A FIVE YEARS REVIEW OF COMPLICATIONS OF IMPLANTABLE VENOUS ACCESS DEVICES (IVAD) IN CANCER PATIENT THROUGH THE CEPHALIC VEIN CUT DOWN APPROACH

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ABSTRAK

KAJIAN SEMULA LIMA TAHUN MENGENAI KOMPLIKASI *IMPLANTED VENOUS ACCESS DEVICE* (IVAD) DALAM PESAKIT KANSER MELALUI *CEPHALIC VEIN CUT DOWN APPROACH*

Pengenalan: *Implanted venous access device (IVAD)*merupakan salah satu kaedah yang membolehkan capaian terus kepada peredaran vena pusat. Kaedah ini digunakan secara meluas pada masakini dan ianya boleh digunakan bagi pelbagai tujuan disamping ianya boleh di kekalkan di dalam badan pesakit sehingga 2 tahun. IVAD memerlukan penjagaan yang minima dan risiko komplikasi terutamanya jangkitan kuman yang rendah menyebabkan ia sesuai untuk kegunaan pesakit terutamanya kepada pesakit yang mempunyai kesukaran mendapat laluan salur darah seperti pesakit kanser. "*Cephalic vein cut down approach"* adalah salah satu cara untuk memasukkan IVAD kepada pesakit. Kaedah ini mempunyai risiko komplikasi yang rendah, tetapi ianya jarang digunakan kerana memerlukan pembedahan dan mengambil masa yang panjang. Kajian ini adalah untuk menilai komplikasi-komplikasi alat IVAD yang diimplantasikandi dalam pesakit kanser melalui kaedah "*cephalic vein cut down approach".*

Kaedah Kajian: Kajian ini merupakan kajian retrospektif melibatkan pesakit kanser yang diimplantasi dengan IVAD melalui kaedah "*cephalic vein cut down approach"* di HUSM dari Januari 2010 hingga Disember 2014. Rekod pesakit di kaji dan penilaian untuk demografi, kaedah pembedahan, jenis alat IVAD, komplikasi-komplikasi selepas implantasi IVAD dan factor-faktor yang berkait rapat dengan komplikasi yang dianalisa. Semua maklumat yang diperoleh dikumpul dan dianalisa dengan menggunakan program SPSS versi 22.0.

Keputusan: Kajian ini melibatkan 197 pesakit dimana 54.3% merupakan pesakit lelaki dan 45.7% adalah pesakit perempuan. Pembedahan dilakukan oleh Pakar Bedah Tulang keatas sebanyak 132 (67%) pesakit dan selebihnya 65 (33%) pesakit dilakukan oleh pegawai perubatan. Kesemua pesakit mendapat antibiotik sebelum pembedahan sebagai langkah pencegahan. Secara purata, tempoh pembedahan adalah selama 59.37 minit dan purata tempoh masa rawatan susulan yang juga merupakan tempoh alat IVAD berada di dalam badan pesakit adalah selama 715 hari. Komplikasi keseluruhan adalah sebanyak 12.7%. manakala komplikasi secara khusus adalah 0.5% (n=1) iaitu kedudukan yag salah alat *IVAD*, 7.6% (n=15) jangkitan kuman, 3.6% (n=7) penyumbatan alat dan 1.0% (n= 2)kepatahan dan beralih kedudukan. Tiada kaitansignifikan diantara jenis tiub alat IVAD dengan komplikasi keseluruhan. Terdapat kaitandiantara jenis kanser dengan kadar jangkitan kuman. Kami juga menemui tiada kaitandiantara foktor umur dan "*Absolute Neutrophil Count (ANC)"* dengan kadarjangkitan kumandan diantara bilangan platelet dengan kadar penyumbatan alat IVAD.

Kesimpulan: **"***Cephalic vein cut down approach"*adalah kaedah yang selamat untuk implantasi IVAD dengan kadar komplikasi keseluruhan yang rendah, Rawatan ini menawarkan alternatif rawatan yang lebih baik dan member manfaat kepada pesakit di HUSM.

ABSTRACT

A RETROSPECTIVE FIVE YEARS REVIEW OF COMPLICATIONS OF IMPLANTABLE VENOUS ACCESS DEVICES (IVAD) IN CANCER PATIENT THROUGH THE CEPHALIC VEIN CUT DOWN APPROACH

Introduction: Implanted venous access device (IVAD) is one of the options that give access to the central venous circulation. It is widely used nowadays and can be used for various reasons. It can be retained in the body for a period of up to two years with minimal care and low risk of infection thus it is suitable for patients especially for those who had the difficult vascular access example in cancer patients. Cephalic vein cut down approach is one of the methods of insertion of IVAD with minimal complication associated to this technique, however, it is not widely used as it needs to be done in operating theatre setting and it took longer duration. This study was done to evaluate the complication of the IVAD that implanted in cancer patient through cephalic vein cut down approach.

Methodology: This is a retrospective study involving cancer patients that were implanted with IVAD through cephalic vein cut-down approach in HUSM from January 2010 to December 2014. All medical records reviewed and evaluated for demographics, surgical procedure, and types of IVAD, complications post implantation and possible associated factors with the complications studied. All the information collected and analyzed with SPSS programme 22.0.

Results: There were 197 patients included in this study which involved 54.3% male patients and 45.7% female patients. The procedure performed by orthopaedic surgeons in 132(67%) patients, 65 patients (33%) performed by the medical officers. All patients received intravenous antibiotic prophylaxis, Cefuroxime prior to implantation. The mean duration of surgery was 59.37 minutes while the mean duration of follow up, was 715 days. The overall complication rate was 12.7% (n= 25). There were 7.6% (n=15) infection rate, 3.6% (n=7) thrombosis, 1.0% (n= 2) for fracture and migration and 0.5% (n=1) mal-position of IVAD. There was no association between the types of catheter with the overall complication rate. There was an association between the types of cancer with the infections rate. We found no association between age and absolute neutrophil count (ANC) with the infection rates and the platelet levels with thrombosis rates.

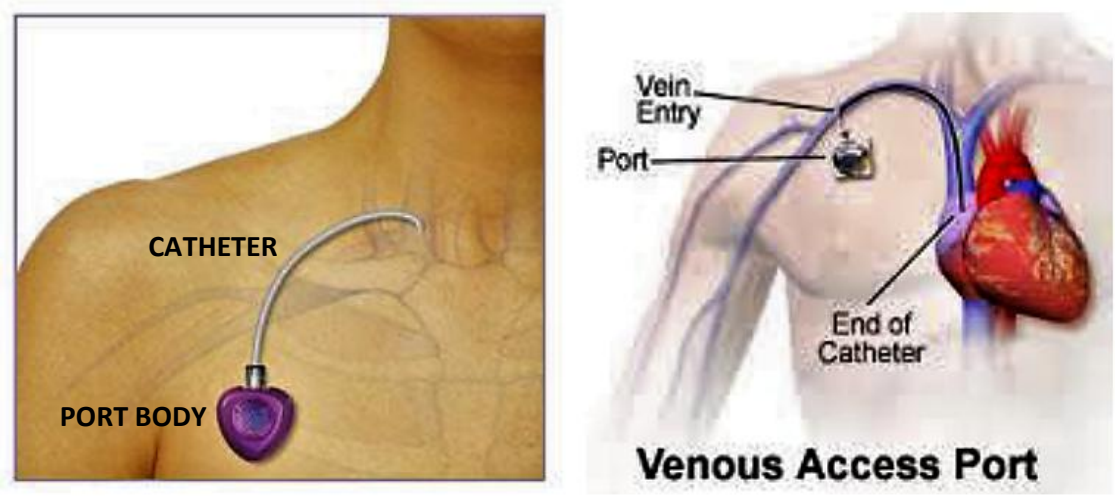
Conclusions: Cephalic vein cut down approach is a safe approach for IVAD implantation with an overall low rate of complications. These treatments offer an alternative and provide benefits to patients in HUSM.

Chapter 1

INTRODUCTION

1.1 INTRODUCTION

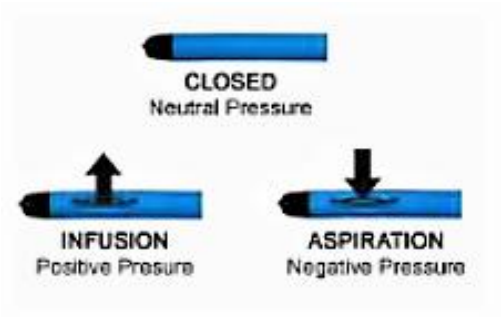
Implanted venous access device (IVAD) is a device implanted subcutaneously, which can give access to the central venous circulation. IVAD is also known as an indwelling central access device, port-A-cath, port or chemoport. It has 2 components which are a port body and a catheter. Aport body is implanted subcutaneously and connected with the catheter. The tip of the catheter is placed in the central venous circulation. The ideal location of the tip of the catheter is at the junction between superior vena cava and right atrium.



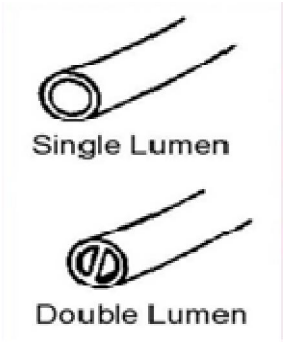
Images courtesy of Bard® adopted from Central Venous Catheters In Adult Patients, a Self-Learning Module by Patty Hignell, RN, BSN, MN, ENC(C) Vascular Access Clinical Practice Committee Fraser Health Authority October 2016 – Version 8

Figure 1: Component of the IVAD which are made up by body port and connected to the catheter.

There are two type of catheter tip which is closed-ended and open-ended tip. A closed-ended tip has a valve which is open during the infusion of the fluid into the IVAD only whereas open-ended tip doesn't have a valve, so it is open all the time and can cause a backflow of the blood into the catheter.The valve allows infusion and blood aspiration while reducing the risk of air embolism, blood reflux, and clotting.Negative pressure opens the valve inward, permitting blood aspiration, positive pressure opens the valve outward, allowing infusion. In a neutral pressure the valve remains closed, so there is no movement of the fluids, thus reducing the risk of air embolism, blood reflux, and clotting inside the catheter.



Closed Ended Tip



Open Ended Tip

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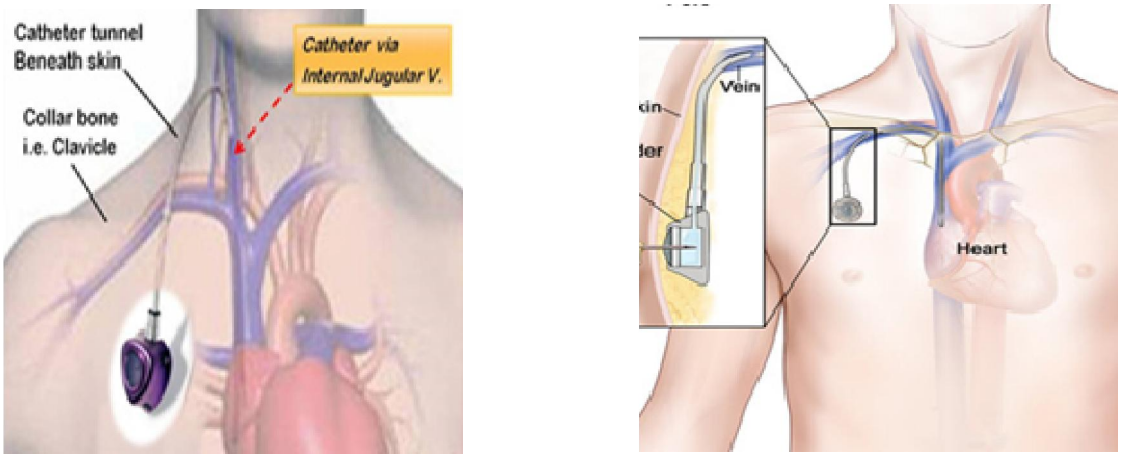
Figure 2: Figure shows the differences between closed-ended and open-ended catheter. The closed-ended catheter has a valve that control the opening of the catheter. The open-ended catheter doesn’thave the valve thus it remains open all the time.

There is various type of IVAD in the market, depending on the manufacturer. Examples are Bardport, Cellsite, Port A Cath, and Power Port. Each type of IVAD have both types of catheter, closed-ended and open-ended.

Implanted venous access devices (IVAD) can be inserted using a percutaneous technique orsurgical technique. The percutaneous technique usually is done via a Seldinger technique and guided by ultrasound. This technique is commonly used because of a shorter duration of implantation and not involved with operating suite. Surgical techniqueby venous cut down approach was introduced because percutaneous technique was reportedto be associated with incidence of pneumothorax, bleeding, arterial puncture and hematoma.Many different venous sites can be used as an entry point for the IVAD including the external jugular vein, the internal jugular vein, the axillary vein, femoral vein and cephalic vein. A venous cut down approach is usually performed through a cephalic vein, whereas percutaneous technique is easier performed through a subclavian vein or internal jugular vein.



Internal jugular vein approach

Subclavian vein approach

Figure 3: Various insertion site of IVAD

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The cephalic venous cut-down method has been widely described as a safe and rapid approach. Cephalic venous cut-down techniques when compared to the other vascular access were associated with a lower rate of catheter related complications (Hsu CCT *et al*., 2016). However, this technique is not widely used for the placement of IVAD (Shinichiro Koketsu*et al*., 2010). Cephalic venous cut down approach was performed in the operation theater. It can be done both under general anesthesia or local anesthesia. The cephalic vein passes through the clavipectoral (deltopectoral) triangle to join the axillary vein. A 3-cm wide skin incision was made in the infraclavicular region between the pectoralis major muscle and the deltoid muscle. The cephalic vein is identified in the adipose tissue along the deltopectoral groove. An venotomy is done to insert the catheter.The port was implanted in the subcutaneous space over the anterior chest wall at least 2.5cm away from the incision. The position of the catheter tip is confirmed by X-ray intraoperatively.

IVAD can be used for various reasons such as administration of medication, continuous infusion of intravenous vesicants, and also for blood drawing. It can be retained in the body for a period of up to two years with minimal care (Narendra H *et al*., 2016). Due to its advantages, it gives benefits to the management of a patient with a chronic disease that requires prolonged intravenous access, especially for the cancer patient who had difficulties in peripheral venous access. It does not restrict the mobility of patient and needs minimal maintenance post-implantation.

However, the use of central venous catheters is associated with adverse events that are both hazardous to the patients and an expensive to treat (Petit *et al*.,1994). A long term study showed that 13% of IVAD were removed due to complications, (Jorge et al.,1996). Special care needs to be taken to prevent the complication of IVAD due to increased risk of mortality of patient, increased cost of medical treatment and prolonged hospital stay (GukJin*et al*., 2013). In Malaysia, a study reported that 19 patients (22.1%) out of 86 patient developed

complication after IVAD insertion, four patients who developed complications neededremoval of the implant. (Lim *et al*., 1996)

Complications of the chemo-port insertion included malposition, bleeding, pneumothorax, thrombotic complications (native venous or port-catheter thrombosis), infections (tunnel or pocket infections or catheter-associated bloodstream infections), device fracture and migration, and extravasations of fluid (R. Biffi*et al*., 1997). Device fracture and migration describe as catheter dislodge from the body and migrate.

The purpose of this study is to evaluate the outcome and complication of the IVAD that were implanted into cancer patient in HUSM.

Chapter 2

LITERATURE REVIEW

2.1. COMPLICATION OF IVAD

Implanted venous access device (IVAD) provide a better central venous access to the patient. Since the introduction of the IVAD in 1982, the evolution of the IVAD provides extra benefit to the patient and the use of IVAD became more popular. IVAD are frequently used in patients who have poor peripheral venous access and are in need of long-term administration of vesicant drugs, antimicrobials, blood products, or parenteral nutrition.IVAD provide multiple advantages; patients have improved perceptions of quality of life and body image and less limitation in their mobility. These ports also minimize the need for maintenance care and risk of infectious complications when the IVAD is not in use. These benefits of IVAD port use have also been demonstrated in pediatric cancer patients, with the added advantage of allowing the child to participate in normal activities and preserving body image(Blanco guzman*et al*, 2018).

Despite the evolution and improvement with the IVAD, including the material used and insertion technique, the complication from the IVAD still happened. The use of central venous catheters is associated with adverse events that are both hazardous to patients and expensive to treat (Petit *et al*.,1994). Complication from the IVAD caused morbidity to the patient, hospital admission, prolonged hospital stay, delayed treatment, can lead to bacteremia and in worst case scenario can lead to sepsis and death. Complications of IVAD were associated with additional morbidity and cost and require removal of the IVAD as a part of their treatment in as many as 6.5% of patient (Blanco guzman*et al*., 2018). Special care needs to be taken to prevent the complication of IVAD due to increased risk of mortality of patient, increased cost of medical treatment and prolonged hospital stay **(**GukJin*et al*., 2013).A study entitled 'Totally Implanted Device for Long-Term Intravenous Chemotherapy: Experience in 123 Adult Patients with Solid Neoplasm', showedthat a total of 113 devices were removed during the period of study. Out of 113 devices, only 27% were for completion

of therapy, 60% were removed due to patient death and 13% were removed due to complications conducted by (Jorge *et al*., 1996). A local study in Malaysia reported that 19 patients (22.1%) out of 86 patient developed complications after IVAD insertion, four patients who developed complications need removal of the IVAD(Lim *et al*., 1996).

The complication was classified as an early or perioperative complication and late complication. The classification was made based on the time of the implantation to the time of the first usage of IVAD as early or perioperative and time from the first usage throughout the implantation period as late. Complications were divided into two main categories: (1) early (intra-operative and post-implantation period to first use); and (2) late complications (occurring after the first chemotherapy course given through the device) (Biffi*et al*., 1997). Complications were classified into immediate /early (intraoperative and postoperative before catheter use) and late (those occurring after the use of the catheter)(Esmalio Barroso *et al*., 2012). The latest classification classified early complication as any complication that occurs within the period of 30 days post implantation and late complication occur after 30 days post-implantation(Blanco Guzman *et al*., 2018). Despite the difference in the timeframe of early and late complication, all of the literature stated that early or peri-operative complication was a haematoma, bleeding, primary technical failure, malposition, and pneumothorax. For the late complication, there is an infection, catheter-related thrombosis, catheter fracture and migration and extravasation of the chemotherapy agent.

There are numerous literature studying the outcome of the IVAD. The overall complication rate recorded was 3 – 21 % for the early complication and 5 – 33.7 % for late complication. (Barbetakis*et al*.,2011). Earlier studies conducted in 1996, which is study of the 169 catheters, the peri- and postoperative complication rate were low, although pneumothorax occurred in 6 patients (3.6%) while major complications occurred during treatment,with infection in 4 patients (2.4%), occlusion in 3 (l.8%), thrombosis in 8 (4.7%),

extravasationin 8 (4.7%) and migration in 3 (1.8%) (Poorter*et al*., 1996).Other literature later showedsimilar result.Early complications included six pneumothoraxes, three arterial punctures and two revisions for port and/or catheter malfunction (overall early complications in 8 patients). Late complications included 3 cases (1.68% of devices) of catheter rupture and embolization (0.093 episodes/l000 days of use), 2 cases (1.12% of devices) of venous thrombosis (0.062 episodes/l000 days of use), 1 case (0.56% of devices) of pocket infection (0.031 episodes/l000 days of use), and 4 cases (2.24% of devices) of port-related bacteremia (0.124 episodes/l000 days of use)(Biffi*et al*., 1997).Perioperative complications occurred in 27 (21.4%) of 126 implanted IVADs: catheter malposition (16.7%) in 21 patients, pneumothorax (0.8%) in one and hemorrhage (4.0%) in five. Long-term complications appeared in 31 (25.2%) out of 123 IVAD: thrombosis in 9 (7.3%), especially associated with malposition of the tip of the catheter; infection in 10 (8.1%); extravasation in 2 (1.6%); migration of the catheter tip in 6 (4.8%); pain at reservoir in 3 (2.4%) and inaccessibility of the port in 1 (0.8%)(Hartkamp*et al*., 2000).A retrospective analysis of 225 catheter and port system implantations detected long-term complications in 6.6% of cases: infection (2.2%), thrombosis (1.3%), extravasation (1.3%) and catheter fracture (1.8%) (Yildizeli et al., 2004**)**.In 45 consecutive patients there were 12 peri-operative adverse events in 45 procedures (27%): 3 pneumothoraces (7%), 3 hematomas (7%), 6 arterial punctures (13%). There was no air embolism, hemothorax, hemomediastinum, lesion of the thoracic duct or nerve palsy (StéphaneTercier*et al*., 2008).

When focusing on the late complication, most of the literature stated that the most common complication was infection and thrombosis. After 30 days, infectious and thrombotic issues dominate port complications. Reported rate of long-term venous access infections ranged from 0.6 to 27%; depending on catheter location, catheter type and immune status of the patient(Yildizeli*et al*., 2004). Other late complications of IVAD were

low.Spontaneous fracture of the catheter and migration of a catheter fragment is a rare complication (Jensen MO*et al*., 2008). The incidence of catheter fracture in recent series varies from 0.4% to 1.8% (Filippou *et al*., 2004). The incidence of port catheter dislodgement with subsequent migration to the heart is low with an estimated rate of up to 0.4% (Chaung *et al*., 2011). Skin erosion has been reported in 0 to 1% of cases in the literature (Lorch *et al*., 2001). Most of the literature concentrates on the infection and thrombosis in the IVAD patient because this cause a significant morbidity and affect patient management comparedto other complication. Port-related infections and venous thrombosis are particularly important because they are associated with additional morbidity and costs and require removal of the IVAD as part of their treatment in as many as 6.5% of patients(Blanco guzman*et al*., 2018).

2.2 Open Ended and Closed Ended Catheter Tip

Closed-ended tip catheter was introducing in 1978, named as a groshong catheter that has a valve at the end of the tip. The valve opens only with the positive or negative pressure inside the catheter and remain closed in neutral pressure, thus preventing backflow of the blood into the catheter when we are not in use. A trial by Biffi and colleagues in 1997 showed a low incidence of major complication related to implantation using closed-ended tip of catheter compared to open-ended tip. However, this study reported a significantly higher rate of withdrawal difficulties with the valvedGroshong catheter versus the open-ended catheter (12.5 vs. 2%; $p<0.001$) (R.Biffi*et al*., 1997).A recent study conducted in 2014 using Groshongcatheters with standardized insertion technique and catheter sizes again demonstrated higher rates of withdrawal failure in the valved catheters (24 vs. 0%; $p<0.001$). Based on the available data, Groshongvalved catheters do not appear to provide an advantage in terms of clotting or occlusion and have no significant differences in terms of other major complications, such as infection or thrombosis, compared with their non-valved counterparts(Zottele*et al*., 2014).

2.3 Percutaneous Technique versus Cephalic Vein Cut Down Approach

Percutaneous insertion of IVAD was noted to have more overall complication compared with a cephalic vein cut down approach. This is supported by the various study of IVAD. A study of358 venous access devices showed an overall complication rate of 14%. In lines successfully placed percutaneously, the complication rate was 15% (25 of 163) compared to 11% (16 of 148) in the successful cephalic cut-down group. Complications including pneumothorax, late catheter transection, and bradycardiawhich occurred only in percutaneously placed lines(Jablon*et al*., 2001). A study entitled 'Outcome of cephalic vein cut-down approach: A safe and feasible approach for totally implantable venous access device placement' showed no intraoperative or postoperative complications(Shinichiro *et al*., 2010). Therefore, the CVCD approach is a safe and feasible method for IVAD placement. Another study compared percutaneous technique with the cephalic vein cut-down approach also showed a similar result**.** Complication rates of infection, pneumothorax, and catheter complications were analyzed, the Seldinger technique (subclavian vein access) was associated with a higher rate of catheter complications compared to the venous cut-down technique(Charlie Hsui*et al,* 2016).

However, multiple studies including a recent meta-analysis of 1006 patients, demonstrated no difference in the overall rate of complications (including hemothorax, pneumothorax, infection, catheterthrombosis, stenosis, kinking or extravasation, migrationof the catheter or dislodging of the port reservoir, hematoma, seroma, nerve palsy, thoracic duct injury, and death) or, in particular, in the rates of infection with either technique. It is worth noting that, when the analysis was limited to a subclavian site for the PT group, there was a higher rate of catheter-related complications (thrombosis, fibrin sheath, stenosis, kinking,

extravasation, migration of the catheter, or dislodgement of the reservoir) compared with cephalic vein cut down approach (Blanco Guzman *et al*., 2018).

2.4 Risk Factor for Early Complication

Early complications were due to mechanical issue related to catheter implantation(Blanco Guzman *et al*., 2018). The duration of surgical procedure during the implantation and number of catheterization attempt increase the risk of early complication (Barbetakis*et al*., 2011). Apart from that, a risk of mal-position, pneumothorax, and the hematoma is increased in a patient who had IVAD implanted by the resident officer (Poorter*et al*., 1996).With the introduction of the ultrasound, the early complication was markedlyreduced in the percutaneous technique of IVAD implantation.Short-term complications of port placement, such as malposition, hematoma formation, and pneumothorax, are practically nonexistent due to the routine use of ultrasound and fluoroscopic guidance during these procedures (Walser *et al.,* 2012). In adding to that, early complication can be controlled with the cephalic vein cut-down approach. No incidence of mal-position, pneumothorax, and hematoma were noted when catheters were placed through a cut down technique (Pulg-La *et al*.,1996)

2.5 Risk Factor for Infection

The 4 major risk factors associated with catheter-related infections are host factors, catheter type, duration of use, and catheter maintenance and management(Aparna*et al*., 2015).

Multivariate analysis identified monthly catheter-stay as a risk factor for CVP-BSI (p=0.000), however, its risk was lower in primary gastrointestinal cancer than in other cancer (p=0.002) (GukJin Lee *et al*., 2013).

Incidences of infection were seemingly higher in the patients who received the procedure during inpatient treatment (p = 0.016), the patients with hematologic malignancy (p = 0.041), and the patients receiving palliative chemotherapy (p = 0.022). From the multiple binary logistic regression, the adjusted odds ratios of infection in patients with hematologic malignancies and those receiving palliative chemotherapy were 7.769 (p = 0.001) and 4.863 (p = 0.003) respectively(Jisue Shim*et al*., 2012)

The rate of catheter-related infections in long-term central venous access catheters ranges from 0.6 to 27%, depending on the catheter type and location and the patient's constitution. Immunosuppressed patients with port systems were found to have a median of 0.2 infections per 1000 catheter-days (range 0–2.7 per 1000 catheter-days) (Bouza *et al*, 2002).

The absolute number of circulating segmented neutrophils (absolute neutrophil count; ANC) is a predictor of infection risk. As the ANC falls below 1 x 10^6/l, susceptibility to infection increases dramatically (Hämäläinen *et al*., 2008).

2.6 Risk factor for thrombosis

Patients with malignancies have various nonspecific thromboembolic risk factors (age, malignancy, hypercoagulability, chemotherapy, infections, and immobility) and specific risk factors such as catheter material, multiple placement attempts, catheter size and length, number of lumens, and catheter tip localization (Aparna*et al*., 2015).

Thrombosis is secondary to central venous catheters and cancer-related hyper-coagulable state.Regarding the catheter, there is chemical structure, diameter, number of lumens, position the catheter tip, insertion side, implantation technique, prior use of central venous access and catheter-related infections.Patients' characteristics include: platelet count, presence and type of malignancy, chemotherapy protocol and hyper-coagulable states(Esmalio Barroso *et al*., 2012)

Thrombotic sequelae of ports occur in two forms: (1) stenosis or occlusion of the host vein due to trauma to the venous wall and (2) catheter tip thrombus from intravascular protein and cell deposition. The latter process begins almost immediately after catheter placement when albumin, lipoprotein, and fibrinogen create a protein sleeve around fresh intravascular catheters within 24 h of placement. Eventually, coagulation factors and platelets congregate to completely envelop the catheter (Beathard*et al*., 2001).

There was a higher risk of venous thrombosis events among participants with abnormal plateletcount (Johanna G. van der*et al*., 2009).

Four prospective studies of catheter-associated thrombosis in patients with solid tumors and hematological malignancies report rates of thromboembolic events between 37% and 66% (Bern *et al*., 1990).

The optimal position for port catheter tip placement is at the cavoatrial junction, which decreases later thrombotic complications (Schwarz *et al*., 2008).

Chapter 3

OBJECTIVES

3.1. GENERAL OBJECTIVES

1.To determine the complication that occur in cancer patients who were implanted with IVAD through the cephalic vein cut down

3.2. SPECIFIC OBJECTIVES

1.To determine the rate of malposition of device, bleeding, pneumothorax, thrombotic, infections, fracture and migration of catheter, extravasation after IVAD insertion.

2. To compare the complication rate between the open-ended tip and closed-ended tip of IVAD

3. To determine the risk factor associated with infection post-implantation of IVAD

4. To determine the platelet level association with the thrombosis post-implantation of IVAD

Chapter 4

METHODOLOGY

4.1. Study Design

This is a retrospective cohort study design.

4.2. Study Sample

All cancer patient who was implanted with IVAD through cephalic vein cut-down approach in HUSM from January 2010 to December 2014 and fulfilled the inclusion and exclusion criteria

4.3. Setting of Study

This study was carried out in Orthopaedic Department Hospital University Malaysia, KubangKerian, Kelantan.

4.4. Sample Size

Universal sampling method involving all patient who fulfilled the inclusion and exclusion criteria were included in the study

4.5. Inclusion / Exclusion criteria

Inclusion criteria:

• All cancer patient that were implanted with IVAD through the cephalic vein cut-down approach.

Exclusion criteria:

• Non-cancer patient who was implanted with IVAD

• A patient who was implanted with IVAD via other than cephalic vein cut-down approach

• An incomplete medical record for 30 % of variables.

4.6. Methods of data collection

This is a single center retrospective study that was conducted in Hospital University Sains Malaysia involving all cancer patients who were implanted with IVAD from January 2010 until December 2014. All patients with retrievable medical records that have fulfilled the inclusion and exclusion criteria will be included in this study.

Patient demographic data; age, sex, type of cancer, type of IVAD used, pre-operativeblood parameter, duration of surgical procedure will be recorded.

Plain chest radiograph post-implantation of IVAD will be reviewed to determine the location of the tip of the catheter of IVAD

The information related to the risk factor of a complication will be recorded, they are:

Level of experience of a surgeon that performed IVAD

Antibiotic prophylaxis

Position of catheter

All the complications that occurred to the patient will be recorded.

Complication; is defined according to Clavien's classification as a deviation from the standard postoperative course requiring intervention

Complications of IVAD are a pneumothorax, malposition of the catheter, hematoma formation, infection, thrombosis and catheter fracture and migration.

The complication was diagnosed based on:

Pneumothorax was diagnosed based on collapsed of the lung in X-ray post-operatively.

A hematoma is a macroscopic subcutaneous blood collection without infection (Christoph et al 2006).

Thrombosis is diagnosed when there is an inability to infuse and/or aspirate of the device (Jablon et al,. 2006).

Infections were classified according to the definition by the Centers for Disease Control and Prevention (CDC). A catheter-related bloodstream infection is defining as at least one positive blood culture from a peripheral vein and no other apparent source. Apositive culture for the catheter segment and a peripheral blood sample was a differential period of central venous port culture versus peripheral blood culture positivity of 2 hours. The isolation of similar organism from central and peripheral blood shows no other apparent source of infection. Port pocket infection is defined as an induration, erythema, and tenderness around the port with culture-positive material aspirated from the port pocket. Cutaneous site infection was defined as induration, erythema or tenderness and exudate at the port surface needle access site.

Catheter fracture and migration are based on the changes of the position of the catheter with respect to prior X-ray (Christoph et al 2006).

Risk factor for each complication will be evaluated

4.7. Statistical Method

Using IBM SPSS statistic 22.0 (Dupont and Plummer, 2014)

Data entry

Descriptive analysis of numerical data as mean or median

Multiple logistic regressionsanalysis was used to find the association between risk factor and complication.

4.8. Ethical Issues

Ethical approval was obtained prior to the commencement of the study. The researcher was the only person able to assess the name of patients to maintain data confidentiality.

Chapter 5

RESULT