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Risk of peritonitis and technique failure by CAPD connection technique: A national study

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Risk of peritonitis and technique failure by CAPD connection technique: A national study. Peritonitis has been a leading complication of long-term therapy with continuous ambulatory peritoneal dialysis (CAPD). This study was designed to evaluate the risk of peritonitis and technique failure according to the initial CAPD connection technique. Patients from all U.S. facilities starting CAPD therapy at home between January 1 and June 30, 1989 were followed for up to 21 months on the initial CAPD connection technique to change in technique or dialytic modality, to transplantation, death or loss to follow-up. Patients were grouped into standard connection techniques (SCT) (N = 1,133), Y-set (N = 1,067), standard UV set (N = 916) and O-set (N = 167). The time to first peritonitis episode was analyzed actuarially and by using the Cox proportional hazards model which adjusted for age, sex, race, cause of ESRD, CAPD program size and ESRD therapy prior to CAPD. Peritonitis occurred on average at 9.0 month intervals with SCT, 15.0 months with Y-set, 13.4 with standard UV and 9.4 with O-set. The relative risk (RR by Cox analysis) of first peritonitis compared to SCT was 0.60 (40% lower) for the Y-set ($P < 0.01$), 0.75 for standard UV ($P < 0.01$), and similar to SCT (RR = 0.96) for the O-set (NS), all else being equal. Analysis time to second (N = 1,271) peritonitis episode gave similar results as did analysis of time to CAPD technique failure. Significantly higher RR of peritonitis and technique failure was observed for younger and black patients. These findings suggest the utilization of connection techniques with superior results.

Continuous ambulatory peritoneal dialysis (CAPD) is an established treatment for patients with end-stage renal disease (ESRD), and in the U.S. 14,800 patients (12.7% of all dialysis patients) were being treated by CAPD at the end of 1989 [1]. This number has continued to increase in recent years as did that for all dialysis patients, and the number for CAPD patients has reached 17,000 at the end of 1990, while that for all peritoneal dialysis patients exceeds 20,000 [1]. The major limitation of CAPD has been the problem of peritonitis, the most common reason for hospitalization [2] and for discontinuation of this form of dialysis [2, 3]. Peritonitis is most commonly secondary to the introduction of bacteria during dialysis bag-tubing connection (usually 4 times daily) or to infection along the peritoneal catheter (exit site or "tunnel" infection). Several different connection techniques have been in use, and single and multicenter studies of peritonitis rates have compared various connection techniques with the standard manual system.

The present study examines a national census of patients who started CAPD in early 1989 to determine the U.S. experience with CAPD and the risk of peritonitis and technique failure associated with various connection techniques after adjustment for a variety of factors.

Methods

Data sources

All data for this study come from the United States Renal Data System (USRDS) [4], and the specific clinical CAPD data were collected in a USRDS Special Study on CAPD peritonitis. This study sampled essentially all CAPD patients completing self-care training during the first six months of 1989. These patients were followed for varying lengths of time from first CAPD treatment at home to change in technique, change in modality of care, death, or the end of the reporting period. Follow-up ended between May 15, 1990 and November 20, 1990, since abstraction of patient records occurred between these dates.

The Peritonitis Special Study data were reported by individual dialysis units using special data collection forms; the forms used were published with the USRDS 1990 Annual Data Report [4]. Forms were submitted by the dialysis facilities to the local ESRD Network office and were forwarded via the Health Standards and Quality Bureau of the Health Care Financing Administration (HCFA) to the USRDS for data entry. Patient demographic and other historical data from the USRDS data base were merged with the data collected on the USRDS "Special Study Form for Peritonitis in CAPD Patients" to obtain complete records on all patients studied.

Selection of patients

All patients in the United States who started home CAPD for the first time between January 1, 1989 and June 30, 1989 were eligible to be included in this study. To limit the respondent burden for large CAPD programs, dialysis units were instructed to provide data for all patients who initiated CAPD for the first time, up to a maximum requirement of 14 patients. In fact, less than five percent of units had more than 14 patients submitting the requested first 14 eligible patients.

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Dialysis units were identified for this study by reviewing the 1989 Facility Survey. This reports for ESRD facilities both activities during 1989 and the status of all treated patients on December 31, 1989 [1]. Units were included in this study if they indicated any CAPD self-care training, any CAPD patients on December 31, 1989, or if they were certified by HCFA to do CAPD self-care training. All such units were mailed CAPD Special Study forms and detailed instructions. To ensure compliance, the ESRD Networks monitored the submission of completed forms by all facilities. This process achieved a response rate by dialysis units of almost 100%.

Calculation of risk periods and peritonitis episodes

For each patient the study period begins on the date the patient started CAPD at home. The study stop date for individual patients was determined by the date on which the patient's medical records were abstracted (May 15 to November 20, 1990) or, whichever occurred earlier, the date of switch to a different CAPD connection technique, or to a different treatment modality (other PD, hemodialysis or renal transplant), or of loss to follow-up or death. Thus, for a patient who continued using the same CAPD connection technique when the medical records were abstracted, the study ended at the study form completion date, for a follow-up duration which ranged from 10.5 to 21 months.

All peritonitis episodes were considered, with the following exceptions: (1) Peritonitis episodes detected within three days of the home CAPD start date were excluded, as they may have actually developed prior to the first CAPD treatment at home. (2) Subsequent peritonitis episodes were not counted as distinct episodes if they were identified as relapses in the medical records, or if they occurred within four weeks of the start of the previous episode *and* had the same organism or no growth identified in the culture. Peritonitis episodes that were detected within three or fewer days after the study stop date were included in the analysis.

For all analyses CAPD techniques were grouped as: (1) "standard" including spike with and without Luer lock or assist and the sterile connecting device, (2) disconnect "O-set" system, (3) disconnect "Y-set" system with and without use of antiseptic instillation, and (4) "standard UV" system excluding the UV systems utilized in some disconnect techniques which are counted under the O-set or Y-set. Unspecified connection techniques accounted for less than two percent of cases and are excluded from these analyses.

Calculation of peritonitis rates

This peritonitis rate was calculated counting all peritonitis episodes per time at risk (that is, each patient's days of the study period). In agreement with most reports, the reciprocal of this peritonitis rate is reported as the average time interval per episode. Relapses of peritonitis, as defined above, were not counted. Average days per episode were calculated and reported in months per episode for subgroups of patients, particularly by connection technique.

Actuarial analysis of remaining peritonitis-free

Time from start of CAPD at home to first peritonitis episode was analyzed as the cumulative time without peritonitis. This variable was measured in days, from the day a patient started CAPD at home to the day of the first episode of peritonitis, or to the date of change in status or end of follow-up. Similarly, time from first peritonitis to second peritonitis episode was analyzed for all patients who developed a peritonitis episode during the period of study.

This actuarial analysis was expanded using the Cox proportional hazards model [5] to compare the relative risk (RR) of remaining peritonitis free by the four connection techniques with adjustment for the following covariates: patient age in 1989 (5 age groups), patient race (white, black, other), cause of ESRD (diabetes, hypertension, glomerulonephritis, cystic kidney disease, other), CAPD program size (1 to 6, 7 to 20 and > 20 patients enrolled in 1989) and duration of ESRD therapy prior to going home on CAPD (< 1 month, 1 to 3 and > 3 months). Additionally, this analysis provided estimates of relative risk of a first peritonitis episode for each covariate, when adjusting for connection technique and all other covariates. The same methodology was utilized in a Cox proportional hazards analysis to estimate the relative risk of developing a second episode of peritonitis calculated in days from first peritonitis episode.

Technique failure analysis

Technique survival was analyzed by actuarial technique and the relative risk of technique failure by the Cox proportional hazards model. Any change in connection technique or change in dialytic modality was counted as technique failure. Patients dying or receiving a renal transplant were censored on that date. Additionally, the impact of defining death as technique failure rather than censoring event was analyzed.

For all analyses, statistical significance applied to P values of 0.05 or less.

Results

Patient characteristics

Valid data forms were submitted on 3,366 CAPD patients who started CAPD at home for the first time between January 1, 1989 and June 30, 1989. A total of 706 CAPD units submitted data forms. The number of patients per unit ranged from one to 23. For 74% of these patients CAPD was the first treatment modality. Of the remainder, 3% had a prior renal transplant, while 17% had previously used hemodialysis without transplant, and 6% of patients had other or unknown reporting of prior treatment status.

Linking the study forms to the USRDS data base on Medicare patients was successful in 94 percent of patients; the remaining 6% likely had insurance coverage other than Medicare. This agrees with other estimates that 93% of ESRD patients are covered by Medicare [1]. For patients matched with USRDS files the gender, race and primary cause of ESRD can be described. As shown in Table 1, age, race and diagnosis distributions vary somewhat by connection technique. Through statistical methods, adjustments are made in subsequent analyses for the observed differences in these distributions.

Connection and catheter factors

The distribution of connection techniques among study patients is shown in Figure 1. The groups of Standard, UV and Y-set accounted for 27 to 34 percent of first techniques used at

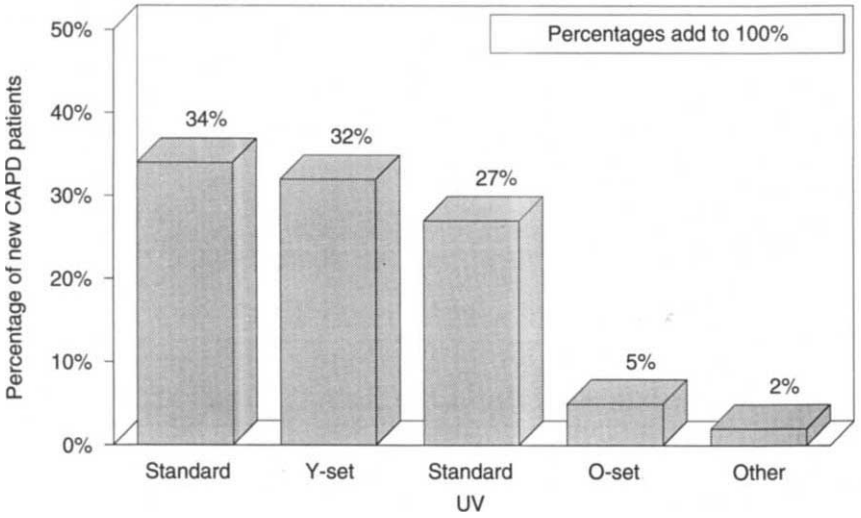

Fig. 1. *Percent distribution of CAPD connection techniques in the study sample* (N = *3,344, January-June 1989).*

Table 1. Characteristics of the CAPD peritonitis study population by CAPD technique[a]

	Standard	Y-set	Standard UV	O-set
N[b]	1,133	1,067	916	167
Median age	55	45	59	43
% Male	54	53	53	57
Race %				
Black	22	25	17	30
White	75	71	79	66
Other	3	4	4	4
Cause of ESRD %				
Diabetes	30	28	41	26
Hypertension	23	19	22	26
Glomerulonephritis	19	20	14	21
Other causes	15	19	12	15
Unknown/missing	13	15	12	12

[a] Percentages calculated above do not include 'missing' observations (<7%).
[b] Other techniques not shown (*N* = 61)

Table 2. Peritonitis rates by technique, new CAPD patients, 1989[a]

Technique (Patient days)[c]	Peritonitis rate *months*[b]		
	First	Subsequent	Total
Standard (194K)	11.4	6.3	9.0
Y-set (240 K)	20.6	8.2	15.0
O-set (33 K)	13.0	6.2	9.4
Standard UV (191 K)	16.4	9.1	13.4

[a] *N* = 3,188
[b] Months per episode, first and subsequent peritonitis
[c] Patient days in thousands (K)

home, whereas the O-set and other techniques contributed only 5% and 2%, respectively. The use of an antiseptic agent in the connection tubing was recorded in 93 percent of O-sets and in 7 and 9% of standard and Y-sets, respectively.

Peritonitis rates

Assessment of average months per episode (inverse peritonitis rates), counting days at risk and all peritonitis episodes (except relapses as defined above) revealed the numbers shown in Table 2. The total of 3,109 patients excludes those with other connection techniques, prior transplant and more than 10 years of prior ESRD therapy. The latter were excluded because of the potential effect of immmunosuppressive agents on the peritonitis risk and the questionable accuracy of USRDS data (such as cause of ESRD) before 1979. The standard set had a peritonitis rate indicator of nine months/episode while the Y-set had a rate of 15 months/episode, or 67% longer intervals on average ($P < 0.01$). The rate ratios for Y/SCT and UV/SCT were essentially unchanged when this analysis was repeated counting presumed relapses as new peritonitis episodes.

Probability of remaining peritonitis-free

The time in days from starting CAPD at home to first episode of peritonitis or censoring was analyzed as the actuarial probability percentages of remaining on the same connection technique without peritonitis. Figure 2 shows the actuarial curves for the four types of connection techniques during the 1.5 years of study. The curves are highest for the Y-set, lowest for the standard and O-sets, and intermediate for the standard UV-set technique. At one year the fraction remaining without peritonitis was 56% for the Y-set, 49% for the UV-set, 40% for the O-set and 38% for the standard sets. The odds ratio of first episode of peritonitis at one year relative to the standard set (1.0) was 0.48 for the Y-set (that is, odds are reduced by 52%), 0.64 for the standard UV-set, and 0.92 for the O-set.

For patients developing a first episode of peritonitis the probability of subsequently remaining peritonitis-free or the time to second episode was analyzed in the same fashion. Figure 3 shows the actuarial probability of remaining without a second peritonitis after the first episode of peritonitis for each connection technique group. The Y-set and the standard UV set have higher percentages of not developing peritonitis than do the standard and the O-sets. At one year, the odds ratio of second episode of peritonitis was 0.67 (that is, 33% lower) for the standard UV-set and 0.65 for the Y-set when compared to the standard set.

Analysis of the relative risk of first peritonitis according to connection technique by using the Cox proportional hazards

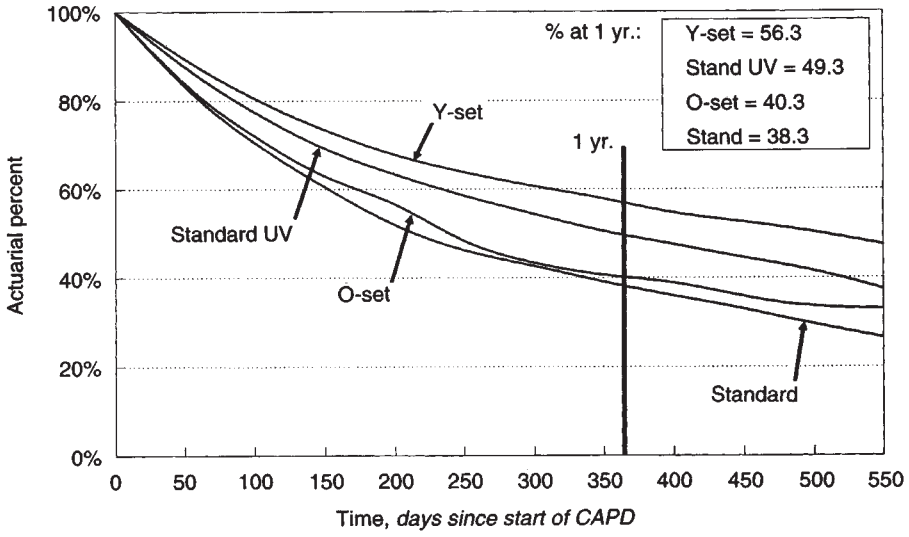

Fig. 2. *Actuarial percent of patients remaining peritonitis-free in days since the start of CAPD at home by connection technique. N* at start: Y-set = 1,067, Stand UV = 916, O-set = 167, Stand = 1,133.

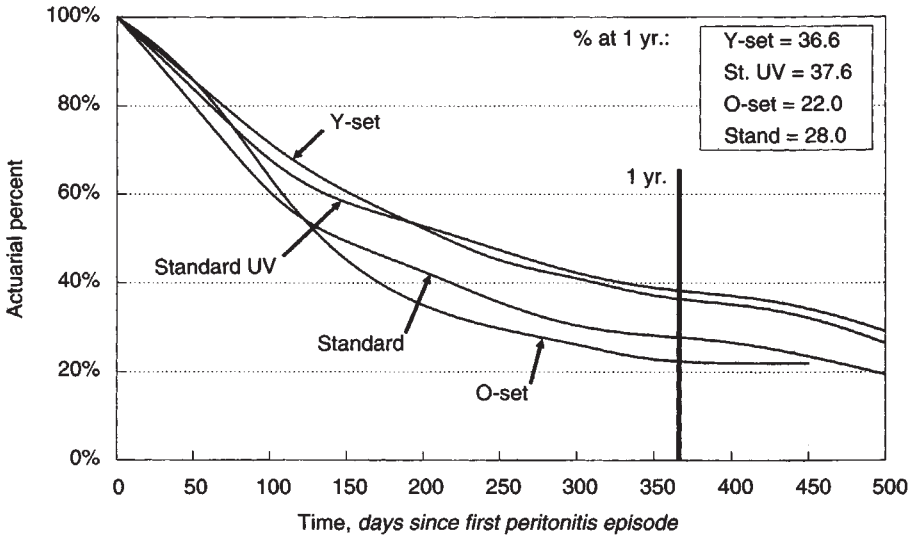

Fig. 3. *Actuarial percent of patients remaining peritonitis-free after the first peritonitis in days from first to second peritonitis episode by connection technique. N* at start: Y-set = 415, Stand UV = 400, O-set = 90, Stand = 594.

model confirmed these findings. When adjusted for age, race, primary disease, center size and months of prior ESRD therapy, the relative risk of first peritonitis was significantly lower for the Y-set (RR = 0.60, $P < 0.01$) and for the standard UV set (RR = 0.75, $P < 0.01$) than for the reference (1.0) of the standard set (Fig. 4). The difference in RR between Y-set and standard UV set was also statistically significant ($P < 0.01$). Results for the O-set were not significantly different (RR = 0.96) from those with the standard set. Results for the other covariates are also shown in Table 3. Patients aged 40 to 59 years had a 16 percent lower relative risk of first peritonitis (RR = 0.84) than patients aged 20 to 39 years ($P = 0.02$). Black patients had a 61% higher risk of first peritonitis than White patients (RR = 1.61, $P < 0.01$). Diabetic patients had a relative risk of 1.20 compared to patients with ESRD due to glomerulonephritis ($P = 0.03$). Size of the CAPD program was not significantly associated with peritonitis risk, but a trend toward lower risk for larger programs existed, all else being equal. Longer duration of prior ESRD therapy was associated with a higher risk of peritonitis which did not reach statistical significance. In a separate Cox analysis limited to patients using the Y-set, those with reported use of an antiseptic had a peritonitis risk not significantly higher than those without an antiseptic (RR = 1.11, $P = 0.6$). Another Cox analysis limited the maximum length of follow-up to 10.5 months for all patients: All findings on relative risk of first peritonitis (Table 3) remained essentially unchanged except for a slightly lower risk associated with diabetes (RR = 1.17, $P = 0.07$).

Results for the Cox proportional hazards model analysis of the relative risk of second peritonitis from date of first peritonitis (excluding relapses) are also shown in Figure 4. The relative risk for the Y-set was 0.69 ($P < 0.01$), for the standard UV set 0.72 ($P < 0.01$), and for the O-set 1.02 ($P > 0.1$). The covariates of age, race and diagnosis gave results similar to those for first peritonitis risk, but the relative risks for these covariates did not reach statistical significance.

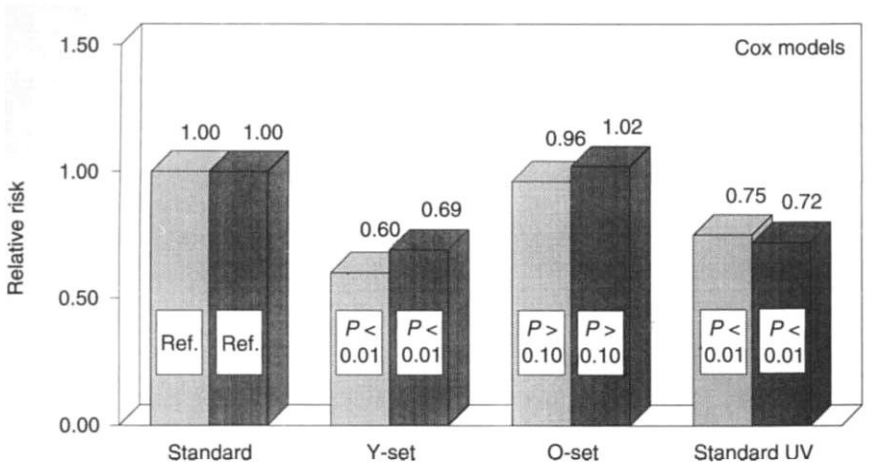

Fig. 4. *Relative risk of developing first peritonitis (from start of CAPD at home) and second peritonitis (from first peritonitis episode) in days to event by connection technique, compared to the standard sets using two Cox proportional hazard models.* For adjusted covariates see Table 3. Symbols are: (▨) RR of first; (■) RR of second. *N* of the first = 2,807, of the second = 1,271.

Table 3. Relative risk of first peritonitis and technique failure by Cox Proportional Hazards Model, 1989–90

		First peritonitis		Technique failure	
Covariate	*N*	RR	*P*	RR	*P*
Connection technique					
Standard (ref.)	956	1.00	—	1.00	—
Y-set	876	0.60	<0.01	0.49	<0.01
Standard UV	786	0.75	<0.01	0.73	<0.01
O-set	136	0.96	NS	0.64	<0.01
Other	53	0.68	NS	0.55	<0.05
Age					
<20	58	0.99	NS	1.06	NS
20–39 (ref.)	665	1.00	—	1.00	
40–59	1,014	0.84	0.02	0.79	<0.01
60–69	626	1.00	NS	0.72	<0.01
70+	444	1.00	NS	0.77	<0.05
Race					
White (ref.)	2,103	1.00	—	1.00	—
Black	615	1.61	<0.01	1.20	<0.05
Other	89	1.08	NS	1.18	NS
Sex					
Male (ref.)	1,503	1.00	—	1.00	—
Female	1,304	1.01	NS	0.97	NS
Diagnosis					
GN (ref.)	483	1.00	—	1.00	—
Diabetes	936	1.20	0.03	1.12	NS
Hypertension	627	1.09	NS	1.06	NS
Cystic disease	98	1.03	NS	1.82	<0.01
Other	478	0.92	NS	0.91	NS
Missing	185	1.01	NS	0.79	NS
CAPD program size					
1–6	215	1.20	NS	1.09	NS
7–20 (ref.)	741	1.00	—	1.00	—
21+	1,851	0.90	NS	0.77	<0.01
Prior ESRD Rx					
<1 month (ref.)	1,143	1.00	—	1.00	—
1–3 months	1,030	1.02	NS	1.11	NS
>3 months	634	1.13	NS	1.19	NS

Technique failure

The actuarial percentage of patients remaining on the same CAPD connection technique is shown in Figure 5. The Y-set had the highest percentage with 77% on the same technique at one year followed by the O-set (71%) and the standard UV-set (70%), with the standard set having the lowest probability (61%). At one year the odds ratio of technique failure compared to the standard set (1.0) is 0.46 for the Y-set (that is, 54% lower), 0.63 for the O-set, and 0.67 for the standard UV set ($P < 0.01$ each). When including death as a technique failure, the fraction of patients remaining on the same technique at one year is reduced, ranging between 50 and 70% although the order of actuarial technique survival curves remains unchanged (data not shown).

When adjusted for age, race, sex, primary cause of ESRD, CAPD program size and months from onset of ESRD to start of CAPD, the Cox proportional hazards analysis for technique failure gave the results shown in Table 3. Compared to the standard set each of the other three techniques had significantly lower risks of changing connection technique or dialysis therapy ($P < 0.01$ for each) and are ranked in the same order as in the unadjusted actuarial technique survival analysis. The covariates had statistically significant correlations with technique survival when adjusted for technique used. Older patients (age > 70 years) had a lower relative risk for technique failure when censoring for death and a higher risk when including death (RR = 1.38, $P < 0.01$, not shown) compared to the age group of 20 to 39 years. These observations are at least in part due to the higher death rate among older patients. The risk of technique failure for Black patients was 20% higher than that for White patients (RR = 1.20, $P < 0.05$); large CAPD units had a 23% lower risk than medium size units (RR = 0.77, $P < 0.01$), and patients on ESRD therapy more than three months prior to the start of study had a higher risk (RR = 1.19, $P = 0.07$) than patients with less than one month of ESRD therapy before going home on CAPD.

Description of first peritonitis episode

At the time of first peritonitis 13% of patients had documented exit site infections and 3% had leakage of peritoneal dialysate. Three percent of patients developed their first peritonitis during an unrelated hospitalization. First peritonitis resulted in hospitalization in 31% of patients. For the first peritonitis episode effluent dialysate culture results were reported in 92% of patients, and showed no growth in 20% of patients. Gram positive organisms predominated, as shown in

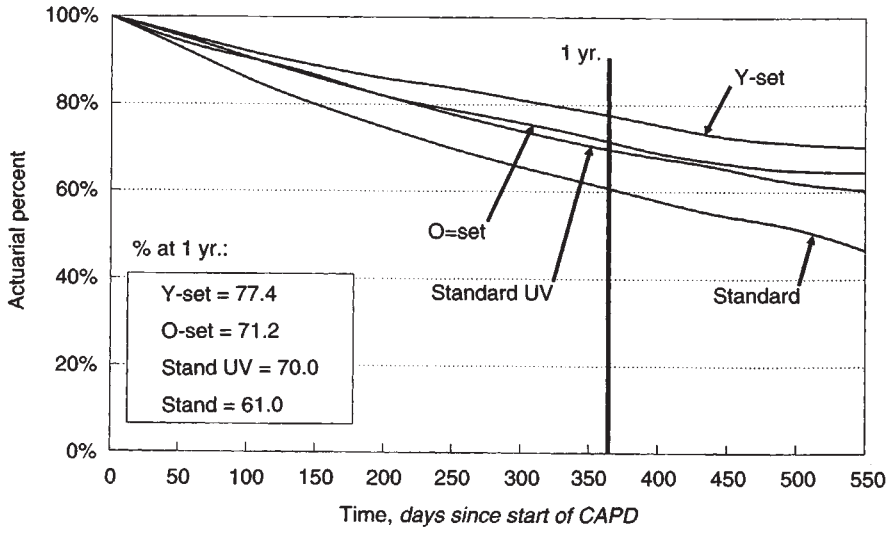

Fig. 5. *Actuarial percent of patients remaining on the initial connection technique (technique survival) in days since the start of CAPD at home (deaths and transplants are censored in this analysis). N* at start: Y-set = 1,067, O-set = 167, Stand UV = 916, Stand = 1,133.

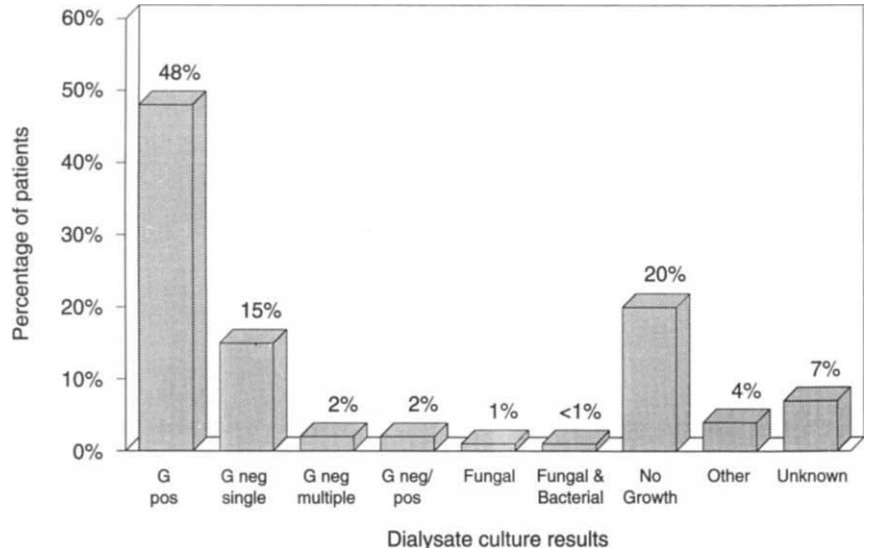

Fig. 6. *Percent distribution of peritoneal dialysate culture results for first peritonitis episode* (N = *1,517).*

Figure 6, followed by gram negative infections; fungal cultures were positive in less than 2% of cases.

Discussion

This study has the advantage of a large sample size. In addition, it represents a virtual national census of patients new to CAPD in the time period studied and so describes actual practice in the U.S. rather than the practice of several large collaborating research-oriented institutions. This study was designed to investigate the early course (first 10 to 20 months) of patients after starting CAPD at home, and thus provides no information about patients treated with CAPD long-term. Several other studies included all prevalent CAPD patients, some of whom had been on CAPD for long periods of time [6]. Such differences in study design must be considered when results are compared. One example is the relatively low frequency of positive fungal cultures in this study, (less than two percent for the first (Fig. 6) episode of peritonitis), whereas other studies report fungal infections in 3 to 15 percent of prevalent (including long-term) CAPD patients [2, 7].

The overall peritonitis rates observed here are similar to those described by others for the standard connection technique. The U.S. CAPD registry showed 9.2 months per peritonitis episode in patients trained in 1987, which was nearly constant for yearly cohorts from 1981 to 1987 [2], and matches standard connection technique in the present results of 9.0 months for the 1989 cohort. Similarly, the Canadian multicenter study showed an average of 9.9 months [8], but the multicenter study from Italy reported a longer average interval of 13.1 months per episode for 1983 through 1985 [9]. The latter two studies also present peritonitis rates for the Y-set technique (Table 4). Compared to the present finding of 15 months, the Canadian and Italian studies show longer intervals of 20.2 to 21.5 months per episode, respectively, whereas the Canadian [8] and Italian Y-set connection technique [9, 10] commonly employ an antiseptic, it is rarely used in the U.S. [11, 12]. However, among the 9% of Y-set patients reported to utilize an

Table 4. Comparison of time to first peritonitis episode: Canada, Italy, U.S.

Technique	Peritonitis-free at 12 months (%)		
	Churchill et al	Fellin et al	USRDS
Standard	27	38	38
Y-set	46	66	56
Odds ratio (Y-set/Stand)	0.43	0.32	0.46
N (at start)	124	791	2,200[a]

[a] Standard and Y-set only

antiseptic, the peritonitis risk was not lower than that of the remaining Y-set patients. The fact that the present study deals with the experience of a national census rather than that of collaborating institutions interested in CAPD research may explain the better results for the latter.

The actuarial approach to estimating the time to an episode of peritonitis or probability of remaining peritonitis-free has been used by others, and the results of this study are similar to those of the Canadian and Italian multicenter studies [8, 9]. Analyzing the relative risk of developing peritonitis with adjustment for covariates using the Cox proportional hazards model provides new insights into the role of covariates and confirms the findings from the univariate analysis for the connection techniques. The adjusted relative risk of developing peritonitis is 40 percent lower for the Y-set and 25 percent lower for the standard UV set when compared to the standard set ($P < 0.01$ for each). Analysis of the relative risk of remaining peritonitis-free after a first episode of peritonitis (time from first to second episode) gives very similar results ($P < 0.01$) and provides confirmatory evidence of the significant correlation of connection technique and peritonitis risk.

When adjusted for technique and other factors, the significantly higher risk of peritonitis among younger adult patients is intriguing since it was not detected in the CAPD registry [2]. Perhaps lower compliance in younger patients plays a role in this. The increased risk of peritonitis among Black as compared to White patients confirms previous reports [2]. This finding, and the increased technique failure in Blacks, may be among the reasons why there is a lower utilization of CAPD in Blacks compared to Whites [2, 13]. The observed increased peritonitis risk among diabetic patients is consistent with their generally increased susceptibility to infection. Intraperitoneal use of insulin theoretically would increase the peritonitis risk, although the U.S. CAPD Registry could not document such an added risk [2]. Whether the increased peritonitis risk among diabetics explains in part the finding in some studies of greater mortality among diabetic CAPD patients compared to diabetic hemodialysis patients [13, 14] deserves further investigation.

The actuarial technique survival analysis showed beneficial results for the Y-set and intermediate results for the standard UV set compared to the standard sets, and agrees with the peritonitis risk analyses. However, this analysis shows for the O-set a strong benefit for technique survival compared to the standard sets which could not be shown for peritonitis risk. The risk for the comparison group in this analysis may be unfairly high, due to the growing popularity of newer disconnect sets (O-set and Y-set) which may have caused elective technique changes from standard connection techniques without necessarily indicating problems with the standard sets. The relatively high ranking of the O-set above the UV-set deserves further study since it is based on a relatively small sample size ($N = 167$). The results of these actuarial analyses are confirmed by statistically significant findings in the Cox proportional hazards analysis. The latter yields several significant findings regarding other covariates. When adjusted for technique, age, race, sex, cause of ESRD and duration of prior ESRD, large CAPD centers had a significantly lower risk of technique failure than medium size centers. A similar finding for peritonitis risk did not reach statistical significance. The higher technique failure in Black than White patients is consistent with the finding for peritonitis risk by race and deserves further study.

The main technique failure analyses used a definition that is the same as that employed by others [2] in that death is censored and not considered a technique failure. Using this definition, patients over 40 years had a significantly lower risk of technique failure than those aged 20 to 39 years. This observation, however, is not significant if death is counted as technique failure. The analyses of technique survival are particularly interesting for their corroboration of the corresponding analysis of peritonitis risk for all connection techniques except the O-set.

For the disconnect sets, a sixfold difference was observed in the number of patients utilizing the Y-set ($N = 1067$) compared to the O-set ($N = 167$). In part this difference may be explained by the requirement of an intraluminal disinfectant for the O-set and associated potential risks of accidental intraperitoneal instillation [15]. Whereas in Europe and Canada both Y-set and O-set commonly use a disinfectant [8–10], it is rarely employed with the Y-set in the U.S. [11].

Although the Cox analysis adjusted for a possible effect of CAPD program size on peritonitis risk, there remains potential concern that differential technique selection by better centers may account for the benefits of certain techniques being utilized by these centers. To address this concern, adjustments for each medium size and large center ($N = 239$) were made, while all small centers (<5 patients entered) were aggregated into one cell. While most large centers utilized multiple techniques, those using a single technique preferred the standard technique (12%), followed by the Y-set and the standard UV set (9% each). The Cox proportional hazards analysis was repeated, stratifying on 239 individual centers with five or more study cases plus the small center group. This analysis confirmed the findings of first peritonitis risk compared to standard techniques for the Y-set (RR = 0.57, $P < 0.01$), for the standard UV set (RR = 0.72, $P < 0.01$) and for the O-set (RR = 0.85, P = NS). When the cell of centers (less than 5 study patients) was excluded, the results compared to the standard set were essentially unchanged (RR for Y-set = 0.54, for standard UV set = 0.71, for O-set = 0.99). Thus, a center effect does not likely explain the findings of this study.

The selection of patients to utilize certain connection techniques could not be evaluated in the present study and might have affected some of the results. Should more compliant and better educated patients be selected to use the Y-set, then the results could be more related to patient factors than to the connection device. One may suspect, however, that the O-set (requiring instillation of an antiseptic) would be utilized by an

equally or more selected group of patients, yet their results on peritonitis risk argue against this hypothesis.

To conclude, this national study on over 3000 ESRD patients starting CAPD at home in early 1989 revealed large and statistically significant differences in peritonitis rates and connection technique survival rates by CAPD connection technique. Patients treated with the Y-set had much better outcomes, while those treated with the standard UV-set had intermediate benefits regarding both peritonitis and technique failure risks. The O-set technique showed little benefit for reducing the peritonitis risk over the standard technique. Analyses with multiple adjustments for patient and center effects confirmed these significant results. Newer connecting devices have reduced peritonitis rates to levels well below those reported by the National CAPD Registry [2] for 1981 to 1987.

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Note added in proof

The use of intraperitoneal drugs in diabetic and nondiabetic CAPD patients was associated with an increased relative risk of first peritonitis (RR = 1.14, P = 0.08 overall). Since diabetics predominated in the intraperitoneal drug administration, this finding explains in part the observed increased peritonitis risk among diabetic patients. Reference: *United States Renal Data System, USRDS 1992 Annual Data Report*, Chapter VI, Catheter-related factors and peritonitis risk in CAPD patients, Bethesda, NIH/NIDDK, August 1992, p. 39–46

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