Pilot study: Preparation for a randomized trial comparing gauze dressings to no dressings for tunneled right atrial catheters (TRACs)

By Karin Olson, Shirley Gaudet and Robert Rennie

Abstract

The purpose of this pilot study was to prepare for a large randomized trial comparing a dressing and a no-dressing intervention for patients with tunneled right atrial catheters (TRACs). Twenty-four patients, some undergoing bone marrow transplants, were accrued. In the dressing group, four out of 11 participants developed sepsis, compared to three out of 13 in the no-dressing group.

Infection prevention is a central concern of cancer nurses. Infections occur due to several factors, each of which is necessary but not sufficient. These factors include a pathogenic organism, a reservoir in which the organism can grow, a mode of transmission, and a susceptible host. Measures to control infection can be grouped into one of three categories: Measures directed against the reservoir, measures that interrupt transmission of organisms, and measures that reduce host susceptibility (Mausner & Kramer, 1985). Cancer patients are particularly susceptible hosts for many reasons including their general state of health and the administration of medications such as steroids, antimetabolites, anti-cancer agents and radiotherapy, all of which impair the patient's immune system. The risk of infection is increased when TRACs are inserted to facilitate medical treatment, because they provide a point of entry for pathogens. It has been hypothesized that the dressing and/or the area beneath the dressing may act as a reservoir for pathogenic organisms.

The particular TRAC considered in this study is the Raaf TRAC manufactured by Quinton. It is inserted surgically into the external or internal jugular or cephalic vein. Prophylactic antibiotics are not ordered. The TRAC tip is positioned in the lower superior vena cava at the entrance to the right atrium. The distal end is tunneled under the skin for 10-15 cm and exits the body near the mid-line. The portion of

the TRAC surrounded by a dacron cuff is embedded in the tunnel, roughly 2 cm from the exit point. The cuff is thought to reduce infection by preventing transmission of organisms further into the body. The TRAC is secured with two sutures until the tissue surrounding the cuff has adhered to the cuff and the exit site is healed (about 14 days).

Literature review

Although a number of factors are thought to contribute to TRAC-related infections, this literature review will focus primarily on dressing type. Studies have shown that patients who have occlusive dressings covering their TRAC exit sites are more likely to develop exit site infections and septicemia than are patients who have gauze dressings covering their TRACs. This is particularly true if the dressings are left on for longer than 48-72 hours (Conly, Grieves & Peters, 1989; Dickerson, Horton, Smith & Rose, 1989; Callahan & Wesorick, 1987; Anderssen, Herlevesen & Schaumburg, 1986; Parsa, Lau, Jampayas, Tan, Sampath, Freeman, Fox & Ellis, 1985). McCredie, Lawson, Marts and Stern (1984) randomly assigned 365 oncology patients with newly inserted TRACs to either an occlusive dressing group or non-occlusive dressing group and concluded that there was no difference in infection rates between the two.

Petrosino, Becker and Christian (1988) randomly assigned 52 patients to one of four dressing groups (Op-site, Tegaderm, gauze and no dressing) and found that, while there were no significant differences in infection rates between the groups, there were fewer infections in the group with no dressing. Eisenberg, Howard and Gianino (1990) developed a complex cleansing and dressing method for use with occlusive dressings. Using this method, the rate of TRAC-related infections in their study was two per cent.

While the results of the above studies are difficult to compare, due to the differences in the definition of infection and sample populations, they suggest that TRAC-related infections and septicemia are related to both the care of the exit site and to the type of dressing used. The purpose of this pilot study is to prepare for a large randomized trial designed to extend the findings of Petrosino, Becker and Christian (1988) regarding the effect of a "no dressing" intervention on TRAC-related sepsis.

Objectives

The specific objectives of this pilot study were:

- 1) to estimate the rate of accrual,
- 2) to evaluate patient teaching materials,

ÉTUDE PILOTE - PRÉPARATION D'UN ESSAI RANDOMISÉ COMPARANT LES PANSEMENTS DE GAZE À L'ABSENCE DE PANSEMENTS POUR LES CATHÉTERS TUNNELISÉS DANS L'OREILLETTE DROITE

ABRÉGÉ

La présente étude pilote avait pour but de préparer un vaste essai randomisé comparant les pansements de gaze à l'absence de pansements pour les cathéters tunnellisés dans l'oreillette droite. Elle a porté sur vingt-quatre patients dont certains subissaient des greffes de moelle osseuse. Dans le groupe utilisant les pansements, 4 des 15 participants ont fait une septicémie alors que cette dernière touchait 3 des 13 participants du groupe sans pansements.

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- 3) to design patient tracking and data management systems,
- 4) to develop the training program for data collectors,
- 5) to obtain initial data regarding frequency of TRAC-related septicemia for patients with gauze dressing, or no dressing, over their exit site.

Definitions

Research in this area has been characterized by the lack of common definitions of exit site infection and TRAC-related sepsis. For the purposes of this study, an exit site infection was defined as that which produced a skin swab result of 2+ or greater (moderate growth of potential pathogenic organisms). TRAC-related septicemia was defined as a positive blood culture (same organism isolated from TRAC tip and peripheral blood sample in a patient who had an oral temperature of 38.5° C or greater, with no other apparent source of infection (Abraham & Mullen, 1982; Conly, Grieves & Peters, 1989).

Method

Sample

The population of interest consisted of adult cancer patients. Following ethical clearance, 24 patients (18 males and six females) from a cancer treatment centre in western Canada agreed to participate. Three of the males were bone marrow transplant (BMT) patients and 15 were non-BMT patients. Three of the females were BMT patients and three were non-BMT patients.

Design

This study was a prospective randomized trial, stratified for gender and bone marrow transplant status.

Data collection

All patients' TRACs were flushed with heparinized normal saline (10:1) weekly or following use and all participants received the same initial dressing care. Patients were instructed to wear a gauze dressing over their exit site until Day 21. Neutropenic patients (WBC below $1.5 \times 10^9/L$) changed their exit site dressing daily and non-neutropenic patients changed their exit site dressing every second day, using clean technique. All patients cleansed their exit sites when they changed their dressing, using betadine, followed by alcohol. On Day 14, exit site sutures were removed, an initial swab of an area 5 cm x 5 cm around the exit site was obtained, and an oral temperature was taken.

Consistency in the area swabbed was maintained by constructing a plastic template with an opening 5 cm x 5 cm, that could be autoclaved between uses. The template was placed around the exit site, with the TRAC in the centre of the open area. On Day 21, patients with negative test results on the Day 14 swab, and no positive blood cultures since insertion, were randomized to receive either a gauze dressing or no dressing over their exit site.

All patients experiencing any clinical signs of infection (temperature greater than 38.5° C, purulent drainage, tenderness 3 cm or more in its longest dimension around the exit site, or erythema 3 cm or more in its longest dimension) were examined by the study nurse or principal investigator and physician. Additional skin swabs, as described above, were taken at Day 44, Day 74 and, if drainage, tenderness or erythema were present. Blood cultures from the TRAC and a peripheral vein were drawn each time the study participants' temperature was above 38.5° C.

Findings

Rate of accrual

As a second cancer treatment centre with a similar patient population was willing to also gather cases for the large prospective dressing trial, it was estimated that 44 patients could be accrued yearly. Setting α at 0.05 and power at 0.80 for our survival analysis, 142 patients will be required. Thus accrual will take approximately three years.

Patient teaching material

A teaching booklet and model were developed by the investigators to describe all aspects of TRAC care. Patients and family members were

encouraged to provide input regarding areas that required more clarification, and thus the booklet was revised several times. The study nurse met with participants weekly for the first three weeks after TRAC insertion to provide instruction regarding TRAC care. The information given progressed from general to specific. At the initial visit, the information included TRAC purposes, safety precautions, recognition of early signs and symptoms of infection and use of the home care record form to monitor these parameters. Trouble-shooting tips were also discussed. During the second and subsequent sessions, the study nurse performed demonstrations of the cleansing, dressing change and heparinization procedures. Patients and a family member were required to provide a satisfactory return demonstration of cleansing, dressing change and heparinization. A flow sheet of all patient teaching was maintained in the patient's hospital record. We are confident that study participants had a thorough understanding of all matters relating to their TRAC. One participant, who developed a fever while on holidays, reported to the nearest hospital, informed the staff that he was on a special study, and requested the appropriate lab work. We received copies of the blood work results two weeks later!

Patient tracking and data management issues

Following receipt of written informed consent, demographic information including address and phone number was obtained from each participant's hospital record. Participants living in outlying areas were referred to home care and these agencies were provided with all necessary materials, and follow-up phone calls if necessary, to maintain continuity of care. We initially attempted to involve community health care providers in the collection of skin swabs, but transportation of swabs in a timely fashion was not possible. Thus, participation was subsequently limited to those individuals who would be residing within an hour's drive of the cancer centre during treatment. No participants were lost to follow-up.

Data collection forms were developed to facilitate complete recording of data and ensure that all patient teaching was completed. The data collector training program was carried out by the principal investigator. Inter-rater agreement between the principal investigator and two data collectors for the assessment of exit site infection and septicemia was 100%.

Frequency of sepsis

The dressing and the no-dressing groups yielded similar results. In the dressing group, four out of 11 developed sepsis, compared to three out of 13 in the no-dressing group (Table One). Due to the small sample, it is difficult to interpret these results. If these infection rates continue or if the no-dressing group experiences a lower infection rate,

Table One: Infection frequency by dressing type, BMT status and gender

Group Dressing	Sepsis	No Sepsis
BMT		
Male		2
Female		1
No BMT		
Male	2	4
Female	2	
Subtotal	4	7
No Dressing Group		
BMT		
Male		1
Female	1	1
No BMT		
Male	2	7
Female		1
Subtotal	3	10

significant savings to the health care system would result. On average, our patients who become septic require 10 additional days of hospitalization and IV antibiotics. Our estimated cost of one TRAC-related septic episode is approximately \$13,000.

A number of organisms were cultured from these TRACs, demonstrating the susceptibility of immunocompromised individuals to a wide variety of organisms (Table Two). For interest, the white blood count at the time of the skin swab was included, if it was available.

The mean time to onset of sepsis for the dressing group was 63 days, compared to 64 days for the no-dressing group. However, the female BMT patient in the no-dressing group developed sepsis sooner than did any of the other patients (Table Three).

Conclusions

In this study, the pilot assisted in estimating the length of time required for accrual in the main study, and in the development of tools to minimize bias and manage data.

The trial of our patient teaching material proved particularly helpful, since patients were available to identify inconsistent and unclear passages in the text. Because the trial will require data collection at more than one site, it was important to ensure that it was possible to establish acceptable levels of inter-rater reliability. Based on the results of the pilot, we realized that we could not reliably collect skin swabs in the community, but believe that this may vary between study centres.

Finally, we were able to obtain some estimates of infection rates in

the dressing and no-dressing groups. In those cases in the pilot where white blood cell count data were available, we found, as expected, that the majority of the infections occurred when patients were neutropenic. We also identified additional variables, such as absolute neutrophil count and use of colony stimulating factors, that will need to be collected in the main study, since they will affect the interpretation of the data. Arrangements have been made to isolate and compare organisms from skin, TRAC and blood, using biochemical profiles, antibiotic susceptibility patterns, plasmid, DNA or RNA profiles. This technique will allow discrimination between isolates and determination of whether the strains that colonize the skin are the same as those isolated from the TRAC and blood. These measures will assist in establishing the true source of the infection.

Completion of pilot studies in preparation of large randomized trials is recommended in many textbooks on clinical research. In our view, this pilot increased the reliability of the data being collected, and made a significant positive contribution to the overall design of our large randomized trial.

Authors' notes

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Table Two: Organisms identified from blood cultures

Dressing group - No BMT, male	
1 person had 2 septic episodes	
<i>Clostridium</i> species	
Coagulase negative staphylococci, WBC $0.3 \times 10^9/L$	
1 person had 1 septic episode	
<i>Flavobacterium</i> species	
Dressing, No BMT, female	
1 person had 1 septic episode	
<i>Enterobacter cloacae</i> , WBC $0.2 \times 10^9/L$	
1 person had 2 septic episodes	
<i>Acinetobacter anitratus</i> , WBC $1.4 \times 10^9/L$	
<i>Corynebacterium</i> species, WBC $3.1 \times 10^9/L$	
No Dressing, No BMT, male	
1 person had 1 septic episode	
<i>Candida tropicalis</i>	
1 person had 1 septic episode	
<i>Stomatococcus mucilaginus</i>	
No Dressing, BMT, female	
1 person had 1 septic episode	
<i>Streptococcus</i> , WBC $0.5 \times 10^9/L$	

Table Three: Mean catheter days to removal or sepsis

Group	Sepsis	No Sepsis
Dressing		
BMT		
Male		67
Female		
No BMT		
Male	57	303
Female	69	
Mean time to onset of sepsis = 63 days		
No Dressing		
BMT		
Male		38
Female	24	56
No BMT		
Male	103	150
Female		411
Mean time to onset of sepsis = 64 days		

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