University of Alberta

Infection Rates in Tunneled Hemodialysis Central Venous Catheters: A Comparison Between Chlorhexidine and Amuchina

by

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Dedication

This thesis is dedicated to my clinical supervisor, Dr. Ray Ulan, whose compassion for the patient and dedication to the improvement of patient care provided the stimulus and continued interest in this study.

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CHAPTER ONE

Introduction

Chronic renal failure is the insidious, progressive deterioration of renal function. The most common causes include diabetes mellitus (31.3%), renal vascular disease including hypertension (20.7%), and glomerulonephritis (15.1%) (Andreoli, Carpenter, Griggs, & Loscalzo, 2004; Canadian Organ Replacement Register, 2002; Lancaster, 1991). Chronic renal failure is described as insidious because it is not until there is a loss of approximately 75% function that the patient's vaguely described symptoms become more pronounced and are then investigated. Even in the face of deteriorating numbers, glomeruli adapt with hyperfiltration and the surviving tubules adjust in order to maintain a normal homeostatic environment (Andreoli et al., 2004; Parker, 1998). When function has decreased to 5 to 10% of normal, the diagnosis of end stage renal disease (ESRD) is made.

As of 1998, more than 210,000 people with ESRD in the United States were receiving dialysis therapy, the annual growth trend of the condition being 7.8% (Kinzer, 1998). In Canada, as of December 31, 2000, the number of patients alive on renal replacement therapy (hemodialysis, peritoneal dialysis, and transplantation) was 24,921 including 10,354 with a functioning transplant and 14,567 patients on dialysis. The majority of these patients were on hemodialysis (77.7%), and the balance on peritoneal dialysis (22.3%). In 2000, there were 4,386 new patients receiving treatment, representing a rate of 142.6 per million population. From 1981 to 2000 the annual growth rate of the condition was 7.3%

(Canadian Organ Replacement Register, 2002). With the increase in life expectancy in the aging population, the United States reported a 50% increase in renal failure in people over 60 years between 1984 and 1993; 36% of whom had diabetes mellitus (Kinzer, 1998). Between 1981 to 2000, 38.5% of Canadians with ESRD were 70 years and older, representing an increase from 28.5% 10 years ago. These numbers reflect a growing trend in chronicity that will burden the health care system in coming years.

The patients with ESRD require ongoing medical interventions to sustain life. The treatment options available include peritoneal dialysis, hemodialysis, or transplantation. Peritoneal dialysis requires the use of a catheter to access the peritoneum, which acts as the dialyzing membrane. A sterile, physiologically prepared solution is introduced into the peritoneal cavity and by the principles of osmosis and diffusion, fluid is removed and the blood is cleansed of its toxic impurities. The patient is required to do 4 to 5 exchanges each day. In contrast to peritoneal dialysis, hemodialysis involves passing the patient's blood through an artificial kidney where diffusion and ultrafiltration remove fluid and the waste products of metabolism, normally excreted by the kidneys. This procedure averages 4 hours three times per week. Both peritoneal and hemodialysis require the use of a patent, long-term, functional access, a means through which to dialyze the patient.

The three types of vascular access used for hemodialysis include the arteriovenous (AV) fistula, synthetic AV graft, and the tunneled and non-tunneled

central venous catheter (CVC). Since 1966, the AV fistula has been, and continues to be the preferred form of hemodialysis access (Brunier, 1996; Beathard, 2000; Berkoben & Schwab, 1995; Mysliwiec, 1997; Kapoian & Sherman, 1997; Ezzahiri, Lemson, Kitslaar, Leunissen, & Toridor, 1999; Tisher, 1999; Laski, Pressley, Sabatini, & Wesson, 1997; Konner, Nonnast-Daniel, & Ritz, 2003; Cernadas, Grandjean, & Tosi, 2003). Primary AV fistulae are typically established by the anastamosis of an artery to an adjacent vein. They take 2 to 6 months to mature. Once mature, they have long term patency rates and are rarely associated with infectious complications (Tanriover, Carlton, Saddekni, Hamrick, Oser, Westfall, & Allon, 2000; Taylor, Gravel, Johnston, Embil, Holton, Canadian Hospital Epidemiology Committee, & Canadian Nosocomial Infection Surveillance Program, 2002). Not all patients however, are suitable for fistula creation. If the veins have been previously used for medication infusion, intravenous therapy, phlebotomy, or laboratory blood sampling they will be precluded from developing into a successful access. Also, in the elderly and in the diabetics often there is a lack of suitable blood vessels for fistula access creation (Konner, 1999; Kapoian & Sherman, 1997; Laski et al., 1997; Polaschegg & Levin, 2000).

In the event that the dialysis patient is unable to support a native fistula, an AV graft using synthetic materials such as polytetrafluoroethylene (PTFE) may be created. PTFE is a durable material and will withstand multiple thrombectomies and revisions but it does have a finite functional life and will wear out with repeated needle puncture. The complications associated with grafts include

infection, thrombosis, steal syndrome, and aneurysm formation (Kohler & Kirkman, 1998; Obialo, Robinson, & Braithwaite, 1998).

Central venous catheters are routinely used in the medical management of many types of patients including those who are acutely or chronically ill (Patel, Revanur, Khanna, Hodges, & Jindal, 2001; Maki, 1991). They provide access for the delivery of fluids and electrolytes, medications, blood products, chemotherapy, and parenteral nutrition. They are also useful for frequent blood sampling, hemodynamic monitoring, or hemodialysis. Often they are the only means available to dialyze the patient described as a hemodialysis access failure. The disadvantage associated with the use of these catheters is that they offer lower blood flow rates than other accesses. Associated complications include central vein stenosis, thrombosis, and infection (Johnson, 1998; Maki, 1991; Choudhury, Ahmed, Girgis, & Kronfli, 1999; Taylor, McKenzie, Buchanan-Chell, Caballo, Chui, & Kowalewska-Grochowska, 1998; Rocklin, Dwight, Callen, Bispham, & Spiegel, 2001).

Mermel (2000) stated that each year in the United States several million intravascular devices are purchased to deliver managed patient care including the provision of dialysis for the patients in ESRD. The majority of these devices are peripheral venous catheters, but greater than 5 million CVCs are inserted each year, resulting in more than 200,000 nosocomial bloodstream infections (Mermel, Farr, Sherertz, Raad, O'Grady, Harris, & Craven, 2001; Maki, 1992; Sitges-Serra, Pi-Suner, Garces, & Segura, 1995; Barendregt, Tordoir, & Leunissen, 1999). Infection related to these devices results in significant

increases in cost and morbidity (Gaynes, 2001). The risk of infection is related to the type of device used, site of placement, type of barrier precautions used during insertion, and material of which the catheter is made. The sources of infection include hematogenous seeding, infusate contamination, and skin surface and hub colonization (Hadaway, 2001).

There are many potential targets for intervention aimed at reducing the incidence of catheter-related infection. Hand washing, use of appropriate barrier precautions, insertion technique, ointments, dressings, and antiseptics have been reviewed (Clemence, Walker, & Farr, 1995; Maki, 1992; Gaynes, 2001). Presently, povidone-iodine and chlorhexidine are the two antiseptics used both at the time of insertion and during catheter maintenance (Mimoz, Pieroni, Lawrence, Edouard, Costa, Samii, & Brun-Buisson, 1996; Traore, Allaert, Fournet-Fayard, Verriere, & Laveran, 2000; Garland, Buck, Maloney, Durkin, Toth-Lloyd, Duffy, Szocik, Mcauliffe, & Goldman, 1995). Chlorhexidine has been shown to be more effective as a skin cleansing solution than povidone-iodine (Maki, 1992; Band, 2001). Electrolytic chloroxidizer (EC) commonly known as Amuchina® is a chlorine-based solution composed of sodium hypochlorite and sodium chloride. Amuchina has been used for many years, to externally and internally clean dialysis machines, and as an antiseptic in the peritoneal dialysis population (50% concentration); however it has not been considered as a hemodialysis skin and catheter antiseptic until recently (10% solution). Despite a lack of scientific evidence, a number of Canadian Dialysis Units are presently using Amuchina.

The question arises, how would Amuchina 10% compare to Chlorhexidine as a skin and hub antiseptic solution?

Purpose of the Study

The purpose of the study was to determine whether Amuchina 10% is more or as effective than the standard skin and hub antiseptic solution of Chlorhexidine 0.5% with 70% alcohol in decreasing the central venous catheter-related exit site infections in long-term, maintenance hemodialysis patients over a 3 month period. The hypotheses tested were:

1. There will be a decreased number of localized CVC exit site infections in the experimental group receiving Amuchina 10% than the control group receiving Chlorhexidine 0.5% with 70% alcohol.

2. There will be a decreased number of catheter-related blood stream infections in the experimental group receiving Amuchina 10% than the control group receiving Chlorhexidine 0.5% with 70% alcohol.

3. There will be decreased catheter colonization as measured by semiquantitative methods in the experimental group receiving Amuchina 10% than the control group receiving Chlorhexidine 0.5% with 70% alcohol.

Definition of Terms

Exit Site Infection (local): Purulent discharge at the exit site or/tenderness, erythema with induration of $\geq$2 centimeters (cm) around the exit site, with a positive culture of serous discharge. Confirmed with a swab of the catheter exit site (APIC Text, 2000).

Skin Irritation: Reddened area covering the area where skin had previously been cleansed with antiseptic, approximately 5 cm x 5cm.

Catheter-Related Bacteremia: Two or more positive blood cultures with no evidence for source other than the catheter, or single positive blood culture and positive culture of catheter segment with identical organism, or single positive blood culture and positive culture from discharge from exit site with identical organism (APIC Text, 2000).

Central Venous Catheter Colonization: An intermediate value of > 15 colony-forming units (cfu) on roll plate culture represents a positive colonization obtained from skin swabs, intraluminal brushings and/or catheter tips (CDC Guidelines, 1996).

Antiseptic: A substance that can be used on skin and on wounds that either kills (cidal) or prevents the multiplication (static) of potentially pathogenic organisms (Gaudet & Beaufoy, 1996). Antiseptics can be dilute disinfectants; they are not selective and therefore can be toxic to the host tissue, particularly at higher concentrations.

Significance of the Study

Infection is a well-documented complication associated with central venous catheters for hemodialysis. It is imperative that strict aseptic technique is adhered to and all strategies employed in an effort to reduce or prevent the infections associated with these catheters. Included in these strategies is the use of antiseptic solutions on the catheter exit site. If it can be demonstrated that an antiseptic is as or more effective in reducing exit site infections than others

presently in use then there is potential to improve the care delivered for the dialysis patient. It is a primary concern that health care providers continue to study and search for methods to protect the patients from preventable infections.

CHAPTER TWO

Literature Review

End Stage Renal Disease

Chronic progressive decline in renal function is primarily attributed to diseases such as diabetes mellitus, hypertension and renal vascular disease, glomerulonephritis, pyelonephritis, polycystic kidney disease, and others (Andreoli et al., 2004; Canadian Organ Replacement Register, 2002). The deterioration in function, as measured by a glomerular filtration rate (GFR) of less than 10 milliliters per minute (ml/min), in combination with the retention of nitrogenous wastes, is described as end stage renal disease (ESRD). Uremic toxins can cause symptoms of fatigue, nausea, vomiting, and headaches (Daugirdas, Blake, & Ing, 2001). Andreoli et al. (2004) and Vanherweghem et al. (1986) described the uremic syndrome as the consequence of the combined effects of several retained molecules and the deficiency of important hormones, rather than the effect of a single uremic toxin. Virtually every body system is affected by the retention of the waste products of metabolism (Rose & Black, 1988; Parker, 1998). The National Kidney Foundation (Laski et al., 1998, p. 404) includes in its description of the uremic syndrome: retarded wound healing, susceptibility to infection, increased incidence of cancer, and inadequate production of antibodies, which all suggest an immune deficiency in uremia. Uremia is associated with depression of the total lymphocyte count and of both cell mediated and humoral immune responses (Panno & Powell, 1989). In addition, granulocyte phagocytosis and killing function appears to be impaired by cellulosic dialysis membranes used during hemodialysis because of the

neutropenia complement activation caused when blood comes in contact with the membrane. The implication is that this patient population is at increased risk for developing infection, especially when the CVC is the access selected to provide essential care (Aube, Milan, & Blettery, 1992; Parker, 1998).

Incidence and Cost of Renal Replacement Therapies

Prior to 1960, treatment for ESRD was not available, but with the development of the external shunt by Quinton and Scribner, a means to repeatedly access the vascular system became available, allowing those patients to receive life-sustaining treatment (Ahmad, 1999). According to projections by Schaubel, Morrison, Desmeules, Parsons, and Fenton (1999), progression to ESRD is recognized as a major health concern in both Canada and the United States. Though relatively rare, it poses an important health problem because of the high cost of renal replacement therapy, the associated high mortality, and the effect on patients' quality of life (Sehgal, Dor, & Tsai, 2001). As of December 31, 1996, there were 17,807 patients receiving therapy in Canada. At the end of December 1999, the number of patients receiving treatment for ESRD had increased to 23,601. This number is projected to climb to 32,952 by the end of 2005, for a relative increase of 85% between 1996 and 2005 and a mean annual increase of 5.8% (Schaubel et al., 1999). The increased prevalence was projected to be greatest for peritoneal dialysis (6.0% annually), followed by hemodialysis (5.9%), and functioning kidney transplants (5.7%). The increase in projected rates was highest among the diabetic population and those over 65 years of age irrespective of diabetic status. Schaubel et al. (1999) project that by 2005, 41.7% of the ESRD

population will be receiving hemodialysis, 19.7% will be receiving peritoneal dialysis, and 38.5% will have a functioning renal transplant. These increases represent cause for concern because many dialysis units are already working beyond their actual capacity. This predicted rise in prevalence indicates that there will be a substantial burden on health care resources. Hutchinson (1999) reported that it costs an estimated $47,400 to keep one patient with ESRD alive for one year in the United States. He relates that these costs are comparable in Canada. Beathard (2002) wrote that the high cost required to maintain a patient on dialysis in 1996 was approximately $62, 400.00; 41.2% was spent on the dialysis treatment, 33.5% was spent on related costs, and 25.6% was spent on the vascular access.

Renal Replacement Therapies

Hemodialysis, peritoneal dialysis, and transplantation represent the various forms of renal replacement therapies available for the treatment of renal failure. Dialysis involves the movement of molecules across a semi-permeable membrane (Ahmad, 1999). Hemodialysis is the modality of treatment for more than 100,000 people in ESRD in the United States (Andreoli et al., 2004; Chopra, 2001). During treatment, blood is obtained by means of a permanent or temporary vascular access, is pumped at an average rate of 400 ml/min through the fibers of a dialyzer, where electrolytes are normalized and the waste products are removed by a process of diffusion. Excess fluid is removed by ultrafiltration. The average patient on hemodialysis requires 4 hours of dialysis three times per week to achieve a creatinine clearance of greater than 140 Liters per week. Andreoli et

al. (2004) stated that such low clearance can support patient survival only if strict dietary management is followed. Patients on hemodialysis are at high risk for developing volume overload, pulmonary edema, hyperkalemia, hyperphosphatemia, and metabolic bone disease if fluids are not restricted and dietary restrictions are not adhered to (Andreoli et al., 2004; Parker, 1998). However, the major factor limiting effective hemodialysis and contributing to decreased creatinine clearances, involves vascular access (Schaubel et al., 1999).

Peritoneal dialysis uses the peritoneum as the dialyzing membrane. A specially prepared, physiological, sterile solution is infused into the peritoneum 4 to 5 times per day. By the process of osmosis and ultrafiltration, the end products of metabolism and fluid are removed. The advantage of choosing peritoneal dialysis includes allowance for a more liberal diet, reduced fluid restriction, greater independence, and freedom from the tight schedules of the hemodialysis unit. One disadvantage associated with peritoneal dialysis is inadequate dialysis in patients with a large body mass. The greatest complication is peritonitis. The Canadian Organ Replacement Register (2000) reported a 7.1% rate per annum of peritonitis as a cause for withdrawing from peritoneal dialysis. Hemodialysis serves as a supportive therapy for peritoneal dialysis failure. However, though less costly, peritoneal dialysis is not selected as often as hemodialysis as a treatment modality for ESRD for a variety of reasons, one reason being that hemodialysis is readily accessible through the use of central venous catheters (CVCs).

Kidney transplantation is the preferred form of therapy for renal failure (Norman, 1998). The dialysis patient, however, will have to contend with long waiting lists for a limited supply of cadaveric organs, the presence of disqualifying co-morbid conditions such as cardiovascular disease, and the low transplantation rates in an aging ESRD population. Dialysis, then, will remain the primary method of renal replacement therapy for these patients.

Dialysis Access

One of the most important aspects in the total management in the patient with ESRD is the creation and maintenance of a permanent access for dialysis (Schwab, 1999; Barendregt, Tordoir, & Leunissen, 1999). In peritoneal dialysis, a single or double cuffed catheter is placed into the peritoneum. The cuff serves as an anchor to hold the catheter in place and it also serves as a barrier against microorganisms that may migrate from the skin surface along the tunnel of the catheter to the peritoneum.

In hemodialysis, a vascular access is required to access the patient's blood. The most effective, durable access is the arteriovenous fistula. It is associated with a long term patency rate and lower incidence of infection. Berkoben and Schwab (1995, 1999) related that infection, though rare, may contribute to fistulae access loss. Infections most commonly are due to *Staphylococcus (Staph) aureus* and are treated with systemic antibiotic therapy. The basic requirement for creation of a fistula is an adequate artery and vein in close proximity to each other for surgical anastamosis. Fistulae are created by an end-to-side vein-artery anastamosis of the cephalic vein and radial artery or the brachial artery and the

cephalic vein in the nondominant arm. Upper extremity fistula creation is associated with higher flows and can contribute to high output cardiac failure. Another complication associated with fistula creation is steal syndrome whereby blood is "stolen" from the hand to feed the low resistance fistula. If the patient is symptomatic with manifestations of pallor, coolness, pain, and cyanosis in the fingers distal to the fistula, ligation of the access is imperative to preserve circulation to the hand. Thrombosis is another well-recognized complication associated with this access. If it occurs early, thrombosis may be related to surgical technique. Late thrombosis is attributed to hypercoaguability, hypotension, or reduced flow as a result of stenosis (Tonelli, Jindal, Hirsch, Taylor, Kane, & Henbrey, 2001). A balloon angioplasty is used to treat stenosis whereas surgical intervention may be required for thrombosis (Tessitore, Mansueto, Bedogna, Lipari, Poli, Gammaro, Baggio, Morana, Loschiavo, Laudon, Oldrizzi, & Maschio, 2003). The patency rate of fistulae is 65-75% at three years (Parker, 1998). Berkoben and Schwab (1995) reported one year fistulae patency rates to be 60 to 70%, and 50 to 65% at two to four years.

In the event that fistula creation has failed or the vessels are not suitable for fistula development, synthetic graft material such as polytetrafluorethylene (PTFE) may be used (Patel et al., 2001; Berkoben & Schwab, 1995). PTFE grafts are placed in the forearm, upper arm, or upper thigh, in either a straight (distal radial artery to basilic vein) or loop (brachial artery to basilic vein) configuration. Maturation requires 3 to 6 weeks. More tissue-related trauma is associated with the creation of the graft than a fistula, resulting in pain and edema. Infections are

more common with grafts than fistulae, accounting for 20% of all access complications (Berkoben & Schwab, 1995). *Staphylococcus aureus*, *Coagulase-negative Staphylococci*, and *Escherichia coli* are the most common organisms responsible for the infection. Infection that presents soon after the creation may be related to the surgical technique; whereas late infection may be attributed to an infected puncture site (Counts, 1993). Infection is more serious in grafts than fistulae because of the risk of disintegration and hemorrhage (Parker, 1998). Treatment includes antibiotic therapy or surgical revision and rarely, removal of the graft material. Another complication, early thrombosis, is related to technical, surgical problems, hypotension, or low flow through the graft. Late graft thrombosis is related to stenosis at the outflow tract due to neointimal proliferation, or narrowing within the graft lumen, at the graft vein anastamosis (Torres-Melendez, 1996; Spalding, 1992). Schwab (1999) reported that in three large studies carried out by investigators from Duke University, Austin Clinic, and the University of California, San Diego, greater than 80% of graft failures were caused by outflow stenosis in the venous circulation; 84%, 86%, and 92% were reported at those institutions respectively. Treatment includes radiological declotting or surgical revision (Cynamon & Pierpont, 2002). Berkoben and Schwab (1995) reported a one year patency rate of 62 to 83%, 50 to 77% at two years and fewer than 50% at three years. In 1999, Schwab again reported that the three-year patency rate for grafts is 50%, suggesting that unless methods are developed to eliminate associated complications, the life span of grafts will remain low, making this a problematic access for hemodialysis patients.

Central Venous Catheters

The use of a CVC for either temporary or chronic hemodialysis has become an acceptable bridge to internal, permanent vascular access (Farrell, Walshe, Gellens, & Martin, 1997; Brunier, 1996; Ouwendyk & Helferty, 1996; Choudhury et al., 1999; Berkoben & Schwab, 1995; Tanriover et al., 2000; Rocklin et al., 2001). CVCs are inserted into deep veins such as the subclavian, jugular, or femoral veins and are advanced into the vena cava (Brunier, 1996). They may be placed percutaneously or using cutdown technique. Maturation time is not required; rather they may be used immediately after radiological verification of placement (Farrell et al., 1997; Chopra, 2001). CVCs are easily inserted with radiological fluoroscopic guidance or at the bedside, thereby reducing the need for expensive and often times unavailable operating room time. They can provide long term access in children, the elderly, morbidly obese patients, or in patients with diabetes whose vessels are not acceptable for the creation of an internal fistula or graft (Rocklin, Dwight, Callen, Bispham, & Spiegel, 2001). They are necessary for the patients requiring emergency dialysis or those patients who are described as access failures, having used up the vessels required to create a permanent access. CVCs serve as a backup for the fistulae and grafts that require ligation due to high output failure states and steal syndrome. Further, CVCs are inserted as a temporary access while awaiting the development of a permanent access. The survival rates of CVCs are reported to be 75% at one year and 50% at two years, thereby allowing CVCs to become alternate forms of long-term accesses (Parker, 1998; Rocklin et al., 2001). Berkoben and Schwab

(1995) reported a survival rate of 47 to 74% at one year and 41 to 43% survival rate at two years. Despite the consensus that the construction of the primary AV fistulae represents the best choice for permanent vascular access, the trend since 1980 has been a continual increase in the use of CVCs because they are readily available and convenient. Kapoian and Sherman (1997) reported a 5% use of CVCs in 1980 that increased to 30% in 1993.

Central Venous Catheter Infection

Hospitalized patients frequently develop nosocomial infections that are caused by normal flora colonizing the patient at the time of admission, or by exogenous pathogens that are acquired and subsequently colonize the patient after admission to the hospital (Boyce, 1996). Approximately 200,000 nosocomial blood stream infections occur each year in the United States. Most of these infections are related to the use of intravascular devices (Gaynes, 2001). Maki (1991, 1992) has estimated that 90% of intravascular device-related blood stream infections are secondary to CVCs. Although new dialysis patients should have a functioning fistula upon entry into the hemodialysis unit, frequently a CVC is placed, predisposing an immunocompromized patient to the possibility of a local or systemic catheter-related infection (Zeylemaker, Jaspers, van Kraaij, Visser, & Hoepelman, 2001).

In the guidelines for prevention of intravascular device-related infections prepared by the Center for Disease Control and Prevention (CDC Guidelines, 1996), catheter-related infections can be described as a colonized catheter, exit site infection, tunnel infection, catheter-related blood stream infection, and

infusate-related bloodstream infection. A colonized catheter infection is described as the growth of greater than 15 colony-forming units (cfu) (semiquantitative culture) or 10^3 cfu (quantitative culture) from a proximal or distal catheter segment in the absence of accompanying clinical symptoms (Maki, 1992). A local catheter-related infection might comprise an exit site infection or a tunnel infection. The CDC Guidelines (1996) described an exit-site infection as inflammation around the insertion site that consists of erythema, warmth, tenderness, induration, or purulence within 2 centimeters (cm) of the skin at the exit site of the catheter. The incidence of exit site infections range from 1.2 to 2.2 per 1000 catheter days. They may result from inadequate skin disinfection at the time of catheter placement, incorrect suture material or technique, improper site care by dialysis staff, or poor patient hygiene (Saad, 2001). A pocket infection is erythema and necrosis of the skin over the reservoir of a totally implantable catheter, or purulent exudate in the subcutaneous pocket containing the reservoir. A tunnel infection is characterized by erythema, tenderness, and induration in the tissues overlying the catheter more than 2 cm from the exit site. Tunnel infections are relatively uncommon with an incidence of 0.12 per 1000 catheter days (Saad, 2001).

Systemic catheter-related bacteremia has often been used as a diagnosis of exclusion to describe a bloodstream infection caused by an organism from the skin of a patient with a vascular catheter who has clinical manifestations of sepsis and no apparent source for the infection except the catheter. The implicating

evidence is isolation of the same organism from a culture of a catheter segment and from the blood of a patient, with accompanying clinical symptoms of blood stream infection and no other apparent source of infection. In the absence of laboratory confirmation, if there is resolution of clinical sepsis within 48 hours of catheter removal during which time the patient does not receive antibiotics, the catheter is implicated as the source of infection. The patient may present with signs and symptoms of systemic infection ranging in severity from minimal to life-threatening. Fever and shaking chills are typical. Nausea, vomiting, back pain, headache, myalgia, arthralgia, and changes in mental status can also occur. The patient may develop hypotension. Some patients present to the dialysis unit with little or no evidence of infection and then develop symptoms after initiation of dialysis via the CVC, suggesting a release of bacteria or endotoxin from a sequestered source (Saad, 2001). Infectious complications of CVC associated bacteremia may include osteomyelitis, endocarditis, epidural abscess, septic arthritis, or death (Tanriover et al., 2000; Saad, 2001). The incidence of tunneled, cuffed catheter bacteremia was reported to be 1.2 episodes per 100 patient months (Marr et al., 1998). Saad (2001) and Tanriover et al. (2000) reported catheter-related infections of 3.4 to 5.5 episodes per 1000 catheter days. Oliver, Callery, Thorpe, Schwab, and Churchill (2000) related that temporary internal jugular catheters show a marked increase in rates of bacteremia three weeks following insertion. The episodes of bacteremia followed the occurrence of exit site infections.

Infusate-related bloodstream infection is defined as isolation of the same organism from infusate and from separate percutaneous blood cultures, with no other identifiable source of infection (Greene, 1996). These infections are rare but easily identified. They should be suspect when sepsis occurs in an otherwise low-risk patient receiving an intravenous solution, or when there is a cluster of primary bloodstream infections with an unusual organism. Organisms may contaminate infusate by several mechanisms: during manufacture, solution preparation, handling by health care workers or by retrograde contamination from a contaminated catheter (Gaynes, 2001).

Hemodialysis catheters are described by the CDC Guidelines (2002) as devices used for long-term vascular access. These catheters fall into two main categories: noncuffed catheters used for shorter-term venous access and cuffed catheters, which are tunneled under the skin, have a Dacron cuff just inside the exit site, and are used for longer-term access. The cuff is designed to inhibit migration of organisms into the catheter tract by stimulating growth of the surrounding tissue thereby sealing the catheter tract and providing a natural anchor for the catheter.

The patient requiring a venous catheter for greater than three weeks should have a tunneled catheter. Darouiche and Raad (1997) stated that septicemia associated with noncuffed CVCs range from 4% to 14%, while long-term cuffed silastic catheters have a septicemia rate of 8 to 43%. Similarly, Taylor et al., (2002) found in their multicenter study that the rates of infection associated with cuffed CVCs ranged from 0 to 4.8 per 1,000 dialysis procedures and the rates of

infection associated with uncuffed CVCs ranged from 0 to 12.0 per 1,000 dialysis procedures. The rate of septicemia for cuffed catheters is dependent upon the patient's comorbid conditions, history of previous bacterial infection, immunosuppression, and length of time the catheter is left in place.

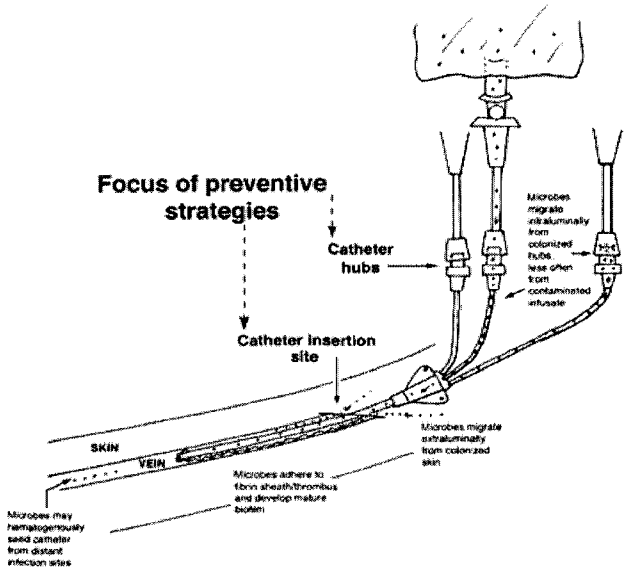

Figure 1 Sources of intravascular contamination
From Mermel L.A. (2000) Annals of Internal Medicine 132 (5)
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Catheter-related bloodstream infections are a result of hematogenous seeding, infusate contamination, and the skin surface and hub colonization (Figure 1) (Hadaway, 2001; Raad, Costerton, Sabharwal, Sacilowski, Anaissie, & Bodey, 1993; Civetta, 1996; Maki, 1991). While the first two causes are relatively uncommon, the two main sources of infecting pathogens are the skin at the catheter insertion site and bacterial or fungal strains that colonize the catheter hub (Macias-Hernandez, Hernandez-Ramos, Munoz-Barrett, Vargas-Saldo, Guerrero-Martinez, Medina-Valdovinos, Hernandez-Hernandez, & Ponce-de-Leon-Rosales,

1996). For short-term, nontunneled, noncuffed catheters, the organisms migrate from the skin insertion site along the intercutaneous segment eventually reaching the intravascular segment or the tip. For long-term catheters, the hub is reported to be a major source of colonization of the catheter lumen, which ultimately leads to blood stream infections through luminal colonization of the intravascular segment. The hub is often contaminated by the hands of the medical personnel during frequent manipulations of the catheter (Sitges-Serra et al., 1995; Raad et al., 1993; Raad & Bodey, 1992; Parker, 1998; Gaynes, 2001).

When the CVC is inserted into the vein, the body responds by irreversibly encapsulating it into a fibrin sheath rich in host proteins that covers the internal and external surfaces of the intravascular segment of the catheter (Donlan, 2001). The sheath is called a biofilm. The proteins in the sheath such as fibrin, fibrinogen, fibronectin, laminin, thrombospondin, and collagen, act as adhesions (Raad & Bodey, 1992). Organisms, such as *Coagulase-Negative Staphylococci* (CNS), bind to fibronectin. *Staphylococcus aureus* binds strongly to both fibronectin and fibrinogen, while *Candida albicans* binds well to fibrin (Hanna, Raad, & Darouiche, 2001). Microbial organisms enhance their adherence by producing a fibrous glycocalyx, known as extracellular slime, which constitutes the microbial substance of the biofilm (Raad & Bodey, 1992). The sheath can also cause complete thrombosis of the vessel in which the catheter is residing (Chopra, 2001; Raad & Bodey, 1992). Thrombosis can set up an inflammatory process, which can progress to an infective process (Maki, 1991).

Gram-positive bacteria, gram-negative bacteria, and yeast can also produce biofilms. Approximately 40% of central venous catheter infections are due to *Staphylococci,* 30% to Gram-Negative Bacilli, 12% to *Candida albicans*, and 12% to Enterococci (Mermel et al., 2001; Zeylemaker et al., 2001). Biofilms can create a protective environment for bacteria. There are at least three mechanisms that make biofilms resistant to antimicrobial action. There is delayed antibiotic penetration because the antibiotic is unable to reach the bacteria through the biofilm gel matrix. The slower growth of the bacteria in the biofilms may make them less susceptible to antimicrobial therapy, and as the biofilm ages the bacteria may become more resistant to the killing action of the antimicrobials (Chopra, 2001; Maki, 1991).

Catheter-Related Variables Associated with Increased Risk of Infection

Bacterial adherence varies with the source and the texture of material that makes up a catheter. Most catheters are made of polyvinylchloride, silicone, polyethylene, and polyurethane. Bacterial adherence appears to be greater to polyvinyl chloride than to polyurethane, greater to latex than to silicone, and greater to synthetic than to biologic materials. It is greater to textured and irregular surfaces than to regular and smooth surfaces, and greater to hydrophobic than to hydrophylic surfaces (Rovner et al., 1992; Raad & Bodey, 1992; Civetta, 1996; Joyeux, 1991; Maki, 1992).

There is controversy concerning increased risk of infection with the use of multi-lumen catheters versus single lumen catheters. In an editorial written

by Dr. Pearson from the CDC (1997), he stated that some studies have demonstrated that multi-lumen central venous catheters are associated with a higher risk of infection than single lumen catheters. In a review of the literature by Cook (1999), multi-lumen catheters are described as being no more likely to result in catheter-related infections than single lumen catheters, and multi-lumen catheters reduce the need for peripheral vascular accesses which are just as susceptible to infection and in greater number. This statement was supported by Farksa et al. (1992) in which 146 catheterizations were prospectively studied in medical/surgical intensive care unit (ICU) patients over a 28-month period. The patients were randomized into one of two groups, the single lumen or triple lumen group. Strict aseptic technique with maximal barrier precautions was observed. During the study, 53 of 129 patients had a bacteremia, and in 19% of these patients, the infection was diagnosed as a catheter-related septicemia. It is interesting to note that in the single lumen group, 25 of the 68 patients required 95 peripheral catheters, while in the triple lumen group one patient required a peripheral catheter. The authors concluded that triple lumen catheters are suspected by the staff to be at higher risk of sepsis because of the increased number of manipulations and subsequent inoculation of hub-colonizing organisms into the catheters. Further, because these catheters are larger in diameter, they require the use of an introducer to dilate the vein thereby increasing tissue trauma, stimulating an inflammatory process, and potentially increasing the opportunity for bacterial growth and subsequent infection. The mean length of time the

catheters were in place was 16 days, with the triple lumen catheters in place 2 days less than the single lumen catheters. The rationale for removing the triple lumen catheters was described as uselessness of the catheter, meaning they were no longer required, but the authors questioned whether the subjective decision to remove the catheters was related to the reputation of increased septic events that may be associated with triple lumen catheters. The authors concluded that there was no difference in rates of sepsis between the two types of catheters. The added benefit of the triple lumen catheters was that the need for peripheral vascular access decreased.

Strategies for the Prevention of Catheter-Related Infection

Nurse-patient ratio. The literature appears to be consistent it its support of an educational program and/or a specialized team of individuals dedicated to the care of intravascular devices (Darouiche & Raad, 1997; Raad & Bodey, 1992; Parras, Ena, Bouza, Guerrero, Moreno, Galvez, & Cercenado, 1994). In a cohort study of surgical ICU patients with CVC associated bloodstream infections, the corresponding patient to nurse ratio was reviewed by Fridkin, Pear, Williamson, Galgiani, and Jarvis (1996). They hypothesized that an increase in the patient to nurse ratio, in combination with an increase in the total parenteral nutrition (TPN) use, may have placed time constraints that prevented the nurses from caring for the CVCs properly. During an outbreak of CVC blood stream infections a high patient to nurse ratio was identified. Further studies have found a decrease in infection rates associated with CVCs, with the implementation of vascular access

teams (Maki, 1992). These reports indicate that increased time, care, and attention paid by individuals dedicated to a single task may result in fewer infectious complications.

Maximal sterile barriers. Use of maximal sterile barriers and careful hand washing prior to and during the insertion of a CVC are reported to be the most important steps in preventing catheter-related infections (Sitges-Serra et al., 1995; Raad, Darouiche, Hachem, Mansouri, & Bodey, 1996; Maki, 1992; Raad, Hohn, Gilbreath, Suleiman, Hill, Bruso, Marts, Mansfield, & Bodey, 1994; Band, 2001). A maximal sterile barrier involves wearing sterile gloves, a mask, a gown, and using a large drape. The usual procedure involves wearing gloves and using a small drape. Darouiche and Raad (1997) reported a four fold decrease in the rate of pulmonary artery catheter related bacteremia and a more than six fold decrease in the rate of CVC related sepsis following the use of maximal sterile barriers during the insertion of CVCs.

Topical ointments. Theoretically, the application of topical ointments should confer some protection against microbial invasion (Maki, 1992). In the study by Levin, Mason, Jindal, Fong, and Goldstein (1991) where the treated group (n = 63) received povidone-iodine ointment with the dressing changes and the control group (n = 66) used dry dressings, there was a reported 93% relative risk reduction of septicemia in the treated group. This finding was attributed to the use of povidone-ointment. In a comparative study of a polyantibiotic and Iodophor by Maki and Band (1981), (n = 827 catheters from 381 patients), the

rates of catheter-related septicemia was too low to make a valid comparison. The conclusions drawn were that the polyantibiotic ointment offered some protection against catheter-related infection but only slightly.

Dressings. Microorganisms that colonize the skin are responsible for most of the infections that occur around catheter exit sites. Improper handling of the device by staff may also contribute to an infectious process. The dressings that cover the exit site could therefore have considerable influence on the incidence of nosocomial infection. The purpose of an intravascular site dressing is to prevent trauma to the catheter wound and the cannulated vessel as well as to prevent extrinsic contamination of the wound (Maki, 1992; Little & Palmer, 1998). Numerous studies have been carried out in an attempt to identify the most appropriate dressing for intravascular access sites (Maki, 1991; Claeys & Degrieck, 1991; Wille, Blusse van Oud Alblas, & Thewessen, 1991; Keenlyside, 1991; Joyeux, 1991; Mermel, 2000). Criteria for insertion site dressings includes: they should be sterile, capable of preventing moisture, allow visible inspection, are cost-effective, easy to apply and fix securely to the insertion site, and are easy to remove (Campbell & Carrington, 1999). The traditional dressing is gauze, covered by nonsterile tape. It does not allow visible inspection, will allow the passage of organisms when wet and should be changed daily. This increases the amount of manipulation of the device and could potentially encourage contamination of the hub. The alternative to the gauze dressing is the transparent polyurethane dressing. Specific types of transparent dressings have been proven

to be more effective in their physical properties, particularly moisture vapor transmission (MVT) rates, oxygen transmission and cutaneous adherence (Maki, 1991; Cook, 1999). Further, the patients are permitted to shower with the transparent dressings in place.

The disadvantage associated with transparent dressings is greater cost, difficult removal, poor adherence to the skin over the catheter, and leakage due to drainage from the exit site wound. To obviate the disadvantage of cost, these dressings are left in place for up to 7 days or longer. It is possible that transparent dressings left on for prolonged periods of time increases the risk of catheter-related infection. There is conflicting evidence associated with this statement. In the studies by Maki et al. (1991), Richardson (1991), Claeys and Degrieck (1991), Willie et al., (1991), and Besley (1991), leaving the transparent dressings on for 7 days did not increase the incidence of catheter-related infections when the OpSite 3000 transparent dressing was used. Most of these studies took place in an ICU setting with the study periods being less than three weeks total. In the study by Bijma, Girbes, Kleijer, and Zwaveling (1999), it was reported that there was an increase in cutaneous colonization and CVC-related infection with transparent dressings. Bijma and colleagues therefore, elected to do a study with 206 CVCs over a seven-month period in a surgical ICU setting. During the study, the transparent dressing was replaced with a gauze dressing and it was reported that colonization rates were greatly reduced (206 CVCs in 128 patients, $p<.025$).

Catheters with silver-impregnated cuffs. The use of catheters with attachable silver-impregnated cuffs has been proposed to lessen the risk of extraluminal contamination (Sitges-Serra et al., 1995; Boyce, 1996). Silver acts as a heavy metal by impairing the bacterial electron transport system and some of its DNA functions. To do this, the active agents, which are the silver ions, have to be bioavailable to enter the cell at the correct concentration (White, Cooper, & Kingsley, 2001). In the multi-center trial by Maki and colleagues (1988), a catheter with a silver-impregnated cuff was studied and found to confer protection, especially if left in place for greater than four days. Results such as these may not be generalizable to the hemodialysis population where the catheters are left in place for weeks to years.

Antibiotic-impregnated catheters. More recently, work has been done with CVCs incorporating an antiseptic or antibiotic into the CVC material. Chlorhexidine, a cationic biguanide, is a potent broad-spectrum germicide with minimal inhibitory concentrations less than 50 mg/ml against nearly all nosocomially transmitted bacteria and yeasts, such as Candida species. It is an antiseptic whose antimicrobial effect is achieved by disrupting the microbial cell membrane. Chlorhexidine may be very effective against gram-positive bacteria and many viruses but less effective against gram negative bacteria and fungi (Gaudet & Beaufoy, 1996). Silver sulfadiazine has been used topically throughout the world for many years, primarily in the treatment of burn wounds, where it delays colonization and reduces the incidence of major infection. In an eighteen-month study by Darouiche, Raad, Heard, Thornby,

Wenker, Gabrrielli, Berg, Khardori, Hanna, Hachem, Harris, and Mayhall (1999), 865 polyurethane, noncuffed, triple-lumen catheters impregnated with minocycline and rifampin or Chlorhexidine and sulfadiazine were compared with unimpregnated catheters in a multi-center trail. The catheters impregnated with minocycline and rifampin were associated with a lower rate of infection as compared to the Chlorhexidine group, however both groups reported lower rates of colonization and blood stream infections when compared to the unimpregnated groups. The minocycline catheters were one-third as likely to be colonized and one-twelfth as likely to develop catheter-related blood stream infections. The median length of time the catheters were left in place was 11 days. The catheters were coated on the external surface only. In a randomized controlled trial by Maki, Stolz, Wheeler, and Mermel (1997), a standard, multi-lumen, noncuffed catheter was compared to a catheter impregnated with Chlorhexidine and silver sulfadiazine. The antiseptic catheters were reported as less likely to be colonized at removal and were fivefold less likely to produce bloodstream infection.

In the study by Sherertz, Carruth, Hamptom, Byron, and Solomon (1993), seven different antibiotic/antiseptic coated catheters were inserted into a rabbit model to test their effectiveness in preventing a subcutaneous *Staphylococcus aureus* infection. The antibiotics/antiseptics used were dicloxacillin, clindamysin, fusidic acid, ciprofloxacin, cefuroxime, cefotaxime and chlorhexidine. The catheters were left in place for 2 days. Dicloxacillin, clindamycin, and fusidic acid all significantly inhibited the development of *Staphylococcus aureus* infection. Chlorhexidine coated catheters were as effective as dicloxacillin. During the study

by Greenfeld, Sampath, Popilskis, Brunnert, Stylianos, and Modak (1995), Chlorhexidine and silver sulfadiazine-impregnated catheters were implanted in swine to determine if there was decreased adherence and biofilm formation. Biofilm was not found on the outer surface of the antiseptic catheters retrieved after the seven-day trial period. However, the potential drawbacks of using antibiotics to treat the surface of the vascular catheters are: the ineffectiveness of these agents against antibiotic resistance, nosocomial bacteria and fungi; the risk for the emergence of bacterial resistance during long-term use; and the potential for hypersensitization (Maki et al., 1997; Stephens, Mythen, Kallis, Davies, Egner, & Rickards, 2001).

Central venous catheter change over a guidewire. The ESRD patient who uses a CVC for long-term access does so because vascular access sites are limited. Health Canada (1997) stated that a hemodialysis catheter should not be changed over a guide wire if infection is suspected. If the catheter is infected, reoccurrence is probable in the newly inserted catheter whether the infection occurred intraluminally or extraluminally (Maki, Stolz, & Wheeler, 1991; Sitges-Serra et al., 1995). A change over a guide wire is recommended in the case of malfunction. In the event of a catheter-related infection the usual course of treatment is systemic antibiotic coverage but it is not always effective in eradicating the infecting microorganism (Shah & Feinfeld, 2000). Further, the cost to replace a central venous catheter is high, as is the cost of hospitalizations associated with catheter-related infections (Maki, 1991; Horattas, Trupiano, Hopkins, Pasini, Martino, & Murty, 2001).

Catheter salvage. Recently, clinicians have been reviewing the use of an antibiotic lock-solution for the purpose of catheter salvage. Shah and Feinfeld (2000) related that using a combination of systemic and locked-in antibiotics to treat a gram-negative catheter infection was successful in the treatment of a female patient during their study. The authors estimated the cost of treatment to be approximately $10.00 US per day as compared to the cost of antibiotic coverage for 2 to 3 weeks and the cost of catheter removal and replacement. The authors suggested larger studies be done to determine the effectiveness of hemodialysis catheter salvage.

Antiseptics. Skin cleansing of the insertion site is regarded as one of the most important measures for preventing catheter-related infection. Historically, povidone-iodine is an antiseptic that has been used during the insertion and maintenance of intravascular devices. It works by penetrating the cell wall of the microorganism. More recently, Chlorhexidine has been studied and found to be more effective as a skin antiseptic to prevent catheter-related infection (Mimoz et al, 1996; Garland et al., 1995). It works in less time, retains its antibacterial activity against flora longer, is not inactivated by the presence of blood or human protein, and causes minimal skin irritation (Maki, 1991; Gaudet & Beaufoy, 1996; Mimoz et al., 1996; Dickenson, 1997). Chlorhexidine works by disrupting the microbial cell wall. It is active against many gram-positive and to a slightly lesser degree gram-negative bacterium. In a prospective, randomized trial by Fuchs and colleagues (1990) three different methods of catheter exit site care were studied in a peritoneal dialysis population for 14 months. The solutions used included

chlorhexidine gluconate and water, dilute sodium hypochlorite solution, and povidone-iodine. The study failed to demonstrate that one method of care was superior to another. In the prospective, randomized study by Mimoz and colleagues (1996), chlorhexidine gluconate and 10% povidone-iodine were compared in all ICU patients admitted between July, 1992 and October, 1993 requiring a CVC or arterial catheter. Chlorhexidine was superior in preventing catheter colonization and catheter-related sepsis due to gram-positive bacteria (5 vs. 20 [p<.001] and 2 vs. 10 [p<.001], respectively), whereas the Chlorhexidine was not significantly superior in preventing gram-negative infections (7 vs. 4 [p=.5] and 4 vs. 2 [p=.8], respectively). Maki et al. (1991) compared three antiseptics for disinfection of 668 central venous and arterial catheters. Chlorhexidine was associated with the lowest incidence of local catheter-related infection and catheter-related bacteremia in comparison to alcohol and povidone-iodine. Traore, Allaert, Fournet-Fayard, Verriere, and Laveran (1999) compared povidone-iodine to Chlorhexidine in 2 groups of 22 healthy subjects and concluded that both antiseptics are equal in bactericidal activity at 0 time, 30 seconds, 3 minutes, and 2 hours. There is a high alcohol content in the Chlorhexidine solutions, which has damaging effects on some catheter materials, thereby restricting its use. In a survey by Clemence, Walker, and Faar (1995) of 94 persons attending a vascular access meeting, it was reported that nearly all respondents continued to use povidone-iodine as their skin antiseptic.

Electrolytic chloroxidizer, otherwise known as Amuchina® is a chlorine-based solution with a 17% sodium chloride component and 0.057% sodium

hypochlorite. Exsept is the 5% or 10% dilution of Amuchina. It is said to be effective against all spectrums of pathogens including gram-positive, gram-negative bacteria, viruses and spores (Exsept, Unpublished Manuscript). Amuchina is similar in molecular size and structure to water, and because it does not present with an electrical charge, the undissociated hypochlorous acid may easily cross the microbial cell membrane. Its intracellular targets are enzymes containing sulfhydril groups involved in aerobic and anaerobic pathways. The action of hypochlorous acid on these enzymes consists of irreversible oxidation of the thio-group, thus abolishing enzymatic action and resulting in the destruction of the bacteria (ExSept, Unpublished Manuscript).

Amuchina is reported to be non-toxic, non-irritating (Billhimer, 1985; Buoncristiani, Bianchi, Barzi, Quintaliani, Cozzari, & Carobi, 1980). Roveda, Pulvirenti, and Colombo (1993) conducted a controlled randomized study on 48 patients comparing the antiseptic properties of Amuchina 10% to 10% povidone-iodine. Both antiseptics produced an immediate reduction in bacterial load during a single application, however, the absolute values were more significant with Exsept ($p<0.05$). Jones and Mulberry (1987) repeated the study with 24 female volunteers, 12 per group. The bacterial flora of the skin and abdomen were studied. Both products produced an immediate large reduction of bacteria at the abdominal area but Amuchina appeared more effective than povidone-iodine at the auxillary area ($p < .05$). Cruz, Donabedian, Peterson, and Neblett (1993) conducted a similar study comparing skin surface bacterial counts of three groups of 9 voluntary patients and found no difference between products ($p < .05$). No

side effects occurred suggesting Amuchina was well tolerated. In 1989, a Canadian clinical trials group lead by Churchill, Taylor, Vas, and Oreopoulos, conducted a multi-center trial comparing the Y-set, which used Amuchina 50% as the in-line disinfectant and compared it to the standard peritoneal dialysis systems. There was a 61% risk reduction with Amuchina, however accidental infusions into the peritoneal cavity related to patient error caused moderate to severe abdominal pain for patients. De Vecchi, Scalamogna, Castelnovo, Abbiati, Baiguini, and Castellanta (1994) used Amuchina as an inline disinfectant in some Y-systems to prevent exogenous peritonitis. The results were inconclusive because the researchers suggested that glucose in the solution, in combination with organic compounds like peritoneal dialysate, could reduce the bactericidal effect of the product. Therefore, it could not be determined as to what the clinical role of Amuchina was with the Y-set. To date, there have not been any published studies done with Amuchina as a skin and hub antiseptic in the hemodialysis population who use CVCs as their dialyzing access.

CHAPTER THREE

Methods

The purpose of the study was to determine whether Amuchina 10% is as effective or more effective than the standard skin and hub antiseptic solution of Chlorhexidine 0.5% with 70% alcohol in decreasing the central venous catheter-related exit site infections, bacteremia, and exit site skin colonization in long-term, maintenance hemodialysis patients over a 3 month period.

Design

A randomized clinical trial with repeated measures was used to examine the effect of Amuchina on infection rates in patients with end stage renal disease (ESRD) using central venous catheters (CVCs) as their dialyzing access. The control group used the standard Chlorhexidine 0.5% with 70% alcohol as the catheter exit site and hub antiseptic and the treatment group used Amuchina 10% on the skin and 50% on the hub (Amuchina concentrations were based on recommendations by Alcavis International Inc.). The presence of exit site infection and catheter-related bacteremia were the primary outcome variables. Exit site skin colonization was a secondary outcome variable. Signs and symptoms of infection were monitored from the time of catheter insertion, at each dressing change to the end point of the study, which was the development of a catheter-related bacteremia or termination of the study at 3 months post catheter insertion. Catheter brushings were done part way through the study period on a convenience sample of patients and exit site swabs were collected monthly on each patient (Figure 2).

OBSERVATIONS	TIME/FREQUENCY		
	START	EACH RUN	MONTHLY END
EXIT SITES: CLINICAL FINDINGS			
EDEMA	X	X	
ERYTHEMA	X	X	
TENDERNESS	X	X	
DISCHARGE	X	X	
TEMPERATURE	X	X	
CULTURE OF EXIT SITES	X		X
CATHETER BRUSHINGS			Random
CATHETER TIP			Random
BLOOD CULTURES			Random
MRSA NASAL SWABS	X		

Figure 2. Study Design

Sample

The eligible sample included all new patients with ESRD who were initiated on hemodialysis, or who required a new CVC and were currently receiving hemodialysis. These patients were enrolled in the Northern Alberta Renal Program. The convenience sample consisted of patients with ESRD who required a CVC inserted as the dialyzing access, were infection free, and were 18 years or older. The patients excluded from the sample were those who were not of legal age for consent, those with a confirmed infective process, carried methicillen resistant *Staphylococcus aureus* (MRSA) positive nasal swabs, or had an allergy to either antiseptic solution.

Data Collection Protocol

The Clinical Supervisor, Incenter Hemodialysis Unit, University of Alberta Hospital, reviewed potential study patients, as their names were submitted by the attending Nephrologist, for CVC line insertion. The researcher was contacted by the Clinical Supervisor regularly to provide the names of potential subjects. Patients were approached in the Incenter Hemodialysis Unit by the researcher on the day of their CVC insertion and the study explained (Appendix A). An informed consent was then obtained from patients willing to participate in the study (Appendix B). A package containing the data collection sheet and group assignment was selected. (All packages were previously prepared and randomly organized). The researcher completed the demographic information sheet (Appendix C). Nasal swabs were carried out on each patient to determine the presence of MRSA and *Staphylococcus* carrier status, as those patients who are MRSA carriers are at greater risk for colonization of the skin and developing infection (Hoen, Paul-Dauphin, Hestin, & Kessler, 1998). One of three experienced nephrologists inserted the CVC, using the same method of insertion (Seldinger). The catheters were soft, dacron-cuffed, polyurethane, dual lumen catheters (Cardiomed ®) used for long-term maintenance hemodialysis.

One to two days following the CVC line insertion, at the time of the first hemodialysis treatment, and thereafter three times per week, the catheter dressing was removed and the exit site observed for signs of infection by a hemodialysis nurse. This information was documented on the data collection sheet, which remained on the front of the patient's chart (Appendix D). One of two randomly

assigned antiseptics was used as per the hospital-approved procedure for care of the CVC and initiation of the dialysis procedure (Appendix E). Polysporin triple therapy antibiotic ointment (Taro Pharmaceuticals Inc.) was used consistently on the exit sites during the study. The ointment was removed prior to obtaining the skin swab. Once per month, for three months, swabs were taken of the catheter exit sites (Appendix G). Brushings (Endoluminal Catheter Brush, IDI Technologies, Ltd.) from the internal lumens of the catheters were obtained at the middle of the study period on a convenience sample of patients (11%) to determine endoluminal catheter colonization. In the event of clinical signs of infection, exit site skin swabs and blood cultures were drawn and appropriate antibiotic therapy instituted as required by standard practice in the unit. In the event of CVC removal, the catheter tip was to be collected and sent to the laboratory to be analyzed for colonization of microorganisms. The end point of the study was a confirmed catheter-related bacteremia or termination of the study at 3 months.

Data Analysis

Descriptive statistics were used to describe the sample characteristics and outcome variables. To determine the difference between the treatment and control groups on the number of exit site infections, rate of bacteremia, and exit site skin colonization, Chi-square analysis was conducted. Associations were also examined among catheter-related infection rates and patient demographics such as age, gender, cause of renal failure (diabetes mellitus), and serum albumin levels.

Ethical Considerations

Support for the study was obtained from the Division of Nephrology and the Clinical Supervisor of the Incenter Hemodialysis Unit. Ethical approval for the study was attained from the Health Research Ethics Board, University of Alberta. Upon introduction to the study, the participants were informed of the purpose of the study, procedures involved, risks, benefits, voluntary participation, and confidentiality (Appendix A). It was stressed that the patient were not under obligation to participate, may withdraw from the study at any time, and that withdrawal from the study would not influence care given. Consent to participate (Appendix B) was signed by the participants prior to the initiation of the study. Amuchina is reported to be non-toxic and non-irritating. An allergic reaction to any drug product was considered. Observation of the patients' skin was to be monitored 3 times weekly for a skin rash covering the area of skin where the Amuchina was applied as well as for signs of infection. In the event of a catheter-related infection, the patient was treated with the appropriate antibiotics.

CHAPTER FOUR

Findings

The purpose of this randomized controlled clinical trial was to determine whether Amuchina 10 % was as effective or more effective than the standard skin and hub antiseptic solution of Chlorhexidine 0.5% with 70% alcohol in decreasing central venous catheter (CVC) exit site infections, catheter-related bacteremia, and exit site skin colonization, in long-term, maintenance, hemodialysis patients. Enrollment and randomization of study patients took place in the Incenter Hemodialysis Unit, University of Alberta Hospital. All patients had their CVCs inserted by an experienced Nephrologist via the right internal jugular vein. Prophylactic antibiotics were used at the discretion of the attending Nephrologist. Thereafter, three times per week, hemodialysis nurses were responsible for cleansing the exit sites with the designated antiseptic and documenting their assessment on a supplied data collection sheet. Also every month from the initiation of the study, routine swabs were taken of the patient's CVC exit site.

Data were analyzed using SPSS software, version 11.5. Descriptive statistics were performed on patient characteristics and study outcomes. An independent t-test or Chi-square was conducted on patient demographics to assess group differences. As the information collected for the outcome variables of exit site infections, bacteremia, and skin colonization, was nominal, Chi-square or Fisher's Exact test was used to compare groups. Associations were also examined among catheter-related infection rates and patient demographics such as age, gender, cause of renal failure (diabetes mellitus), and serum albumin levels.

Study Enrollment

There were 136 patients approached to participate in the study, with 121 patients being enrolled between January 1, 2003 and July 8, 2004. The primary reason for refusal to participate was related to the length of time required to stay in the study. The patients who were being transferred to peritoneal dialysis within 3 months, being prepared for transplant, or those who could not commit to three months were not enrolled. One patient was not interested and one Nephrology Fellow was late in becoming involved in the study therefore those patients were not enrolled in the study. Each patient's progress was tracked for 3 months, 36 dialysis treatments, or 90 catheter days. The cumulative study time for 121 patients was 10,890 catheter days (5,445 days per group), 363 patient months, or 4,356 treatments.

The final sample consisted of 103 patients, as 18 patients did not complete the study (14.87%). Reasons for not completing the study are listed in Table 1. Seven patients died during the study (5.78%). Causes of death were listed as peritoneal failure that subsequently developed into a peritonitis (n=1), cardiac arrest secondary to cause unknown in two patients (n=2), myocardial infarction (n=1), ischemic gut secondary to cardiovascular disease (n=1), cardiac arrest secondary to aortic dissection (n=1), and hemothorax secondary to catheter insertion (n=1). Two patients required hernia repair associated with peritoneal dialysis and were to be supported by hemodialysis for 12 weeks but returned to peritoneal dialysis earlier than anticipated. Two patients recovered kidney function and were discharged from the program. One patient received a cadaveric

transplant. Two patients related that the smell of the Amuchina solution made them nauseated. Turning their faces away or wearing masks did not alleviate the problem. One patient's CVC fell out. Rather than replacing the catheter, the AV graft was used earlier than was planned. One patient who had developed skin cancer secondary to immunosuppressive therapy subsequent to a renal transplant found the Amuchina solution irritating to the skin. One patient decided to discontinue dialysis and leave the treatment program. One patient who had emotional issues to deal with felt he could not cope with continued participation in the study.

Table 1

Reasons for Study Termination

Reason	Group	Frequency
Death		7
Peritoneal Membrane Failure/Peritonitis	Amuchina	1
Cardiac arrest – cause unknown	Amuchina	1
Cardiac arrest – cause unknown	Amuchina	1
Myocardial infarction	Amuchina	1
Ischemic gut secondary to CVD	Chlorhexidine	1
Hemothorax	Amuchina	1
Cardiac arrest secondary to aortic dissection	Chlorhexidine	1
Recovered kidney function	Amuchina	2
Transplanted	Chlorhexidine	1
Could not tolerate smell of Amuchina	Amuchina	2
Transfered to Peritoneal Dialysis	Chlorhexidine Amuchina	1 1
CVC fell out	Chlorhexidine	1
Amuchina irritating to skin	Chlorhexidine Amuchina	1 1
Emotionally unstable	Amuchina	1

Characteristics of Study Cohort

Patient randomization to the two treatment groups was as follows: 64 (52.9%) to the Chlorhexidine group and 57 (47.1%) to the Amuchina group. Table 2 illustrates the demographic characteristics of the sample. Overall, the patients ranged in age from 18 to 70 years (M±SD = 63.18 ± 15.47). The mean age for the Chlorhexidine group was 63.28 ± 15.23 years and 63.07 ± 15. 87 years for the Amuchina group (t = .075, p=.882).

Table 2

Characteristics of the Subjects

	Group		
Characteristic	Chlorhexidine 64 (52.9%)	Amuchina 57 (47.1%)	p value
Age (years, M±SD)	63.28 ± 15.23	63.07 ± 15.87	.882
Gender			.103
Male [n(%)]	39 (32%)	26 (22%)	
Female [n(%)]	25 (21%)	31 (26%)	
Height (cm, M±SD)	165.03 ± 11.34	163.30 ± 13.69	.447
Weight (kg, M±SD)	73.18 ± 20.14	74.04 ± 17.95	.972
BMI (m^2, M±SD)	27.25 ± 7.48	27.70 ± 5.88	.547
Albumin (g/L, M±SD)	32.08 ± 5.49	31.26 ± 5.63	.751
Immunossuppressed [n(%)]	7 (5.78 %)	3 (2.47%)	.213
Disease			.464
Diabetic Nephropathy	29 (23.9%)	21 (17.3%)	
Other	14 (11.5%)	19 (15.7%)	
Glomerulonephritis	10 (8.26%)	4 (3.3%)	
Hypertension	6 (4.9%)	6 (4.9%)	
Unknown	4 (3.3%)	6 (4.9%)	
Renal Vascular Disease	1 (.82%)	1 (.82%)	

Sixty-five (53.7%) of the total sample were males, with no difference found in gender between the Chlorhexidine and Amuchina groups (χ^2= 2.84, p = .103). There was no significant difference between the Chlorhexidine and Amuchina groups in height, weight, BMI, serum albumin levels, and status of immunosuppression. Serum albumin is a reflection of nutritional status. Patients with end stage renal disease (ESRD) often report decreased appetites especially for foods such as protein. Poor nutritional status may contribute to increased susceptibility to infection. Figure 3 depicts the serum albumin levels of the patients participating in the study. No difference was found between the groups in the serum albumin levels (χ^2=30.598, p = .166).

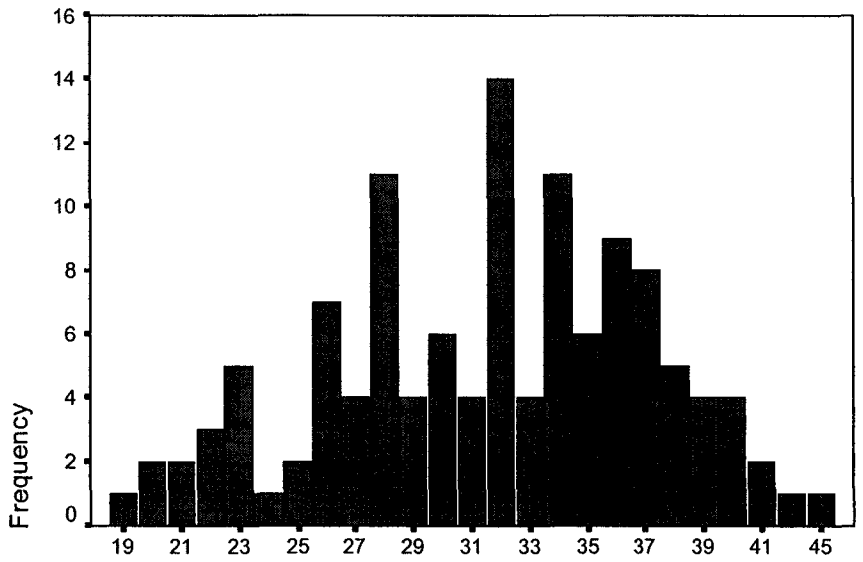

Figure 3. Serum albumin levels of patients enrolled in the study

The diseases responsible for ESRD are listed in Table 2 and Figure 4. Both groups were equally matched. Fifty (41.3%) patients were diabetic. These results are similar to those listed by the Canadian Organ Replacement Register (2001).

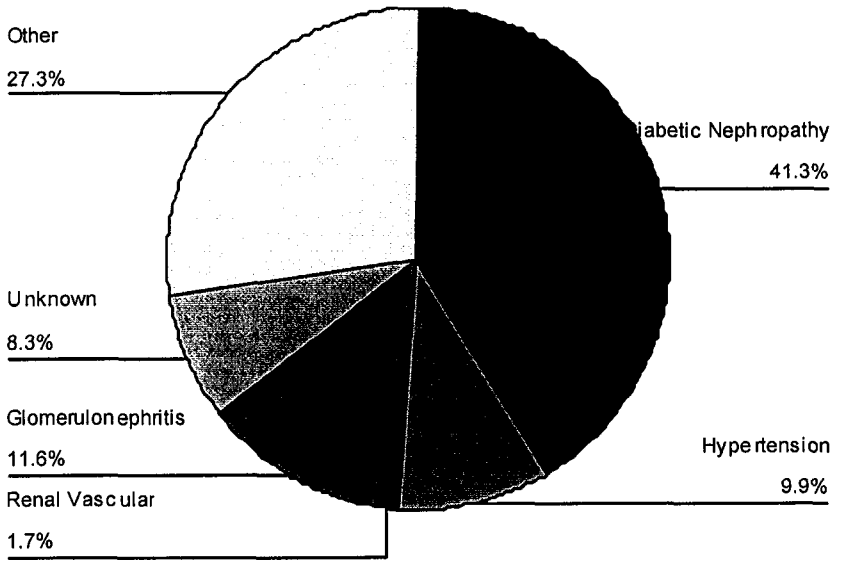

Figure 4. Proportions of Diseases Resulting in ESRD

Ten of the 121 patients were taking immunosupressive therapy at initiation of the study; 7 in the Chlorhexidine group and 3 in the Amuchina group (χ^2= 1.28, p =.213). All patients on immunosupression had previously been transplanted. One patient was a liver transplant, necessitating the use of Cyclosporine for its continued function. A second transplant patient had received a heart transplant and was maintained on Cyclosporine. Six patients were receiving tapering doses of prednisone for failing renal transplants. Two patients were receiving a steroid

to treat the cause of renal failure. All 121 patients participating in the study were MRSA negative.

Exit Site Infections

The first hypothesis to be tested was that there would be a decreased number of localized exit site infections in the experimental group receiving Amuchina 10% than in the control group receiving Chlorhexidine 0.5% with 70% alcohol. The exit sites were observed by hemodialysis nurses for the presence of infection during each treatment for the duration of the study. The sites were evaluated as no infection; discharge only; erythema greater than or equal to 2 cm from the catheter exit site; erythema and discharge; or erythema and tenderness. In total, 8 sites were positive for both clinical signs of infection and positive culture results and 2 were positive for clinical signs but were not confirmed by culture. Of the 10 infected sites, 5 were in the Amuchina group and 5 were in the Chlorhexidine group. There was also no significant difference when separating clinical signs only versus clinical signs and positive culture (Table 3).

Table 3

Exit Site Infections

Exit Site Infections	Group (n)		Total	p value
	Chlorhexidine	Amuchina		.553
Negative culture	59	52	111	
Clinical signs and positive culture	3	5	8	
Clinical signs	2	0	2	
Total	64	57	121	

Patient specific exit site infections are listed in Table 4. Of the 10 positive exit site cultures, 4 cultured *Staphylococci aureus,* 1 *Coryneforms*, and 3 *Coagulase-negative Staphylococci.*

Table 4

Patient Specific Exit Site Infections

Patient	Group	Symptoms	Culture Results
1	Amuchina	Purulent drainage, tenderness, erythema	4+ Staph aureus
2	Chlorhexidine	Erythema, tenderness	3+ Staph aureus, yeast
3	Amuchina	Purulent drainage, erythema, tenderness	4+ Staph aureus
4	Amuchina	Erythema, tenderness	4+ Coag-Neg Staph
5	Chlorhexidine	Purulent drainage, erythema, itchy, tenderness	+1 Coag-Neg Staph
6	Chlorhexidine	Purulent drainage, erythema, tenderness	Swab not done
7	Chlorhexidine	Purulent drainage, erythema, tenderness	Swab not done
8	Amuchina	Purulent drainage, tenderness, erythema	2+ Coryneforms
9	Chlorhexidine	Erythema, tenderness	4+ Coag-neg Staph
10	Amuchina	Purulent drainage, erythema, tenderness	1+ Staph aureus

Nine of the 10 patients who had exit site infections were treated by the Nephrologists with IV antibiotics. One patient was treated by using polysporin ointment.

Incidence of Bacteremia

The second hypothesis tested was that there would be a decreased number of catheter-related bacteremic episodes in the experimental group receiving Amuchina 10% than the control group receiving Chlorhexidine 0.5% with 70% alcohol. Two of four patients had positive blood cultures in three of three vials growing *Staphylococcus aureus* and *Citrobacter freundi*, while the third and fourth patients did not grow microorganisms in culture. One patient maintained an elevated white blood cell count (WBC) of 18.2 x 10^9 and 26.6 x 10^9. Following a thorough medical investigation, it was decided that the only plausible explanation for the elevated WBC was a possible bacteremic episode with the catheter being the source of infection, therefore the patient was treated with antibiotics and the CVC was removed. The other patient presented with fever, chills, discharge, and pain associated with the exit site, and was subsequently treated with antibiotics with the catheter left in place. Thus, these two patients were not included as being bacteremic. Of the two patients treated as catheter-related bactermia, 1 was in the Chlorhexidine group and 1 was in the Amuchina group (Table 5).

Table 5

Bacteremic Episodes

Culture Results	Group (n)		Total
	Chlorhexidine	Amuchina	
Positive	1	1	2
Negative	61	56	117
Possible*	2	0	2
Total	64	57	121

* Not confirmed by culture

Exit Site Skin Colonization

The third hypothesis tested was that there would be decreased skin colonization from the exit site swabs as measured by semiquantitative methods in the experimental group receiving Amuchina 10% than the control group receiving Chlorhexidine 0.5% with 70% alcohol. The skin microorganism that colonized the area surrounding the catheter exit site was primarily *Coagulase-negative Staphylococci* or there was no growth ($\chi^2 = .821$, $p = .663$) (Table 6). Other microorganisms identified by culture were Diptheroids, Enterococcus, Streptococcus, Yeast, Bacillus, Aerobic spore-bearing bacillus, *Klebsella pneumonia,* and *Viridians group Streptococcus*. Colonization of the skin was determined by definition to be greater than 15 colony forming units (cfu) on roll tip culture. Colonization occurred in 111 (91.7%) of the patients; 56 patients in the Chlorhexidine group and 55 in the Amuchina group ($\chi^2 = 3.215$, $p = .069$) (Table 7).

Table 6

Skin Microorganisms

	Group (n)		Total	p value
Microorganism	Chlorhexidine	Amuchina		.663
Coagulase-negative Staphylococcus	38	32	70	
No growth	23	20	43	
Other	3	5	8	
Total	64	57	121	

Table 7

Skin Colonization of Exit Sites

Colonization	Group (n)		Total	p value
	Chlorhexidine	Amuchina		.069
> 15 cfu	56	55	111	
<15 cfu	8	2	10	
Total	64	57	121	

* cfu denotes colony forming units

Catheter Brushings

Initially all patients began treatment in the Incenter Dialysis Unit. Once the patient was considered to be stable on treatment, they were transferred to one of 13 satellite units. Transfer occurred anywhere from one week after initiation of treatment to many months. Though it was originally planned that all patients

would have catheter brushings, it was difficult to bring the patients back to obtain the catheter brushings. Therefore, 13 catheter brushings were obtained on a convenient sample of patients mid-study. No growth was reported in 12 brushings. One brushing reported *Coagulase-negative Staphylococcus*.

Factors Affecting Catheter-Related Infections

Factors that could potentially influence the incidence of catheter-related infections such as older age, diabetes mellitus, hypoalbuminemia, immunosuppressive medications, and the use of prophylactic antibiotics at the time of catheter insertion were reviewed. Older age was described as being greater than or equal to 70 years. No differences were found in exit site infections, bacteremia, or skin colonization in patients who were older than or equal to 70 years compared to patients less than 70 years (Table 8).

A low serum albumin is a reflection of nutritional status. Malnutrition may predispose the patients to delayed healing and increased susceptibility to infection. This was not demonstrated, as patients with a serum albumin level less than or equal to 30 grams/Liter (g/L) did not have a higher rate of exit site infections, bacteremia, or skin colonization (Table 9).

Diabetic patients are described as being at greater risk for infection than other types of ESRD patients. There were no differences for those who were diabetic compared to those who were not diabetic in exit site infections, bacteremia, or skin colonization (Table 10).

Table 8

Factors Affecting Catheter-Related Infections: Age

			Total	p value
Age (years)	< 70	≥ 70		
Exit Site Infection (n)				.319
Yes	4	6	10	
No	66	45	111	
Total	70	51	121	
Skin Colonization (n)				.516
Yes	63	48	111	
No	7	3	10	
Total	70	51	121	
Bacteremia (n)				a*
Yes	2	0	2	
No	69	50	119	
Total	71	50	121	

*a is not computed

Immunosuppressive medications may mask infection thereby predisposing ESRD patients, who are already compromised as a result of the uremia, to infection. No significant difference in those patients taking the immunosuppressive medications was found in those patients not taking immunosuppressive medications in rates of exit site infections, bacteremia, or exit site skin colonization (Table 11).

Table 9

Factors Affecting Catheter-Related Infections: Serum Albumin

			Total	p value
Serum Albumin (G/L)	≤ 30	> 30		
Exit Site Infection (n)				.087
Yes	1	9	10	
No	46	65	111	
Total	47	74	121	
Skin Colonization (n)				.793
Yes	44	67	111	
No	3	7	10	
Total	47	74	121	
Bacteremia (n)				a*
Yes	0	2	2	
No	47	72	119	
Total	47	74	121	

*a is not computed

Table 10

Factors Affecting Catheter-Related Infections: Diabetes Mellitus

			Total	p value
Diabetes Mellitus	Yes	No		
Exit Site Infections (n)				.739
Yes	5	45	50	
No	5	66	71	
Total	10	111	121	
Skin Colonization (n)				.521
Yes	47	64	111	
No	3	7	10	
Total	50	71	121	
Bacteremia (n)				1.0
Yes	1	1	2	
No	49	70	119	
Total	50	71	121	

Table 11

Factors Affecting Catheter-Related Infections: Immunosuppression

			Total	p value
Immunosuppressed	Yes	No		
Exit Site Infections (n)				1.0
Yes	0	10	10	
No	10	101	111	
Total	10	111	121	
Skin Colonization (n)				.193
Yes	8	103	111	
No	2	8	10	
Total	10	111	121	
Bacteremia (n)				a*
Yes	0	2	2	
No	112	7	119	
Total	112	9	121	

* a is not computed

Table 12

Factors Affecting Catheter-Related Infections: Prophylactic Antibiotics

			Total	p value
Prophylactic Antibiotics	Yes	No		
Exit Site Infections (n)				.809
Yes	4	39	43	
No	6	72	78	
Total	10	111	121	
Skin Colonization (n)				.743
Yes	71	7	78	
No	40	3	43	
Total	111	10	121	
Bacteremia (n)				a*
Yes	2	78	80	
No	0	41	41	
Total	2	119	121	

*a is not computed

Prophylactic antibiotics might infer protection prior to insertion of the hemodialysis catheter. However, the Canadian Clinical Practice Guidelines (1999) suggest that the use of antibiotics is not supported by the literature. Thus, the use of prophylactic antibiotics at the time of CVC insertion is at the discretion of the attending Nephrologist. Of the 121 patients who had a CVC inserted, 78 patients received either Cefazolin (n=74) or Gentamicin (4). Forty-three patients did not receive antibiotic coverage. There was no significant difference between the Chlorhexidine and Amuchina groups on antibiotic coverage ($\chi^2 = 1.264$, $p = .462$) (Table 12). As well, use of prophylactic antibiotics had no effect on exit site infections, bacteremia, or skin colonization (Table 13).

Table 13

Prophylactic Antibiotics Administration

Prophylactic Antibiotics	Group (n)		Total	p value
	Chlorhexidine	Amuchina		.462
Yes	44	34	78	
No	20	23	57	
Total	64	57	121	

CHAPTER FIVE

Discussion

The purpose of this study was to assess if Amuchina 10% was as effective or more effective than the standard skin and hub antiseptic of Chlorhexidine 0.5 with 70% alcohol in decreasing central venous catheter exit site infections, bacteremia, and exit site skin colonization. A randomized, non-blinded clinical trial was performed involving patients in ESRD requiring tunneled cuffed hemodialysis central venous catheters as their dialyzing access. The data were collected between January 1, 2003 and July 8, 2004 in the Incenter Hemodialysis Unit, University of Alberta Hospital. The sample consisted of 121 patients; 64 in the Chlorhexidine group and 57 in the Amuchina group. The two groups were well matched on demographic characteristics including gender, age, serum albumin levels, BMI, height, weight, and ESRD etiology. All patients were MRSA negative and all patients had their catheter inserted into the Right Internal Jugular vein. Ten of the 121 patients were on immunosuppressive medications. Prophylactic antibiotics were used in 78 (65%) of the 121 patients.

Exit Site Infections, Catheter-Related Bacteremia and Skin Colonization

Infections are the most serious complications of tunneled, cuffed central venous catheters. The frequency of catheter associated bacteremia has been reported to be 1.2 episodes per 100 patient months (Marr et al., 1998). Saad (2001) and Tanriover et al. (2000) reported catheter-related infections of 3.4 to 5.5 episodes per 1000 catheter days. In comparison, the frequency of infections for AV grafts is 0.2 per patient year and 0.05 per patient year for AV fistulae

(Tanriover et al., 2000). Catheter-related bacteremia may result in serious systemic infections including endocarditis, osteomyelitis, epidural abscess, septic arthritis, and death. Further, infectious complications limit the survival of the access, thereby escalating costs required for antibiotics, a replacement access, and possible hospitalizations (Rocklin et al., 2001). Many different risk factors have been implicated in the literature including insertion sites, duration of catheterization, type of dressing, type of catheter, frequent manipulations, improper aseptic technique, number of catheter lumens, prophylactic antibiotic, and type of antiseptic solution (Oncu, Ozsut, Yildirim, Ay, Cakar, Eraksoy, & Calangu, 2003).

In this study, the first hypothesis was to compare two skin and hub antiseptics on rates of exit site infections. Of the 121 patients participating, 10 patients (8.26%) developed exit site infections; 5 were from each group. Though infections are a serious complication associated with CVCs, the incidence in this study was relatively low (.91/1000 catheter days). Saad (2001) reported an incidence of exit site infections from 1.2 to 2.2 per 1000 catheter days. The exit site infections occurred at various times during the study period. The longer the catheter is in situ, the greater the possibility of catheter colonization resulting in infection (Koch, Coyne, Hoppe-Bauer, & Vesely, 2002). Each of the study patients was monitored for 3 months. A longer study period of 6 to 12 months per patient may have provided more information in relation to exit site infections and the efficacy of the antiseptics.

The second hypothesis studied was the effect of the antiseptics on bacteremia, which was confirmed by the presence of a positive blood culture and the presence of symptoms. The literature relates that the rates vary from .15 to 3.9/1000 catheter days (Saad, 1999). Four bacteremic episodes occurred in this study, 2 proven and 2 possible (.36/1000 catheter days). The source of bacteremia is unknown; however the possible routes of catheter contamination have been discussed extensively in the literature (Sitges-Serra et al., 1995). In long term dialysis catheters, it has been suggested that contamination may occur as a result of frequent manipulations of the catheter hub allowing microorganisms to migrate from the hub to the catheter tip via the endolumen of the catheter. Catheter brushings or aspirate from the lumen of the catheter could provide information concerning the microorganisms that potentially cause catheter colonization, the time in which colonization occurs, and the resulting catheter-related infection (Koch et al., 2002). Though only 13 catheter brushings were performed, one brushing did grow Coagulase-negative Staphylococcus. This patient did not develop a bacteremia. Contamination of the catheter may have come from another source.

The third hypothesis studied was that skin colonization would be reduced by the skin and hub antiseptic, Amuchina. One hundred and eleven (91.7%) of the 121 patients had colonization of the skin surrounding the exit sites. It was interesting to note that although the incidence of skin colonization was high, only 10 exit site infections were observed. Of the 10 exit site infections, all had colonization of the skin surface. The microorganism primarily responsible for

colonizing the skin surface was *Coagulase-negative Staphylococcus* in all 10 patients. Miller and O'Grady (2003) related that the pooled data from 1992 to 1999 indicate that *Coagulase-negative Staphlococcus* are now the most frequent causes of blood stream infections in hospitalized patients with CVCs. Of the 4 patients who were described as having bacteremia in this study, one grew *Citrobacter Freundii* in 3 of 3 vials and grew *Coagulase-negative Staphylococci* in 3 skin swabs and *Stapylococcus Aureus* on 1 skin swab. The episode of bacteremia occurred at the end of the 3-month study period. The patient was treated with antibiotics. The second patient who developed symptoms and an elevated white blood cell (WBC) grew *Coagulase-negative Staphylococcus* on skin swabs but nothing on blood culture. This episode of infection occurred in the first two weeks post catheter insertion. The patient received prophylactic antibiotics at catheter insertion. There was no evidence for the source of infection being anything other than the catheter. The catheter was therefore replaced and the patient received Cefazolin followed by Vancomycin as the second catheter may also have become infected based on the presence of symptoms and an elevated WBC. A third patient grew *Coagulase-negative Staphylococcus* at one month, no growth at 2 months, and then Streptococcus species at the beginning of the third month when the symptoms of infection developed including an elevated temperature, chills, generalized feeling of being unwell. This patient was treated with antibiotics even though there was no growth on blood culture. The fourth patient grew *Staphylococcus aureus* on blood culture and was symptomatic 9 days

post catheter insertion. This patient was not given prophylactic antibiotics at catheter insertion but was treated with Gentamicin for the bacteremia.

Factors Affecting Catheter-Related Infections

It is well documented in the literature that infection is a frequent occurrence in patients with ESRD receiving hemodialysis (Marr et al., 1997). Powe, Jaar, Furth, Hermann, and Briggs (1999) studied a longitudinal cohort over seven years from hospitalization and death records; 11.7% of 4,005 hemodialysis patients and 9.4% of 913 peritoneal dialysis patients were found to have at least one episode of septicemia. Older age and diabetes were identified as independent risk factors in all patients. Among the hemodialysis patients, low serum albumin was also associated with increased risk. Traniover, Carlton, Saddekni, Hamrick, Oser, Westfall, and Allon (2000) reported in their study comparing two treatment strategies for bacteremia associated with tunneled dialysis catheters that patients with hypoalbuminemia were at increased risk of infection. Serum albumin is reported to be a good predictor of morbidity and mortality (Wells, 2003). Malnutrition increases as renal failure progresses. It is the outcome of inadequate dietary protein, calories, minerals, vitamins, trace elements, and other substances such as L-carnitine. In this study, the albumin levels were between 19 and 45 g/L, with a mean of 31.69 g/L. Normal serum albumin ranges from 30-50 g/L. It is evident that the patients were in the low normal range and therefore could potentially be at risk for increased infection. Of the10 patients who did develop exit site infections, 6 were diabetics, 3 were hypertensive, and one patient had multiple myeloma. Six patients were between 72 and 77 years of age, one patient

was 50 years, one was 60 years, and one was 83 years of age. The diagnosis of diabetes and older age did not have any bearing on incidence of infection in this study.

Ten of 121 patients in the study were receiving immunosuppressive therapy for various organ transplants; 7 in the Chlorhexidine group and 3 in the Amuchina group. None of the 10 patients who did develop exit site infections were taking immunosuppressive medications, but one patient who did develop an exit site infection was in ESRD secondary to multiple myeloma. There was no statistically significant difference between the groups taking or those who were not taking immunosuppressive medications in relation to the development of infection. This result was similar to the findings reported by Mokrzycki, Schroppel, Von Gersdorff, Rush, Zdunek, and Feingold (2000). Their retrospective cohort study compared 58 Human Immunodeficiiency Virus (HIV+) patients to 60 low-HIV risk control patients with tunneled, cuffed catheters for 28, 146 catheter days. They found no significant differences between groups being assessed for bacteremia rates and exit site infections. The spectrum of organisms however, was significantly different between the two groups. HIV+ patients were reported to be five times more likely to be infected with a Gram positive microorganism and seven times more likely to be infected with a fungal isolate although the results were not significant. In contrast, hemodialysis vascular access infection rates have also been reported by Marr, Sexton, Conlon, Corey, Schwab, and Kirkland (1997) to be higher in immunocompromised states, such as malignancy and during the use of immunosuppressive medications.

The literature is conflicting regarding the use of prophylactic antibiotic coverage during insertion of central venous catheters. Both the Kidney Foundation DOQI Guidelines (1997) and the Canadian Guidelines (1999) do not support the use of prophylactic antibiotics. In this study there was no statistical difference between the 78 (65%) patients who received antibiotics at the time of catheter insertion and those who did not receive antibiotics in relation to catheter-related infections. Mokrzycki et al. (2000) reported that the use of prophylactic antibiotics significantly lowered the rates in exit site infections. In another study by Mavromatidis, Kontodemou, Tsoulfa, Tsorlini, and Sombolos (1999), where 110 patients were randomized into four groups: Group A (n=35) received Vancomycin during the first treatment following insertion of the CVC; Group A1 (n=31) did not receive antibiotics; Group B (n=24) received Vancomycin during the first treatment and thereafter every 6 days; and Group B1 (n=21) did not receive antibiotics. At the completion of the study, 59 (53.6%) catheter tips were colonized, 37 (33.6%) exit site infections, and 19 (17.2%) catheter-related infections were recorded. The administration of Vancomycin did not demonstrate a reduction in catheter colonization, exit site infections, or bacteremias. It was therefore recommended by the study investigators that administration of prophylactic antibiotics be restricted to specific groups of patients such as those taking immunosuppressants, diabetics, and patients with cancer.

Limitations of the Study

Several limitations of this study warrant review. First, all patients who participated in this study provided a good representation of patients found in hemodialysis units in Canada (CORR, 2000). The limitation is that the power required to demonstrate a significant difference between groups was limited by the size of the sample. Second, the study time was limited to 3 months per patient and/or the presence of an infection. Many infections occur within the first year. A longer study may have demonstrated other results. Third, adherence to the study protocol proved to be a challenge. More than 90 nurses from various satellite units and 121 patients were involved in the study. Though the patients all initiated dialysis in the Incenter Dialysis Unit, over time they were transferred to satellite units. Monitoring was difficult, especially as a large number of patients were tracked by long distance communication. Staff turnover and staff-patient ratio may also have influenced consistency with the protocol. Further, staff were not blinded to the treatment solutions due to their distinctive odors. Fourth, the recorded observations were subjective. Despite orientation of more than 90 nurses to the study protocol, assessment of the symptoms of infection was variable. Last, though polysporin ointment was used consistently on all study subjects as was required by the program, the study would have been cleaner without the influence of this variable if the ointment had not been used.

Conclusion

Infection is a well-documented complication of tunneled, cuffed CVCs. Many strategies have been studied in an effort to reduce the incidence of infection

including the antiseptics used to clean the catheter and skin surface around the catheter. The incidence of bacteremia in this study is too small to draw any valid conclusions, however some interesting observations were made: the use of prophylactic antibiotics did not appear to have any bearing on the subsequent development of bacteremia; it is difficult to correlate the presence of skin colonization with an exit site infection, as there was a high incidence of colonization but only 10 patients who actually developed exit site infections; the microorganisms in blood culture were not the same as those identified by skin swab, therefore the source of infection may have been from another site, such as by manipulation of the hub and the endoluminal pathway; signs and symptoms of infection did not correlate well with the actual presence of infection; frequently, the sites were documented as being reddened yet there was no growth by culture. In conclusion, Amuchina 10% was comparable to Chlorhexidine 0.5 with 70% alcohol for the incidence of catheter-related infections. However, Amuchina is less costly and has less catheter-associated damage such as catheter cracking. Thus, it would be beneficial to dialysis patients to further study Amuchina as an alternative to Chlorhexidine.

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Appendix A

Information Sheet

Project Title: Infection Rates in Tunneled Hemodialysis Central Venous Catheters:
A Comparison Between Chlorhexidine and Amuchina

Principal Investigator: Colleen M. Astle, RN MN Candidate
5B1.14, WC McKenzie Center
University of Alberta
Phone: 407-1346

Thesis Supervisor: Dr. L. Jensen, Professor
Faculty of Nursing
4-112D Clinical Sciences Building
University of Alberta
Phone: 780-492-6795

Purpose of the Study: Dialysis is a treatment when your kidneys have stopped working. It will replace the work normally done by your own kidneys such as cleaning the blood of wastes and extra fluids. Dialysis is done through a catheter in a large vein in your chest. The catheter is cared for by cleaning around it at the beginning of each treatment. The reason for this study is to compare what is used now with a new cleaning solution.

Study Procedures: If you agree to take part in the study, you will be randomly selected for one of two groups. This is like flipping a coin so you have an equal chance of being in either group. One group will use the usual cleaning solution Chlorhexidine. The other group will use the solution Exsept 10% ®. The study will take place for 3 months. During that time regular dialysis blood work will be done and you will be watched for any signs of infection.

Risks: Although both these products are reported to be safe, there is a small risk of a skin rash.

Benefits: You may not benefit from this study at this time. The information gained in doing the study may help improve patient care in the future. Choosing the better skin and catheter cleaning solution will help decrease skin and catheter infections.

Voluntary participation: Taking part in the study is voluntary. Deciding not to take part will not affect the care you receive. If you decide to stop after the study has begun your care will not be affected. If you do not want to be part of the study, tell your dialysis nurse and she will let the researcher know.

Compensation: There will be no cost for taking part in the study. You will not be charged for using either cleaning solution or for any of the procedures related to

this study. The nurses, doctors, and hospital will still be responsible for your care even though you have agreed to take part in the study.

Confidentiality: All study information will be kept in a secure locked cabinet. Your name will not be used. In this study only a code number will appear on the data collection sheet. Your chart will be used to collect information for this study. If you have any questions about this study you may call the researcher at 407-1346. If you have any concerns about any part of this study, you may contact the Capital Health Authority patient care representative at 407-1040. This office has no association with the study or its investigators.

APPENDIX B

CONSENT FORM

Title of Project: Infection Rates in Tunneled Hemodialysis Central Venous Catheters:
A Comparison Between Chlorhexidine and Amuchina

Principal Investigator(s): Colleen M. Astle RN, MN Candidate
Phone: 780-407-1346
Thesis Supervisor: Dr. L. Jensen, Faculty of Nursing
Phone: 780-492-6795

Part 2 (to be completed by the research subject):

Do you understand that you have been asked to be in a research study?	Yes	No
Have you read and received a copy of the attached Information Sheet?	Yes	No
Do you understand the benefits and risks involved in taking part in this research study?	Yes	No
Have you had an opportunity to ask questions and discuss this study?	Yes	No
Do you understand that you are free to refuse to participate or withdraw from the study at any time? You do not have to give a reason and it will not affect your care.	Yes	No
Has the issue of confidentiality been explained to you? Do you understand who will have access to your records?	Yes	No

This study was explained to me by: _____

I agree to take part in this study.

_____ _____
Signature of Participant Date

_____
Printed Name

I believe that the person signing this form understands what is involved in the study and voluntarily agrees to participate.

_____ _____
Signature of Investigator or Designee Date

APPENDIX C

Patient Demographic and Relevant Central Venous Catheter Information

Study Identification Number: _____

Age: _____

Gender: Male:_____ Female:_____

Cause of Renal Failure:
1. Diabetic Nephropathy _____
2. Hypertension _____
3. Renal Vascular Dx _____
4. Glomerulonephritis _____
5. Unknown _____
6. Other _____

Height/Weight: _____cm _____kg BMI:_____

Albumin level: _____

MRSA: Pos:_____ Neg:_____

Immunosuppression: Yes:_____ No:_____

Date of Insertion: _____

CVC Site: Rt:_____ Lt:_____

Location: ICHD:___ X-Ray:___ OR:___

APPENDIX D

DATA COLLECTION
DURING EACH DRESSING CHANGE

DATE: _____ STUDY ID: _____

DRESSING CHANGE # _____

EXIT SITE: NEGATIVE:_____

POSITIVE: _____ DISCHARGE _____

TENDERNESS _____

ERYTHEMA ≥ 2cm _____

SWABS: NEG: _____

POS: _____ MICROORGANISMS:_____

BACTEREMIA: NEGATIVE: _____

POSITIVE: _____

SWAB: NEGATIVE: _____

POSITIVE: _____

CULTURES: NEGATIVE: _____

POSITIVE: _____

MICROORGANISM: _____

COLONIZATION: SWAB: NEGATIVE: _____

POSITIVE: _____ CFU: _____

BRUSHINGS: NEGATIVE: _____

POSITIVE: _____ CFU:_____

CATHETER TIP: NEGATIVE: _____

POSITIVE: _____ CFU:_____

Appendix E

Capital Health
Referral Hospital System
University of Alberta Hospital Site
Procedure Page 1 of 2

Title: Dressing Change for Central Venous Catheter

Number:2.2.2.2

Issue Date: May 15, 2000-05-15 Level: Departmental

Introduction
The dressing is normally changed predialysis and left intact between dialysis for non-tunneled and tunnelled central venous catheters.

Supplies: Hemodialysis tray:
3 towels and 1 fenestrated towel (2 only if not using tray for dialysis)
tray with compartments
2 plastic kelly forceps (not needed if not commencing dialysis)
12 – 4x4 guazes (less if not commencing dialysis)
1 package of Chlorhexidine / Amuchina (Exsept 10%) solution

Others: 1 non-occlusive dressing
mask
sterile gloves

1.0 Mask for patient and nurse.

2.0 Loosen and remove dressing while holding the catheter securely.

3.0 Wash hands.

4.0 Observe exit site for signs of infection, sutures integrity and catheter integrity.

5.0 Take swab of exit site prior to cleansing if there are signs of inflammation/infection.

6.0 Open "dressing tray".

7.0 Use forceps on outer wrap of dressing tray to pick up a 4x4 gauze and place beside the tray.

8.0 Add non-occlusive dressing on the tray.

9.0 Glove.

10.0 Pour Chlorhexidine/ Exsept solution into one compartment of the tray.

Procedure: 2.2.2.2 (Continued) Dressing change for central venous catheter Page 2 of 2

11.0 While holding a catheter with 4x4 gauze, position towels above and below catheter area, while leaving the exit site exposed for cleaning.

12.0 While still holding a catheter with 4x4 gauze, cleanse skin area immediately around catheter exit site with a Chlorhexidine/ExSept soaked 4x4 in a circular motion.

13.0 Using a second Chlorhexidine/ExSept 4x4, cleanse skin in increasingly bigger circle to include area that will be covered by dressing.

14.0 Soak 4x4 gauze in antiseptic solution and wrap around the catheter at the exit site without contaminating the gloves.

15.0 Wrap the catheter with a Chlorhexidine/ExSept soaked 4x4 for specified time of 1 min.

16.0 While holding the wrapped catheter, removed Chlorhexidine/ExSept soaked 4x4 on exit site.

17.0 Allow antiseptic to air dry completely on exit site and skin area.

18.0 Centering catheter exit site, apply a non-occlusive dressing to cover exit site and the catheter, exposing only the catheter extensions.

(a) Wrap catheter extensions with 4x4 gauze and tape in place
or

If catheter needs to be opened for dialysis or withdrawal of blood:

(b) Lay the fenestrated towel below the Chlorhexidine/ExSept wrapped catheter.

19.0 Proceed with dialysis procedure or withdrawal of blood procedure.

APPENDIX F

Capital Health
Referral Hospital System
University of Alberta Hospital Site **Procedure** Page 1 of 4

Title: Initiating Dialysis with Central Venous Catheter Number: 2.2.2.6

Issue Date: November 25, 1997 Level: Departmental

SUPPLIES: Hemodilaysis tray:
- 3 towels and 1 fenestrated towel
- tray with compartments
- 2 plastic kelly forceps
- 12 – 4x4 gauzes
- 1 package of Chlorhexidine/Amuchina (ExSept) solution
- 50% Amuchina for hubs cleansing only
- 1 transfer forceps

2 – 10 ml syringes
2 –3 ml syringes
1 non-occlusive dressing (mepore)
bridging tapes
masks
gloves

For blood sample add:
- Vacutainer & leur adaptor OR syringe & 18 gauge needle
- Blood tubes
- 1 extra package of 4x4

1.0 Masks for patient and nurse.

2.0 Wash hands.

3.0 Loosen and remove dressing and bridging tapes while holding the catheter securely.

4.0 Observe exit site for signs of infection, suture' integrity and catheter integrity.

5.0 Take swab of exit site prior to cleansing if there are signs of inflammation/infection.

6.0 Open hemodilaysis tray.

7.0 Use transfer forceps on outer wrap of dressing tray to pick up towels, antiseptic solution, kelly forceps and a 4x4 gauze and place beside the tray.

8.0 Add syringes, and non-occlusive dressing on the tray.

9.0 Using I.V. saline from dialyzer setup, run some saline into a compartment of the tray.

10.0 Glove.

11.0 Fill 2 – 10 ml syringes with normal saline from saline compartment.

PROCEDURE: (Continued) Initiating Dialysis with Central Venous Catheter

12.0 Pour antiseptic solution into the second compartment of the tray.

13.0 Soak 5 – 4x4 gauzes in antiseptic solution.

14.0 Dressing change and cleansing catheter.

13.1 While holding a catheter with a 4x4 gauze, position towels above and below catheter area, leaving the exit site exposed for cleaning.

13.2 Wrap entire length of the catheter with 1-2 antiseptic soaked 4x4, for 1 minute

13.3 In the Amuchina randomized group, add Amuchina 50% for cleansing and soaking the hub x 1 minute.

13.4 Cleanse skin area immediately around catheter exit site with a antiseptic soaked 4x4 in a circular motion once.

13.5 Using a second antiseptic 4x4, cleanse skin in increasingly bigger circle to include area that will be covered by dressing.

13.6 Using another Chlorhexidine or ExSept soaked 4x4, wrap around the catheter at the exit site without contaminating the gloves.

13.7 While holding the wrapped catheter, remove antiseptic soaked 4x4 on exit site.

13.8 Allow antiseptic to air dry completely on exit site and skin area.

13.9 Centering catheter exit site, apply a non-occlusive dressing to cover exit site and the catheter, exposing only the catheter extensions.

14.0 Initiating dialysis:

14.1 While holding the wrapped catheter, lay the fenestrated towel underneath the antiseptic wrapped catheter.

14.2 Remove antiseptic soaked 4x4 on catheter.

14.3 With catheter clamp closed, remove and discard caps.

14.4 Attach a 3 ml syringe to each catheter extension.

14.5 Withdraw 3 ml from each unclamped extension of the catheter.

14.6 Clamp both extensions.

14.7 Discard the withdrawal blood onto a 4x4 gauze to check for clots.

14.8 Attach a saline filled syringe to arterial extension.

14.9 If drawing blood work is required.

14.91 Using a sterile 4x4 to hold onto vacutainer, remove the cap on the luer adaptor with another sterile 4x4.

14.9.2 Attach vacutainer to venous extension and unclamp venous extension.

14.9.3 Use a 4x4 to insert blood tube in vacutainer to collect blood sample.

14.9.4 Clamp venous extension and remove the vacutainer with attached luer adapter and put outside sterile field.

OR

15.0.1 Use a syringe to withdraw the required amount of blood.

15.0.2 Attach an 18 gauge needle to the syringe.

15.0.3 Using a sterile 4x4 to hold on to the blood tubes, inject blood into the blood tubes.

15.0.4 Put blood tubes outside the sterile field.

15.10 Attach a saline filled 10 ml syringe to venous extension.

15.11 Unclamp and flush each extension alternately with 10 ml normal saline and clamp while instilling to remove all traces of blood.

15.12 Using a 4x4 to turn off the blood pump and clamp normal saline.

15.13 Clamp the arterial and venous bloodline with the sterile kelly forceps.

15.14 Using 2 sterile 4x4, disconnect arterial line from priming connector.

15.15 Attach arterial line to the arterial extension of the catheter.

15.16 Open catheter clamp and remove arterial clamp.

15.17 Using sterile 4x4's, disconnect priming connection from venous line.

15.18 Attach venous line to venous extension of catheter.

Note: Ensure that there is no air present in venous extension of catheter or blood line.

15.19 Apply bridging tapes on both catheter luer-lock connections.

15.20 Open catheter clamp and remove venous clamp.

15.21 Turn on blood pump at 100 ml/min,

15.22 As blood reaches heparin line, give heparin bolus from heparin infusion pump.

15.23 Increased pump speed to prescribed setting.

15.24 Wrap luer lock connections with 4x4 and secure to patient.

15.25 To obtain PT, PTT, or baseline ACT:

15.25.1 Wait until blood enters the dialyzer. DO NOT give heparin bolus until after sample obtained.
For Integra: Turn off HEPARIN program before going to PAT CONNECT.
For Monitrol: Turn heparin pump off BSM 21/22.

15.25.2 Swab arterial port of arterial blood line with betadine swab.

15.25.3 Insert vacutainer with needle into arterial port of blood line and collect sample (for PT or PTT) OR
For baseline ACT: insert 20 g needle with 1.0 syringe and aspirate 0.4 ml of blood.

15.25.4 Give heparin bolus. For Integra: Turn on Heparin program.
For BSM 21/22: Turn on Heparin pump.

APPENDIX G

Capital Health
Referral Hospital System
University of Alberta Hospital Site **Procedure**

Title: Skin Swab of Central Venous Catheter Exit Site **Number: 2.2.2.**

Issue Date: August 11, 2002 **Level: Departmental**

Supplies: 5 cm x 5cm skin template
Sterile cotton tipped swab

1.0 Loosen and remove central venous catheter site dressing.

2.0 Observe for a) signs of infection/inflammation:

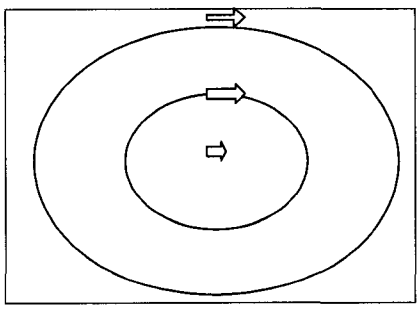
redness > 2.0 cm from insertion site
tenderness
discharge
edema

for b) signs of skin irritation:

reddened area covering the area where skin had previously been cleansed with antiseptic, approximately 5 cm x 5cm

for c) skin integrity and suture integrity.

3.0 Take swab of exit site prior to cleansing, if there are signs of inflammation/infection, using the following pattern for swabbing.
3a. Starting and ending at the 12 o'clock position swab in a clockwise pattern. Swab immediately at the exit site and in two larger circles to include the 5 x 5 cm area.



4.0 Continue with initiating the dialysis procedure.