Peritoneal Dialysis International, Vol. 10, pp. 25~29, 1990
Printed in the USA. All rights reserved.

0896~8608190 $3.00 + .00

Mary Anne Luzar

Exit-Site Care and Exit-Site Infection in Continuous Ambulatory Peritoneal Dialysis (CAPD): Results of a Randomized Multicenter Trial

Mary Anne Luzar1, Colin B. Brown2, Deborah Balf3, Leonard Hill4, Belkacem Issad5, Bernard Monnier6, Jean Moulart7, Jean-Charles SabatierB, Jean-Pierre Wauquier9, and Francesco Peluso1

1Baxter R&O Europe, Nivelles, Belgium, 2Royal Hallamshire Hospital, Sheffield, England, 30erriford Hospital, Plymouth, England, 4Royal Shrewsbury Hospital, Shrewsbury, England, 5Groupe Hospitalier Piti&eaucte;-Salpêtrière, Paris, France, 6Hôpital Pasteur, Nice, France, 7Hôpital Erasme, Bruxelles, Belgium, BHôpital Nord, Saint Priest-en Jarez, France, and 9Hôpital Saint-Jacques, Clermont-Ferrand, France

A total of 127 patients from 8 hospitals were randomized into 1 of 2 exit-site care regimes to evaluate their effect on rate of exit-site infection (ESI). Group 1 used povidone iodine and nonocclusive dressings changed 2 to 3 times weekly; Group 2 simply cleansed the exit site with nondisinfectant soap and water. Incidence, cause, duration, and treatment of ESI and peritonitis (P) were noted. Groups were analysed for age, sex, end-stage renal disease (ESRD), catheter, and systems. Total cumulative follow up time was 95.6 years. There was a significantly higher rate ($p = 0.0183$) of ESI in Group 2 (soap and water). The mean rate of ESI was 0.27 episodes/patient year for Group 1 versus 0.71 episodes/patient year for Group 2. Rates of P for the two groups were not significantly different ($p > 0.50$): 0.446 episodes/year for Group 1 versus 0.574 episodes/year for Group 2. s. *aureus* was responsible for 83% of ESI in Group 1 and 67% of ESI in Group 2. Protective dressing with a disinfectant is associated with significantly less ESI than minimum care. However, further research in exit-site care aimed specifically at reducing S. *aureus* infection is still required.

KEY WORDS: Catheter; disinfectant; dressing; exit-site infection.

The ability of continuous ambulatory peritoneal dialysis (CAPD) to successfully treat end-stage renal disease (ESRD) patients is now well established. Access to the peritoneal cavity using a permanent indwelling catheter is considered a key factor to successful CAPD (1-4). The methods by which the catheter, in particular the exit site, is kept problem free are, however, less subject to unanimous opinion (5-12). Exit-site infection is recognized as an important cause of morbidity in the CAPD patient and is reported a major cause of catheter-related drop out from this therapy (13-16).

The establishment of effective, long-term exit-site care is the basis of successful catheter-infection control in CAPD (15,16). Even the best designed catheter may be predisposed to infection if this aspect of patient care is not optimal. Yet as CAPD enters well into its second decade, exit-site care still remains a subject defined by anecdotal information that overshadows much of the existing research. The subject, it may be argued, does not lend itself to a research format due to inherent aspects, such as patient hygiene, that are impossible to accurately monitor. In spite of this and other drawbacks, several groups have addressed longterm exit-site care in CAPD. Several documented protocols exist, such as: (a) cleansing the exit site with hydrogen peroxide in combination with soap or povidone iodine scrub (7); (b) cleansing with povidone iodine (6, 15); (c) cleansing with soap and water (17).

While the use of no dressing and a simple exit-site care routine appeal to many, most units today do use some type of cover (18). The question of which type of dressing best suits the CAPD catheter exit-site remains open. Both air-occlusive (6) and air-permeable gauze dressings (15) have been recommended. In opposition to various forms of occlusion is the use of no dressing at all. Prowant *et at.* (17) concluded, from a prospective randomized study, that cleaning a wellhealed exit-site with soap and water resulted in a markedly lower rate of infection.

This article presents data from 8 hospitals in a randomized prospective study designed to evaluate 2 commonly used catheter exit-site care procedures and to document the effectiveness of each in preventing infection. The procedures were chosen because they represent 2 extreme approaches of exit-site care currently in use. Elucidation of indications for use of a more complicated long-term exit-site care versus minimal care could have important implications for the well-being and comfort of the patient.

METHODS

PATIENT SELECTION AND STUDY DESIGN

This randomized study of 2 exit-site care regimes includes both new (85%) and current adult CAPD pa

Correspondence to: Mary Anne Luzar, Baxter R&D Eu rope, 7, rue du Progrès, B-1400 Nivelles, Belgium.

Received May 16, 1989; accepted July 4, 1989.

tients from 8 hospitals. Participating units randomized patients into 1 of 2 groups based on randomization table cards supplied by a central coordinator. No limitations for age, sex, or ESRD were applied to enrollment.

Group 1 followed a procedure that required performing the following catheter exit-site care: povidone iodine (concentration: 20 g/L) was applied to the exit site with sterile gauze. Excess disinfectant was removed by a second sterile gauze. A nonocclusive sterile gauze dressing was placed over the exit site and secured by tape in 2 locations. Tape selection was adapted to patients' individual needs in order to avoid allergic reactions. Group 1 performed this procedure 2 to 3 times weekly; this frequency corresponded to that of the majority of patients hygiene and was considered, for this reason, more realistic than daily dressing changes.

Group 2 cleansed the catheter exit site daily with nondisinfectant soap on sterile gauze. Patients from the United Kingdom used the widely available "simple soap" and French patients used "savon de Marseille." This daily cleansing of the exit site was performed regardless of bath or shower frequency.

An important point to note is that disinfectant soap was not used by either group as we did not want the results of povidone iodine to be masked by use of a soap with another disinfectant.

Patients did not alter their routine hygiene practices during the study. The participating units advised patients on hygiene and recorded the routine of the patient on the study form. Prolonged tub bathing was discouraged. The majority of the patients bathed or showered several times a week. Those who wore dressings changed them at this time. Five patients did not shower or take tub baths, but they participated, nonetheless, in the study by following their established routines.

In order to allow sufficient time for healing the exit site, new patients entered the study 2 weeks after catheter implantation (14). During the first 2 weeks postimplantation, the exit site was cared for following the normal routine of the unit (surgical wound dressing) .Current patients were randomized during a clin ical visit. All patients were free of infection at the time of entering the study. Exit sites were monitored monthly during routine line changes. All infections, based on standard definitions outlined in the protocol, were recorded along with date of onset, duration, and treatment. Patients were enrolled for 1 year of follow-up or until a significant difference in rate of exitsite infection resulted in cessation of the study. All reasons for leaving the study were recorded by the physicians.

The study began enrollment in May 1987 and was discontinued in September 1988 when statistical analysis using the negative binomial model (19) showed a significant difference in exit-site infection rate between the 2 groups. Total cummulative follow-up time for 127 patients was 95.6 years, and average duration of patient follow up was 9.03 months.

CATHETER SELECTION AND IMPLANTATION

Prior to CAPD, patients from 7 of the 8 hospitals had a peritoneal catheter inserted by a member of the surgical department of each hospital. In 1 hospital, the nephrologist implanted all peritoneal catheters. The majority of patients (80%) received the Tenckhoff straight double-cuffed catheter: 84% of the patients in Group 1 and 76% of the patients in Group 2. These catheters were implanted using a midline incision. The subcutaneous cuff was positioned 2 to 3 cm from the exit site. The tunnels of these catheters were primarily in a cephalad direction. No suture was placed at the exit site and the belt line was avoided. Other choices of catheters included the swan-neck catheter and Toronto Western Hospital type II implanted surgically through the rectus muscle. Tunnel direction of the swan-neck catheter (5% of total number in study) was caudal while the TWH -II tunnel was positioned in a cephalad direction or laterally. Routine management of all catheters included placing tape between the exit site and the connector for stabilization.

DEFINITION

S

The diagnosis of ESI was based on pericatheter redness and/or exudate with or without a positive culture (5, 13). Formation of a crust around the exit site was not an indication of infection. A positive culture from the exit site in the absence of inflammation did not indicate ESI. The diagnosis of tunnel infection was made if erythema, edema, and/ or tenderness of the subcutaneous tunnel was present with or without discharge and positive culture. A dialysate cell count was obtained when fever, tenderness, abdominal pain, or turbid dialysate was present. Peritonitis was defined as a dialysate leukocyte count of more than lOO cells/mm3 with more than 50% of these cells being polymorphonuclear leukocytes.

New episodes of infection by the same organism in a patient were recorded if the patient had been free of any symptoms at the end of antibiotic therapy and symptoms of the infection reoccurred more than 4 weeks after the date of onset of the preceeding infection.

TREATMENT OF ESI, TUNNEL INFECTION, AND PERITONITIS

Treatment of infections was done in accordance with routine protocols established in each hospital. ESI was generally treated with oral antibiotics for 10 days. Peritonitis was treated with intraperitoneal antibiotics for 4 to 10 days. *s. epidermidis* and *s. aureus* were generally treated with fluxocillin or vancomycin for 10 days; however, antibiotic choice and duration of treatment were modified depending on the culture reports, clinical response to treatment, and condition of the patient.

TABLE 1
Characteristics of CAPD Patients Randomized into Two Exit-Site Care Protocols

Patient characteristics	Percentage of total patient enrollment	Percentage of patients in Group 1 (dressing and PVP-I)	Percentage of patients in Group 2 (soap and water)
ESRD			
Diabetic glomerulonephritis	13	17	11
	14	16	6
Other	73	67	83
Age			
19–44	24	21	28
45–64	35	31	41
65–85	41	48	31
Sex			
Male	61	63	59
Female	39	37	41

One hundred and twenty-seven patients from 8 hospitals were randomized into 2 different exit-site care protocols for subsequent monitoring of exit-site infection rate and peritonitis.

RESULTS

One hundred and twenty-seven patients were enrolled in the study from May 1987 to June 1988. Seventy-four patients used procedure 1 (dressing and disinfectant) and 53 patients used procedure 2 (soap and water). No major differences were observed for age, sex, or cause of ESRD. The characteristics of the patients are shown in Table 1.

In September 1988, statistical analysis using the negative binomial model showed a significant difference between the 2 groups for rate of exit-site infection. The patients using dressing and disinfectant (Group 1) had an infection rate of 0.27 episode per patient year, while Group 2 (soap and water) had an infection rate of 0.71 episode per patient year. In contrast, there was no significant difference ($p > 0.50$) for peritonitis rates between the 2 groups. The peritonitis rate, with 95.6 years of follow-up as of September 1988, was 0.44 episode per patient year for Group 1 and 0.57 episode per patient year for Group 2.

Sixty-eight percent of the total patient population of the study used a standard CAPD connection system (luer lock system II), while 25% used single-use disconnect systems and 7% used reusable disconnect systems.

Exit-site infection (which includes tunnel infection) was most often caused by *Staphylacaccus aureus* in both groups (83% for Group 1 and 67% for Group 2). Table 2 lists all the etiological agents of both exit-site infection and peritonitis in this patient population.

The average follow-up time was 9.03 months per patient (total follow-up time was 95.6 patient years). During this period, 25% of the patients left the study for reasons shown in Table 3. N o significant difference in drop out was observed between the 2 groups.

TABLE 2
Etiology of Exit-Site Infection and Peritonitis in Patients Randomized into Two Exit-Site Care Protocols

	Exit-Site Infections*		Peritonitis	
	Group 1	Group 2	Group 1	Group 2
Cause	Number of infections (%) (18 episodes in 15 patients)	Number of infections (%) (24 episodes in 14 patients)	Number of episodes (%) (27 episodes in 17 patients)	Number of episodes (%) (19 episodes in 14 patients)
Coliforms	—	—	1 (4)	4 (21)
Fungal sp.	1 (6)	—	—	—
Klebsiella spp.	—	—	1 (4)	—
Pseudomonas aeruginosa	—	—	1 (4)	—
Staphylococcus aureus	15 (83)	16 (67)	8 (29)	3 (16)
Staphylococcus epidermidis	—	2 (8)	5 (18)	6 (32)
Other coagulase-negative Staphylococcal spp.	2 (11)	3 (12.5)	1 (4)	1 (5)
Streptococcus spp.	—	—	1 (4)	—
No growth	—	3 (12.5)	9 (33)	5 (26)

* Four tunnel infections were reported during the follow-up period (2 in each group) and are included in ESI.

TABLE 3
Reasons for Leaving the Exit-Site Care Study During Follow-Up Period

Reported cause	Number of patients (N = 32)	Percentage
Death	10	32
Transplantation	9	28
Transfer to hemodialysis	5	16
Exit-site/tunnel infection*	3	9
Recurrent and/or severe peritonitis*	3	9
Other	2	6

* These infections required catheter removal and replacement at which time patients were removed from the study even though they continued CAPD.

DISCUSSION

In this multicenter study, the group of patients using a regime of sterile nonocclusive dressing and PVP-I for catheter exit-site care during CAPD had a significantly lower rate of exit-site infection than the group using soap and water (0.27 episode per year vs. 0.71). The difference in peritonitis rates between the 2 groups was not significant. While the rate of exit-site infection was significantly different, the major cause of infection was the same for both groups. *S. aureus* was the primary agent of exit-site infection in the study regardless of the type of protocol used.

During enrollment, 9 patients randomized into Group 2 were excluded from the study because they refused to follow the soap-and-water procedure. All 9 were current patients (from 3 hospitals) who had been using dressing and disinfectant prior to the study. Parity between randomization groups is seldom obtained; however, this additional complication resulted in fewer patients in Group 2 than in Group 1. Two new patients in the soap-and-water group asked to change to a dressing method and are reported in the drop-out data due to "other causes." Two other patients in the soap-and-water group were changed to the dressing protocol following exit-site infection requiring catheter replacement. No patient in the dressing group requested a protocol change during the study.

As stated previously, this patient population used a variety of hygiene practices. In 2 of the countries where the study took place, showering is a routine practice; in the third country, tub baths are preferred. The fact that some of the patients showered while others bathed in tubs makes it impossible to study the relationship between hygiene practice and infection rate. Indeed, this was not the purpose of the study. We proposed exit-site care methods that fit easily into the patients' lifestyles and evaluated the impact of each on catheter infection. For this reason, we did not advise daily dressing changes and did not request daily bathing in shower or tub. The dressing changes were done 2 to 3 times weekly. A once-a-week dressing change would interfere with most hygiene routines that included frequent bathing, and prolonged use of dressing could give selective growth advantages to certain bacteria requiring, for example, lower levels of oxygen. The only restriction was against prolonged soaking in the bath tub. Patients in the soap-andwater group were asked to gently cleanse the exit-site daily, even if personal bathing was on a less frequent basis. Patients with minimum hygiene did not have more infection than those more meticulous in their habits. However, these patients were too few to draw general conclusions.

The exit-site infection rate in Group 2 is comparable to that recently reported in the NIH registry (20). Group 1 had a much lower rate of exit-site infection. It is unclear if the overall reduction of exit-site infection in Group 1 was due to dressing or disinfectant or their synergism. Further research is required to clarify this point. In the study by Prowant *et at.* (17), use of antibacterial soap was recommended and, in some instances, povidone iodine scrub was used. This variability makes interpretation difficult especially because the study was limited to a small number of patients in a single institution. Our study, based on 127 patients from 8 hospitals, offers a wider base for generalization to other CAPD populations.

Several factors may influence exit-site morbidity. It has always been suspected that placement of the catheter exit site at the belt line could cause inflammation and infection. Such a position is discouraged in most units including those participating in this study. However, in a recent study by Piraino and colleagues, it was reported that location of the exit site in relationship to the belt line was not an important factor in determining catheter infection rates (21).

Tunnel direction has been shown by Twardowski *et at.* to influence duration of catheter infection (22). Although the rate was not significantly lower, down ward directed tunnels required fewer days of antibiotic therapy than catheters placed in a cephalad or lateral direction. We did not investigate tunnel direction in our study other than to note that the majority of patients received the straight Tenckhoff catheter with the tunnel positioned in a cephalad direction.

Although the pathogenesis of ESI is unclear, the fact that *S. aureus* was the main cause of exit-site infection in both groups may be explained in light of recent studies indicating that the *S. aureus* nasal carrier is at higher risk for exit-site infection than the noncarrier (23-25). We do not know how many of the patients were chronic *S. aureus* nasal carriers. Since 19 of the 127 patients were already using CAPD when randomized, we decided that this patient population would not offer a clear epidemiological picture as to the original source of the colonizing organism. Certainly this risk factor associated with catheter infection requires further elucidation.

Thus, the results we obtained indicate that protection of the exit-site during CAPD is an important infection control measure. Further research is re

quired to improve exit-site care so that a reduction of the incidence of *S. aureus* infection may be achieved.

ACKNOWLEDGMENTS

The authors wish to thank Miss Jenny Lewis of Baxter Healthcare Ltd., Egham for her assistance in data collection. We also thank Dr. Edward Vonesh of Baxter Healthcare Corporation, Round Lake for his statistical analysis of the data. Our appreciation is also extended to Mrs. Nelda Claeys for preparation of the manuscript.

REFERENCES

1. Veitch P. Surgical aspects of CAPD. In: Gokal R, ed. *Continuous ambulatory peritoneal dialysis.* London: Churchill Livingston Publishers; 1986:110-144.
2. Khanna R. Peritoneal dialysis catheter exit site. *Perit Dial Int.* 1988; 8:119-123.
3. Tenckhoff H, Schechter H. A bacteriologically safe peritoneal access device. *Trans Am Soc Artif Intern Organs.* 1968; 14:181-186.
4. Tenckhoff H. *Chronic peritoneal dialysis.* Seattle, W A: University of Washington; 1974.
5. Bartelt C, Burrows L, Prowant B, Ryan L, Satalowich R, Schmidt L. *Management of the peritoneal catheter exit site.* Columbia, MO: University of Missouri; 1986.
6. Clayton S, Fine C, Quinton C, *et al.* Training patients for continuous ambulatory peritoneal dialysis at the Toronto Western Hospital. In: Legrain M, ed. *Continuous ambulatory peritoneal dialysis.* Amsterdam: Excerpta Medica; 1980:162-166.
7. Clayton S, Quinton C, Oreopoulos D. Training technique for continuous ambulatory peritoneal dialysis. *Perit Dial Bull.* 1987; 1:S23-S24.
8. Clayton S, Quinton C, Oreopoulos DG. Training technique for continuous ambulatory peritoneal dialysis. *Perit Dial Bull.* 1987; 7:S23-S24.
9. Prowant B, Schmidt L, Burrows L V, *et al.* A tool for nursing evaluation of the peritoneal dialysis catheter exit site. *ANNA J.* 1987; 14:28-29.
10. Poirier VL, Dlay BDT, Dasse KA, Haudenschild CC, Fine RE. Elimination of tunnel infection. In: Maher JF , Winchester JF, eds. *Frontiers in peritoneal dialysis. Proceedings of the III International Symposium on Peritoneal Dialysis. Washington, DC,* 1984. New York: Field, Rich and Associates, Inc; 1986:210-217.
11. Schmidt L, Prowant B. The role of the CAPD nurse in decreasing exit site infections. *Perit Dial Bull.* 1984; 4:S57.
12. Starzomski RC. Three techniques for peritoneal cath eter exit site dressings. *ANNA J.* 1984; 11:7,9-16.
13. Cantaluppi A, Castelnovo C, Scalamogna A, Guerra L, Graziani G, Ponticelli C. ESI in patients on continuous ambulatory peritoneal dialysis. In: Khanna *et al.,* eds. *Advances in continuous ambulatory peritoneal dialysis. Proceedings of the Fifth Annual CAPD Conference, Kansas City, Missouri,* 1985. Toronto: University of Toronto Press; 1985:45-48.
14. Piraino B, Bernandini J, Sorkin M. The influence of peritoneal exit site infections and catheter loss in patients on continuous ambulatory peritoneal dialysis. *Am J Kidney Dis.* 1986; 8:436-440.
15. Tenckhoff H. The peritoneal catheter: Implantation, care and complications including peritonitis. In: Maher J, ed. *An introduction to continuous ambulatory peritoneal dialysis.* Deerfield, IL: Travenol Laboratories; 1980:31-39.
16. Khanna R, Oreopoulos DG. Complications of peritoneal dialysis other than peritonitis. In: Nolph KD, ed. *Peritoneal dialysis.* Boston: Martinus Nijhoff Publishers; 1985:441-524.
17. Prowant BF, Schmidt LM, Twardowski ZJ, *et al.* A ran - domized prospective evaluation of three procedures for peritoneal dialysis catheter exit site care. *ANNA J.* 1988; 18:219-223.
18. Uttley L, Gokal R. Organization of a CAPD programme -The nurses' role. In: Gokal R, ed. *Continuous ambulatory peritoneal dialysis.* London: Churchill Livingston Publishers; 1986:145-162.
19. Vonesh E. Estimating rates of recurrent peritonitis for patients on continuous ambulatory peritoneal dialysis. *Perit Dial Bull.* 1985; 5:59-65.
20. Nolph KD. The current status of CAPD and CCPD. *Dial Transpl.* 1988; 17:457-460.
21. Piraino B, Bernardini J, Johnston JR, Sorkin MI. Exit site location does not influence peritoneal catheter in fection rate. *Perit Dial Int.* 1989; 9:127-129.
22. Twardowski ZJ, Nolph KD, KhannaR, *et al.* The need for a "Swan neck" permanently bent, arcuate peritoneal dialysis catheter. *Perit Dial Bull.* 1985; 5:219-223.
23. Sewell CM, Clarridge J, Lacke C, Weinman EJ, Young EJ. Staphylococcal nasal carriage and subsequent in fection in peritoneal dialysis patients. *JAMA.* 1982; 248:1493-1495.
24. Davies SJ, Ogg CS, Cameron JS, Poston S, Noble WC. Staphylococcus aureus nasal carriage, exit site infection and catheter loss in patients treated with continuous ambulatory peritoneal dialysis (CAPD). *Perit Dial Int.* 1989; 9:61-64.
25. Luzar MA, Coles G, Faller B, *et al.* Staphylococcus aureus nasal carriage-a link to infection. (Abstract) *Perit Dial Int.* 1989; 9(Sl):105.