. The elements include satisfaction with life, happiness in general, satisfaction with self, achievement of personal goals, peace of mind, personal appearance, and faith in God (Ferrans, 1996).

The social and economic domain consists of eight elements include standard of living, financial independence, home (house, apartment), neighborhood, job or unemployment, friends, emotional support from others, and education (Ferrans, 1996).

The family domain consists of four elements; family happiness, children, relationship with spouse, and family health (Ferrans, 1996). All of these domains revealed that there is no single quality of life for all patients who have the same life stressor.

This model has been applied in a Brazilian study and the researcher discovered that it is useful in identifying the satisfactory psychometric properties in different situations. It helps the researcher to develop specific tools to measure the quality of life of individuals and pregnant women (Kimura & Silve, 2009).

CHAPTER 3 METHODOLOGY

3.1 Introduction

The research method is described in this chapter including the research design, setting, sample, and data collection protocol. The instruments used to collect the data are reviewed. The data analysis plan is also addressed.

3.2 Research Design

This is a cross-sectional study. Cross-sectional study is a study that is carried out at one time point or over a short period time (Levin, 2006).

Population and Setting

The population of this study was among HD patient withTVA and receiving regular HD treatment at Hemodialysis Unit in Hospital Universiti Sains Malaysia (Hospital USM), Kubang Kerian, Kelantan.

3.3 Sampling Plan

3.3.1 Sample

The inclusion and exclusion of respondents of this study were as follows;

Inclusion Criteria

1. Adult male and female patients undergoing HD through TVA at Hemodialysis Unit, Hospital USM.
2. Aged 18 years old and above
3. Able to understand, speak and write in Bahasa Malaysia.

Exclusion Criteria

1. HD patients without TVA
2. HD patients with TVA who are not fit to response to the questionnaire.
3. Unwilling to participate in this study

3.3.2 Sampling Method

Participants of this study were selected through convenience sampling method. This is because the method involves the selection of samples that are both easily accessible and willing to participate in this study. Furthermore, it is suitable to be used when in the situation of limited of sample size from the sampling frame such as this study (Teddlie & Yu, 2007). Initially, a list of HD patients with TVA was obtained from the Hemodialysis Unit, Hospital USM. Following this, only those who fulfilled the inclusion criteria and receiving HD from December 2014 to February 2015 were invited to participate in the study.

3.3.3 Sampling Size

The sampling size for this study was identified using the Raosoft sample size calculation software. This was applied to ensure the accuracy by avoiding sampling error during representative and parameters of the sample with a confidence level at 95% and a margin of error that can be tolerated at 0.05. based on this calculation, the initial recommended sample size for this study was 46 respondents.

After considering 10% of potential drop out, therefore, the total respondents that is requires for this study is as follows:

$$= 46 + \text{drop out of } 10\%$$

$$= 46 + 4.6$$

$$= 50.6 \text{ patients}$$

$$\approx 51 \text{ patients}$$

3.4 Variables

3.4.1 Variables Measurement

The independent variables for this study were the selected respondents' demographic data; age, sex, years of HD treatment, family income, marital status and level of education. Whereas the dependent variables were complication of TVA and the impact of TVA on quality of life.

Altogether, the WHOQOL-BREF scale that was used to assess respondents' quality of life has 26 items (WHO, 1996). The domain and facet of this scale are scored in a positive direction whereby higher scores denote higher quality of life. For example, item 5 asks "How much do you enjoy life?" and the available responses are (1 = "Not at all", 2 = "A little," 3 = "A moderate amount", 4 = "Very much" and 5 = "An extreme amount").

Individual item of this scale was rated on a five point Likert scale where 1 indicates low, negative perceptions and 5 indicate high, positive perceptions. Then the total scores were calculated by computing the sum of all items in the scales (range 1 -5), divided by the numbers of items per scale for each individual (Hasanah, Naing & Rahman, 2003).

While data on the type of complication experienced by the respondents were taken directly from respondents' medical records using a standard form (refer Appendix A).

3.5 Instrumentation

3.5.1 Instrument

Data for this study were collected using a set of self-administered questionnaires that consists of three main sections; Part A, Part B and Part C as follows;

Part A: Socio-demographic data

This section comprises of six questions to gather data on age, gender, marital status, years of HD treatment, family income and level of education.

Part B: Impact of TVA on quality of life.

This section comprises of the WHOQOL Malay version (Hasanah, Naing & Rahman, 2003). Of the 26 items, item 21 and 22 are concern on sexual life. Considering the respondents' cultural background and some of them may be single, thus, the researcher had decided to remove it from the original items and left only 24 items to be used for this study (Doss & Polaschek, 2012).

The mean scores of this scale ranged from 3.14 to 3.98 and the standard deviation ranged from 0.56 to 1.10. This indicated a good spread of the scores around the middle portion of the 5-point scale. The items are grouped into four dimensions as follows:

1. Physical domain: Items 3, 4, 10, 15, 17, 16 and 18. It referred to symptoms of pain or discomfort, energy or fatigue and sleep or rest.
2. Psychological domain: Items 5, 6, 7, 11, 19 and 24. It referred to positive or negative feeling, body image or appearance and self-esteem.
3. Social Relationships domain: Items 20. It refers to personal relationship and social support.
4. Environment domain: Items 8, 9, 12, 13, 14, 21, 22 and 23. It referred to financial resource, home environment and safety.

Part C: Types of TVA complication and catheter characteristics.

This part was used to find data regarding the type of complications experienced by HD patient with TVA. Altogether, there are 14 items. This data was collected separately by the researcher herself through patient's medical record from TVA using a specific assessment form. The form consists of information about TVA complication, detail of TVA insertion and patient's health history (Chu, Adams & Crawford, 2013).

3.5.2 Validity and Reliability

Reliability and validity of the WHOQOL-BREF scale Malay version used in this study was tested and validated on other population in previous study by Hasanah, Naing & Rahman, 2003. The Cronbach alpha values of this scale reflects the internal consistency ranged from 0.64 in the domain 2 (psychological domain) to 0.80 in domain 1 (physical domain), which is considered as reliable (Hasanah, Naing & Rahman, 2003). As the scale has been used in the same study setting and was found as reliable and valid by the previous researchers, pilot study was not required for the current study (Kueh YL, statistician at Biostatistics Unit, School of Medical School, USM, pers. Comm., February, 2015).

3.6 Ethical Considerations

Ethical approval to conduct the study was obtained from the Research Ethical Committee (Human), Universiti Sains Malaysia. Permission to conduct the study was also obtained from the Director of Hospital USM and the Manager of Hemodialysis Unit. Explanation on the purposes of the study was given to the respondents prior to survey. Apart from that, how they were involved and their rights to discontinue from the study were honestly explained to them. Respondents were informed that all the information from the study was kept confidential, anonymous and will be used for academic purposes only. Written consent was obtained from patient prior to answering the questionnaire.

3.7 Data Collection Plan

After getting approval from the Research Ethical Committee (Human), and permission from the Director of Hospital USM, data were collected. Questionnaires were distributed to respondents who fulfilled the inclusion criteria and willing to take part in the study after one hour starting the hemodialysis. It took about 20 minutes for each respondent to complete the questionnaire. The flow of data collections for this study is shown in Figure 3.1.

3.7.1 Flow Chart of Data Collection

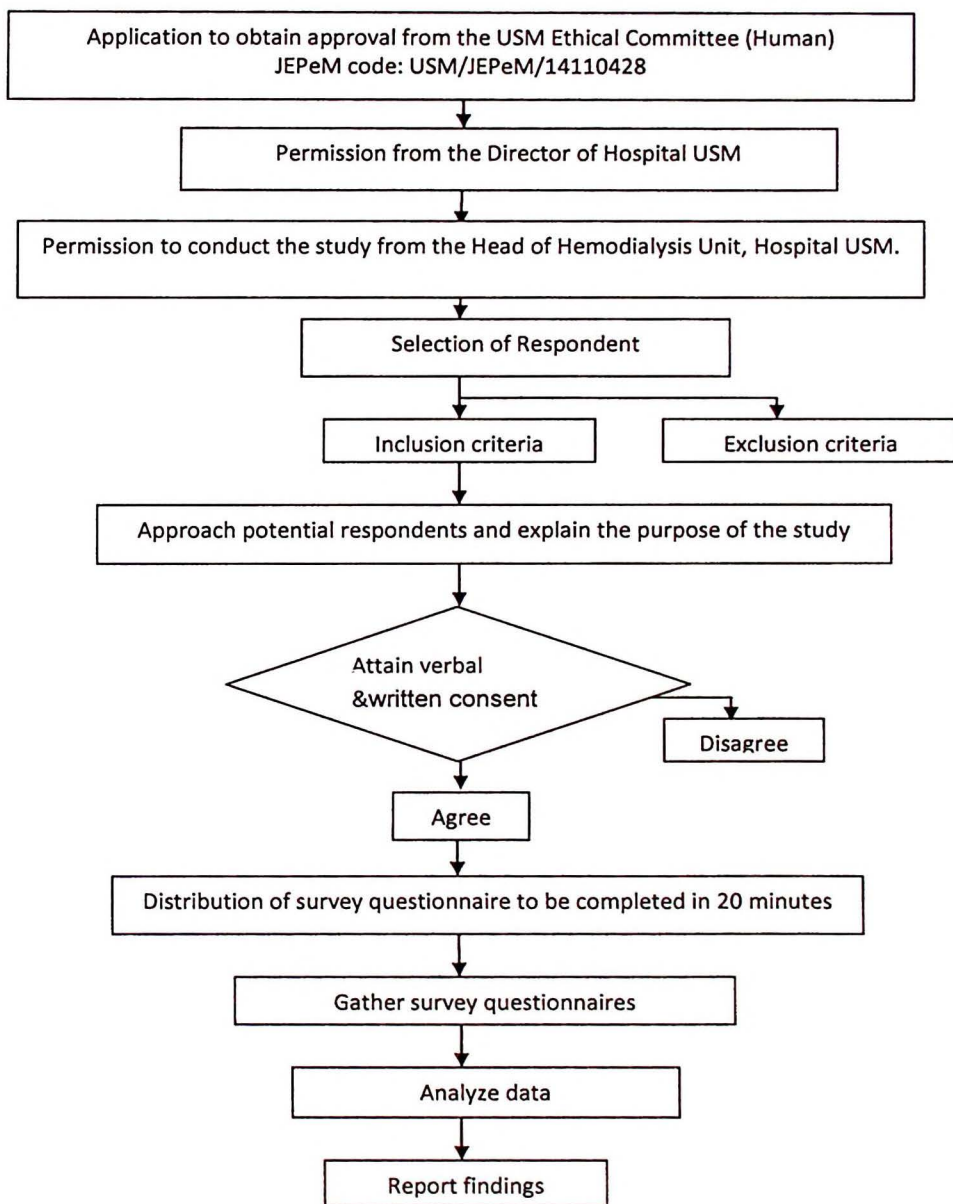


Figure 3.1: Flow Chart of Data Collection.