

Vanguard Multi-Centre Feasibility Trial to Determine if Buttonhole Versus Step-Ladder Cannulation for Home Hemodialysis is Associated with Reduced Overall Cost

Primary Objectives: To determine the feasibility of 1) randomizing patients to step-ladder versus buttonhole cannulation techniques, and 2) coordinating the multiple Canadian sites that are required for the definitive study.

Secondary Objectives: To determine 1) if buttonhole cannulation, compared to step-ladder cannulation is associated with reduced training time for home hemodialysis patients, 2) if buttonhole cannulation, compared to step-ladder cannulation is associated with reduced overall cost, 3) if buttonhole cannulation, compared to step-ladder cannulation is associated with reduced complications (infection – local and systemic, radiologic/surgical interventions, re-trains for needle insertion difficulties, hematoma formation, aneurysm formation, missed insertions), 4) if buttonhole cannulation, compared to step-ladder cannulation is associated with reduced patient discomfort with needling for intensive home hemodialysis patients, and 5) to describe the overall patient population to help explain recruitment challenges

Background

High Dose Hemodialysis

Patients treated for end stage renal disease (ESRD) with conventional hemodialysis have a shorter life expectancy and a poorer quality of life than the general population¹. The intermittent nature of CHD has been hypothesized to contribute to the poor outcomes. In an attempt to reduce morbidity and mortality for this patient population, a few novel therapeutic approaches have been undertaken. As an alternative to CHD, there are an increasing number of patients being treated with daily, or high dose hemodialysis. With short daily hemodialysis, the frequency of dialysis is increased but the overall weekly dialysis time is usually equivalent to conventional hemodialysis (~12 hours). With nocturnal or extended hours hemodialysis, both the frequency and time with which patients undergo dialysis is usually increased. Compared to conventional hemodialysis, high dose hemodialysis has been shown to enhance clearance of urea, β 2-microglobulin,² and phosphate.³⁻⁶ Some patients are able to discontinue fluid, sodium, and phosphate restrictions (including phosphate binders). The cardiovascular benefits of high dose include better control of blood pressure,^{7,8} with most patients no longer requiring anti-hypertensive medication, regression of left-ventricular hypertrophy,^{4,6,9-11} increased ejection fraction,¹² and an improved lipid profile.¹³ In many patients, anemia improves and erythropoietin requirements decrease.¹⁴ Many patients feel better, have a significantly improved quality of life, and some return to work.¹ In addition, high dose hemodialysis has been shown to reduce overall cost in North American economic systems.^{15,16}

Vascular Access in Intensive Dialysis

In spite of all of the potential benefits associated with home hemodialysis, there are significant concerns about vascular access complications. The increased frequency of dialysis access use may have differential effects depending on access type. For patients

who use a central venous catheter (CVC), the increased frequency of opening the CVC in order to connect the access to the bloodlines of the hemodialysis circuit may result in an increased risk of infection, air embolism or hemorrhage. In spite of this theoretical risk, a study of 33 patients pre/post conversion from conventional hemodialysis to nocturnal hemodialysis did not demonstrate an increased risk of infection.¹⁷ For patients with an arteriovenous fistula (AVF) or arteriovenous graft (AVG), the increased frequency of placing needles in the access may be associated with an increased risk of hematoma formation from missed needle sticks, aneurysms, infections and patient discomfort. This is supported by one systematic review of the literature in which the use of an AVF for more frequent dialysis appears to be associated with an increased risk of complications.¹⁸

Buttonhole versus Stepladder Cannulation of an AVF

In conventional hemodialysis, the AVF is recommended as the access of choice for hemodialysis secondary to a lower complication rate than CVCs and AVGs. However, the AVF may be associated with greater challenges for needling because of short segments of useable access or deeper location in the subcutaneous tissue of the arm than an AVG. There is also pain associated with placing the needles (compared to CVC use) that may have a negative impact on quality of life.

The insertion of needles into an AVF has traditionally been via the step ladder or continuous site rotation technique. However, the buttonhole method was introduced in the 1970's in an attempt to address some of the challenging issues associated with AVF accesses.¹⁹ In the buttonhole technique, a constant site is used for needle placement that ultimately results in a fibrous tract. Once the tract has formed blunt needles can be used instead of sharp needles for each treatment. The presence of a tract may simplify the needle insertion technique and lead to enhanced patient confidence with needle placement. Although no studies have reported training times in association with needle insertion technique, Pipkin et al have demonstrated a mean reduction in training time for home hemodialysis patients of 5 days when a central venous catheter was used for an access compared to an AVF.²⁰ It is reasonable to assume that well established buttonholes may also lead to a similar reduction in training times. Other reported benefits of buttonhole cannulation include less painful needling,²¹⁻²⁴ fewer needle infiltrations,^{19,24,25} fewer interventions²⁶ and a reduction in aneurysm size.²³ While earlier studies demonstrated a reduction in pain with buttonhole needling, more recent studies show either no reduction in pain,^{27,28} or even an increase in pain.²⁶ However, the effect of frequency of use on the maintenance of the buttonhole and the perception of pain has not been explored. Importantly however, there has also been increasing concern about the potential for an increased risk of infection using the buttonhole cannulation technique with estimates of *Staphylococcus aureus* (*S. aureus*) bacteremia for patients receiving high dose dialysis between 0.15 to 0.60 episodes per 1000 patient-days across 4 studies.²⁹⁻³² In an indirect comparison between high dose home hemodialysis with buttonhole cannulation versus in-centre conventional hemodialysis with rope-ladder cannulation, the relative risk for bacteremia ranged between 30 to 120. Importantly, *S. aureus* bacteremia was associated with devastating consequences, including septic arthritis, septic pulmonary emboli, vertebral osteomyelitis, and death in a single centre's experience.³³ In one small study, the risk of infection associated with buttonhole

cannulation was prevented by the application of topical mupirocin at the buttonhole sites post hemodialysis.

Differences between Conventional In-Centre and Home Hemodialysis

Although ease of cannulation is important in-centre, it is even more important for patients at home. It is unclear if the potential ease of use of buttonhole cannulation might lead to enhanced home hemodialysis recruitment rates and reduced training time. The ease of use of CVCs likely contributed to the decreased training time that was required for patients with this type of access in the Frequent Hemodialysis Network Trial. There is emerging controversy about reduced pain on needle insertion with buttonhole cannulation in centre. However, it is unclear if using the buttonholes more frequently might result in reduced cannulation pain secondary to 'enhanced' maintenance of the fibrous tract. Lastly, for patients who are treated in-centre, needles are typically inserted by skilled allied health team members. At home, needles are inserted by the patient or a family member helper who must be trained to perform home hemodialysis. It is unclear if allied health team members are more likely to follow strict rules for cleanliness compared to patients at home such that infection risks might be less in-centre. Also, the enhanced frequency of use of the buttonholes for high dose hemodialysis might be associated with an increased risk of infection.

Summary and Conclusions

There is increasing interest in high dose home hemodialysis therapies. Although both needle cannulation techniques have been used for home hemodialysis, the relative benefits and risks of the two techniques have never been explored in a randomized controlled trial. The potential advantages of buttonhole cannulation for this patient population may be enhanced recruitment, reduced training time, reduced aneurysm formation and a reduced number of interventions. The reduction in training time may result in significant savings to the hospitals in which reimbursed training days are fixed. The benefits may be offset by the potential for an increased risk of infection. However, the potential benefits and risks of buttonhole cannulation versus step-ladder cannulation remain speculative as they have not been studied in a rigorous prospective trial of home hemodialysis patients treated with high dose hemodialysis.

Study Design: The proposed 12 month vanguard study will be a randomized controlled trial of patients training for home hemodialysis. The primary outcome for the proposed study is feasibility to recruit to the two different needle cannulation arms and coordination of the study centres. Additionally, demographic data will be retrospectively collected on patients who trained to do home hemodialysis, but were not eligible for the study to help explain recruitment challenges.

Patient Population:

Inclusion Criteria

The following inclusion criteria will be used: 1. Adult patients > 18 years old, 2. Training for home hemodialysis using self cannulation, 3. Returning to train to use an AVF (i.e. went home using a CVC or another access that has failed), 4. Able to give informed

consent, 5. Arteriovenous fistula (patients with segments of grafts that are not at the sites of needle insertion may be included), and 6. Life expectancy of greater than 12 months

Exclusion Criteria

The following exclusion criteria will be used: 1. Potential to be lost from the program within 12 months of training (planned living donor transplant, transfer to PD or move from training centre catchment area), 2. Short segments or aneurysms within the AVF that the attending nephrologist believes require buttonhole cannulation, 3. Mechanical heart valves, 4. Patients who require intradermal lidocaine for needle insertion

Study Overview

After obtaining informed consent, basic demographic data will be collected including age, sex, cause of end stage renal disease, arteriovenous access history [date of creation, previous interventions (angioplasties, surgical revisions), previous infections] and comorbidity information to calculate the Charlson comorbidity index. Demographic data will also be retrospectively collected on patients who were training for home hemodialysis but were not eligible to participate in the study.

All eligible patients will be randomized to either step ladder or buttonhole cannulation technique for needle insertion. Randomization will be determined via a computer generated randomization code with stratification by site and AVF type (incident vs. prevalent). The group assignment will be kept in sealed opaque envelopes and provided to sites via the coordinating centre at the time of study consent. Only the investigators will be aware of the training time as an objective of the study as the intervention cannot be blinded and the outcome is potentially influenced by factors other than needle insertion technique. For consent and the remainder of the health team; the purpose of the study will be to determine feasibility, infection rates and other complications associated with the two different needle insertion techniques. Each Research Ethics Board will need to approve that one of the study objectives will be concealed.

Data collection forms will be developed with the assistance of the Ottawa Hospital Methods Centre and pilot tested at 2 sites (Ottawa and University Health Network) prior to the creation of an electronic data capture form to be used by all participating sites. The amount of time required to consent patients, complete the case report forms and follow each patient for the complication outcomes will be documented at these two sites so that this data can be used to inform the definitive trial budget.

After ensuring that the case report forms and access documentation tool are useable and all necessary information is being collected, the remaining programs will begin to recruit patients. Each program will be responsible for keeping a log of all patients who are training for home hemodialysis and the proportion of patients who are candidates for the study. Of the patients that are candidates for the study, the number of patients who are randomized to the study will be tracked. Reasons for not participating in the study for all potential candidates will be documented and reviewed at quarterly meetings. If themes are identified that are limiting enrollment, solutions will be proposed by the investigators and implemented if possible.

Needle Insertion Techniques

Step ladder insertion technique: The AVF site will be cleaned with 2% chlorhexidine/alcohol 70% prior to needle insertion. If the patient develops contact dermatitis, the AVF site will be cleansed with 2% cholorhexidine, 70% alcohol, povidone iodine or antibacterial soap alone. Sites will be rotated with needles placed at least 2-3cms between needle tips.

Buttonhole insertion technique: The AVF site will be cleaned as above except cleansing will occur before and after buttonhole scab removal. A minimum of 2 buttonholes will be developed for patients undergoing double needle hemodialysis (1 for single needle) by a nurse or patient (at the discretion of the health care team) trained in the technique.

Buttonhole sites will be created at a 20-30 degree angle at least 3 cm from the arterial or venous anastomosis. Once the buttonhole is established with sharp needles, blunt needles will be used. At this time, the patient will be instructed on needle insertion technique if they were not taught to develop the buttonholes initially. Scabs will be removed from the buttonholes either with an alcohol or saline soaked gauze; the use of needles or tweezers to remove scabs will be discouraged.. Post hemodialysis, mupirocin (or other suitable antimicrobial cream if patient develops contact dermatitis/allergy, for example: polysporin, betadine ointment or PHMB antimicrobial dressings) will be applied to the buttonhole sites to reduce the risk of infection.

Time to Train

Patients will be trained according to usual home dialysis unit policies with the exception of the needle insertion protocol. Any difficulties with training needle insertion will be documented by the nurse educator. The time required to teach proficiency in self cannulation will be documented (the number of days required for the patient to competently place their own needles without the assistance of the dialysis nurse). Total training time will be the numbers of days required from start of training to discharge to home. Any missed days secondary to statutory holidays, appointments or other illness unrelated to access needle insertion technique will not be included in the training days calculation. If a patient has to return to the home dialysis unit to develop a new buttonhole site, the training time will also be documented and added to the total training time.

AVF Access Complications

The home hemodialysis run sheet will be modified so that the patient can record any instances of hematoma formation (obvious bruising at the arteriovenous site that occurs at the time of needle insertion or withdrawal) or missed needle sticks (unable to use the needle for dialysis). For buttonhole cannulation, the need to use a sharp needle instead of the usual blunt needle will be considered a missed needle stick even if a separate needle insertion site is not required. Patients will be instructed to come to the home dialysis unit if they notice any localized signs of infection over the AVF including heat, erythema, purulent drainage or induration. A swab will be sent for gram stain, culture and sensitivity; infection will be diagnosed if neutrophils are present with cultured bacteria. Additionally patients will be asked to contact the unit and present themselves to the nearest emergency department if they develop fever, chills and/or hypotension with the hemodialysis treatment. An access related bacteremia will be defined using CDC criteria

(at least one of the following: 1) Patient has a recognized pathogen cultured from one or more blood cultures and the pathogen is not related to an infection at another site or 2) patient has fever, chills, and/or hypotension as well as positive laboratory cultures from two or more blood samples drawn on separate occasions which are not related to infection at another site and do not reflect contamination). As the most common pathogen is *S. aureus*, all patients with *S. aureus* related bacteremia will be monitored for metastatic complications including an echocardiogram at the discretion of the treatment center. Access interventions including angioplasties and surgical revisions will be documented. The vascular access coordinator, or similarly trained individual, will document the presence of aneurysms at the start and completion of the study. A standardized tool for assessment of the number of aneurysms, size and potential risk of rupture (thinness of skin) will be developed with the assistance of skilled vascular access coordinators (access documentation tool).

Costs of Vascular Access

Any additional days of training and any days required for re-training will be included in the overall cost. Any differences in the cost of the blunt versus sharp needles and the mupirocin for buttonhole cannulation will be included in the overall cost. Treatment for infection including antibiotics and hospitalizations will be included and costed according to established principles. Similarly, the cost associated with any required angiogram (leading to an angioplasty), angioplasty or surgical revision will be included.

Visual Analogue Scale – Pain with Needling (Appendix 1)

All patients will continue (or start) with the step ladder insertion technique for the first 2 to 3 days at which time they will use the validated 10 cm visual analogue scale to rate the pain they experience with needle insertion. The visual analogue scale will be repeated at 2 additional time points – at the end of training and approximately 2 months after graduating home hemodialysis training. As many of the programs train 3 days per week, the additional time point is to capture the potential differences in perceived needling pain with increased frequency of needle insertion. It is unclear if buttonholes are easier to maintain when used more than 3 days per week as this may be associated with less pain on needle insertion. Topical anesthetics will not be withheld during assessments of pain with the visual analogue scale but the requirement for use will be documented.

Sample Size Calculation

There are a limited number of patients who start home HD each year in Canada. If we are unable to get at least 70% enrollment in the pilot study – it is very unlikely that we will be able to successfully undertake a study with a larger sample size. For the purposes of the feasibility pilot, the first 2 centres (Ottawa and University Health Network) will recruit participants for 18 months with the remaining centre's participating for 12 months. All patients who are eligible for the study will be approached for recruitment. Our goal is to demonstrate that we can successfully recruit. For the definitive study to explore the differences in training time between the two needle cannulation techniques: The mean number of training days for patients with an AVF in the FHN studies was 27.7 with a standard deviation of 10.4 (20). This was reduced by 5 days for patients using a central venous catheter. Assuming that a buttonhole cannulation would

have a similar impact on training time, 69 patients per groups would give us 80% power to detect this difference. The number required in the trial increases to 107 if the difference is 4 days.

Analysis

For the purposes of the pilot study, basic demographic characteristics of the included and excluded patients will be described using appropriate descriptive statistics. This data will be retrospectively collected on patients who were not enrolled in the study. The percent of qualified patients enrolled in the study for the pilot study to be successful will be $\geq 70\%$. The secondary outcomes will be analyzed on an intent to treat basis upon completion of the main study assuming that this trial is feasible. The comparison of mean training times will be done with an un-paired t-test. A linear regression analysis will also be undertaken to examine predictors of training time including age, sex and Charlson comorbidity score in addition to needle insertion technique. Any differences in pain scores depending of frequency of cannulation will be explored within cannulation techniques. If no differences exist by frequency of cannulation, the data will be combined and the median pain scores will be assessed with a Wilcoxon rank sum test. The different types of complications and costs will be categorized and the overall mean differences will be assessed with an unpaired t-test. Any differences in outcomes by frequency of cannulation will also be explored within each of the secondary outcomes.

For patients who return to train on cannulation technique (started home HD with a CVC or other access that failed); their data will not be included in overall training time but all other study outcomes will be tracked and included in the analysis infections and complications.

The retrospectively collected demographic data will be analyzed in order to describe the patient population.

Data Safety Monitoring Board

Drs. Hiremath and Ramsay in addition to Paula Fraser (vascular access coordinator) have agreed to monitor the outcomes of this study. If we detect infection rates that are comparable to or greater to the benchmark for central venous catheters as adopted by the Ottawa Hospital - the study will be stopped (external benchmark bacteremia rate of 4.6 per 100 patient months, Nephrology News and Issues 2005, 37-43)

Study Investigators

The definitive study will be part of the Canadian Intensive Hemodialysis Physician Group with representation from across Canada. The vanguard study will be collecting information from sites in Ottawa (Dr. Deborah Zimmerman), Toronto (Drs. Jihad Nesrallah, Philip McFarlane and Christopher Chan), Calgary (Dr. Jennifer MacRae) and Vancouver (Dr. Michael Copland). All investigators have experience in high dose hemodialysis and clinical investigation. Dr. McFarlane has additional experience in economic analysis and Dr. MacRae has just published a study of buttonhole versus stepladder cannulation in the in-centre conventional hemodialysis population. All

together, these sites train approximately 70 patients for high dose hemodialysis per year which will provide an adequate number of participants to ensure the success of this pilot study within the 2 years allotted for this grant. If no changes to the protocol are required, feasibility clearly established and sample size achievable, the pilot study data will be retained for the definitive trial.

Appendix 2

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