

# Catheter-Related Interventions to Prevent Peritonitis in Peritoneal Dialysis: A Systematic Review of Randomized, Controlled Trials

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**Abstract.** As many as 15 to 50% of end-stage kidney disease patients are on peritoneal dialysis (PD), but peritonitis limits its more widespread use. Several PD catheter-related interventions (catheter designs, surgical insertion approaches, and connection methods) have been purported to reduce the risk of peritonitis in PD. The goal was to assess the trial evidence supporting their use. The Cochrane CENTRAL Registry, MEDLINE, EMBASE, and reference lists were searched for randomized trials of catheter types and related interventions in PD. Two reviewers extracted data on the rates of peritonitis and exit-site/tunnel infection, catheter removal/replacement, technique failure, and all-cause mortality. Analysis was by a random effects model, and results are expressed as relative risk and 95% confidence intervals. Thirty-seven eligible trials (2822 patients) were identified: eight of surgical strategies of catheter insertion, eight of straight *versus* coiled catheters, 10 of Y-set *versus* conventional spike systems, four of Y-set

*versus* double-bag systems, and seven of other interventions. Despite the large total number of patients, few trials covered the same interventions, small numbers of patients were enrolled in each trial, and the methodologic quality was suboptimal. Y-set and twin-bag systems were superior to conventional spike systems (seven trials, 485 patients; relative risk, 0.64; 95% confidence intervals 0.53 to 0.77), and no other catheter-related intervention was demonstrated to prevent peritonitis in PD. This systematic review demonstrates that of all catheter-related interventions designed to prevent peritonitis in PD, only disconnect (twin-bag and Y-set) systems have been proved to be effective (compared with conventional spike systems). Despite the importance of PD as a renal replacement therapy modality and the large number of patients who receive it, it is still not known whether any particular PD catheter designs, implantation techniques, or modalities are effective, given the limitations of available trials.

Fifteen percent of the U.S. ESRD population is on peritoneal dialysis (PD). In other countries, such as Canada and the United Kingdom (35%), New Zealand (55%), and Mexico (90%), the rates are higher, but the major limitation to the broader uptake of PD is still an unacceptably high rate of peritonitis, which in turn promotes technique failure, increased hospitalization (1), and increased mortality (2–4). Although there has been a dramatic decrease in peritonitis from the inception of continuous ambulatory PD (CAPD), rates >0.5 episodes per patient per year are still common (5–7), and peritonitis tends to be recurrent, with a very

high rate of relapse (~0.5 episodes/patient per yr) (8). The incidence of peritonitis has been reported to vary depending on age (6,7), coexisting diseases (*e.g.*, diabetes), nasal carriage of *Staphylococcus aureus* (9,10), and race (11–13).

The prevention of PD peritonitis has focused primarily on antimicrobial prophylaxis, which has been the subject of a previous systematic review (14), and modifications of the PD catheter and system, which represent the open access to the peritoneal cavity. Interventions that have been studied include modifications of catheter design, implantation technique, connection method, and PD modality (9,10). Although many of these interventions are used routinely, there are conflicting guidelines on the topic (Table 1). The aim of this systematic review of randomized trials was to evaluate the evidence that supports the use of different catheter types and catheter-related interventions for the prevention of peritonitis in PD patients.

## Materials and Methods

### Inclusion Criteria

We included any randomized, controlled trial of different catheter types and catheter-related interventions used to prevent peritonitis or

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Table 1. Current guidelines on catheter type and placement in peritoneal dialysis<sup>a</sup>

Guideline	Country	Year	Recommendation
K/DOQI	United States	2000	No guideline
British Renal Association	United Kingdom	2002	Catheter type -No peritoneal dialysis catheter has proved to be superior to the standard double-cuff Tenckhoff catheter -Pediatric guidelines: No peritoneal dialysis catheter has proved to be superior to the standard double-cuff Tenckhoff catheter. Swan neck tunnel, two-cuff, and downward pointing exit site may have an advantage Catheter placement -No guideline
Canadian Society of Nephrology	Canada	2003	No guideline
European Best Practice Guidelines	Europe	2003	No guideline
ISPD guidelines/recommendations	NA	2000	Catheter type -No catheter seems to be superior to the standard two-cuff Tenckhoff catheter -Double-cuff catheters are recommended to reduce peritonitis and improve catheter survival time Catheter placement -Peritoneal entry should be lateral or paramedian -Exit site should be facing downward or be directed laterally. Upward-directed exit sites should in general be avoided
CARI guidelines	Australia	2003	Catheter type -No peritoneal dialysis catheter has proved to be superior in the prevention of peritonitis (level III evidence) Catheter placement -There is no technique of insertion of a peritoneal dialysis catheter that has consistently proved to be superior in the prevention of peritonitis (level II evidence)

<sup>a</sup> K/DOQI, Kidney Disease Outcomes Quality Initiative; ISPD, International Society of Peritoneal Dialysis; CARI, Caring for Australians with Renal Impairment; NA, not applicable.

exit-site and tunnel infection in PD. Trials of the following interventions were included: types of catheters (straight *versus* coiled, single *versus* double cuffed), types of surgical catheter insertion techniques (laparoscopy *versus* standard laparotomy, midline *versus* lateral insertion, subcutaneous buried *versus* standard insertion with resting but no subcutaneous burying of the catheter), type of PD sets (Y-set *versus* conventional spike systems or modifications of the Y-set, Y-set *versus* double-bag systems), and any other catheter-related interventions.

### Search Strategy

Electronic searches were performed in MEDLINE (1966 to May 2003), EMBASE (1988 to May 2003), and the Cochrane Renal Group Specialized Register using optimally sensitive search strategies for identification of randomized, controlled trials developed by the Cochrane Collaboration (15). The following medical subject heading terms and text words were used: peritoneal dialysis, peritonitis, infection, exit-site, tunnel, PD, CAPD, CCPD, APD, and IPD. The results of the searches were analyzed in title and abstract form by two of the authors (G.F.M.S. and A.T.) according to the inclusion criteria. Reference lists from identified articles and published guidelines were then

searched. Conference proceedings of the American Society of Nephrology (1999 to 2003), the European Dialysis and Transplantation Association (1999 to 2003), and on-line issues of PD International (1981 to 2004) were hand searched. Information about unpublished trials were sought from authors of retrieved, relevant studies. Trials were considered without language restriction.

### Data Extraction and Quality Assessment

Each trial was assessed by two independent reviewers (G.F.M.S. and A.T.). From all included trials, data were extracted on characteristics of the study sample, type of catheter or catheter-related intervention used, methodological characteristics of the trials, and outcomes. The following outcomes were considered: number of patients with one or more episodes of peritonitis, peritonitis rate (number of peritonitis episodes/total patient months on PD), number of patients with one or more episodes of exit-site/tunnel infection and exit-site/tunnel infection rate, catheter removal, catheter replacement, technique failure (transfer from PD to hemodialysis/transplant as a result of peritonitis), and all-cause mortality.

The quality of all trials was assessed using standard criteria (allocation concealment, blinding of participants, investigators and out-

come assessors, analysis by intention to treat, and completeness of follow-up) (16). Any differences and problems in data extraction were resolved by discussion among authors and in consultation with D.J. and J.C.C. When data were missing or incomplete, the authors of the trial were contacted for clarification.

### Statistical Analyses

Data from individual trials were analyzed using the relative risk (RR) measure and its 95% confidence intervals (CI). Subgroup analysis was planned to explore potential sources of variability in observed treatment effect when possible (pediatric *versus* adult population, diabetic *versus* nondiabetic, trial quality, timing of peritonitis or other outcome). Heterogeneity of treatment effects between studies was formally tested using the Q (heterogeneity  $\chi^2$ ) and the  $I^2$  statistics. When appropriate, summary estimators of treatment effects were calculated using a random effects model with RR and its 95% CI. When data on the number of subjects with events (*e.g.*, number of subjects with one or more episodes of peritonitis) were available, the RR was calculated as the ratio of the incidence of the event (one or more episodes) in the experimental treatment group over the incidence in the control group. When data on the number of episodes were available, the RR was calculated as the ratio of the rate of the outcome (*e.g.*, the peritonitis rate) in the experimental treatment group (given by number of episodes of the outcome over total patient months on PD) over the rate in the control group. This approach was used to overcome a limitation of reports of several trials in which event rates were erroneously compared by  $\chi^2$  analysis.

### Results

The combined search of MEDLINE, EMBASE, and the specialist registry of the Cochrane Renal Group identified 382 articles. Of these, 309 were excluded. The major reasons for exclusion were that selected studies were not randomized or that randomized trials evaluated other interventions (*e.g.*, antimicrobial interventions to prevent peritonitis; Figure 1). Full-text assessment of 73 potentially eligible papers identified 37 eligible trials (2822 patients) reported in 40 publications. One trial author responded to queries about study methods and/or requests for additional unpublished information.

### Trial Characteristics

Five groups of studies were identified. The first were studies of surgical approaches for the insertion of the PD catheter. There were eight trials in total (601 patients), of which three (248 patients) compared insertion of the catheter with laparoscopy *versus* laparotomy, three (233 patients) compared the effect of subcutaneous burying and resting of the catheter for 6 wk *versus* standard insertion (resting but no subcutaneous burying of catheter), and two (120 patients) compared midline *versus* lateral insertion (17–24). The second group of studies compared the use of straight *versus* coiled catheters. There were eight trials (405 patients) in this group (24–31). The third group of studies compared the use of the Y-set *versus* conventional spike systems or modified Y-set systems. There were 10 trials (761 patients) in this group (32–41). The fourth group of studies compared Y-set *versus* double-bag systems and included a total of four trials (416 patients) (42–45). Finally, there were seven “miscellaneous” trials in which the efficacy of other catheter-related interventions (*e.g.*, silver ring, antibi-

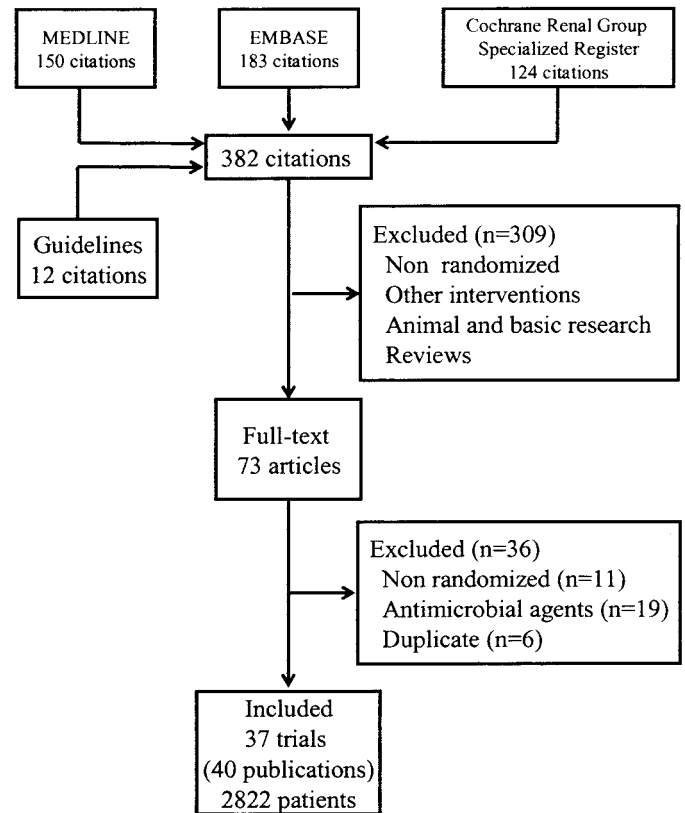


Figure 1. Flowchart indicating the number of citations retrieved by individual searches and the final number of included trials; reasons for exclusions are provided.

otic treated *versus* regular catheters, use of immobilization devices, APD *versus* CAPD) were evaluated (46–52) (Table 2).

### Trial Quality

The quality of the trials was difficult to assess because many details, such as the use of intention-to-treat analysis and the number of patients lost to follow-up, were difficult to ascertain or were not provided. In general, trial quality was variable, and almost all aspects of trials design did not fulfill CONSORT standards for reporting (53). Allocation concealment was adequate in only one trial, clearly inadequate (randomization according to patient even/odd identity numbers and alternation) in one trial, and unclear in all others. Outcome assessors were not stated as blinded in any of the trials. Blinding of participants was used in three (8%) of 37 trials, and blinding of investigators was used in three (8%) of 37 trials. Analysis was based on intention to treat in 12 (32%) of 37 trials. The proportion of patients who were lost to follow-up ranged from 1 to 12%.

### Trial Results

**Surgical Approaches for Insertion of the PD Catheter.** There was no significant difference in the risk of peritonitis (three trials, 238 patients; RR, 0.68; 95% CI, 0.41 to 1.15), catheter removal or replacement (two trials, 90 patients; RR,

Table 2. Characteristics of the populations and interventions in the randomized, controlled trials of catheter-related interventions for the prevention of peritonitis in peritoneal dialysis<sup>a</sup>

Study ID	Proportion of Diabetic Patients (%)	Interventions	No. of Patients	Follow-up (Months)
<b>Surgical catheter insertion technique</b>				
Gadallah <i>et al.</i> 1999 (17)	36	Laparoscopy <i>versus</i> standard laparotomy	148	36
Tsimoyiannis <i>et al.</i> 2000 (18)	NA	Laparoscopy <i>versus</i> standard laparotomy	50	21
Wright <i>et al.</i> 1999 (19)	NA	Laparoscopy <i>versus</i> standard laparotomy	50	24
Danielsson <i>et al.</i> 2002 (20)	28	Subcutaneous buried <i>versus</i> standard insertion	60	24
Moncrief and Popovich 1998 (21)	NA	Subcutaneous buried <i>versus</i> standard insertion	113	NA
Park <i>et al.</i> 1998 (22)	43	Subcutaneous buried <i>versus</i> standard insertion	60	24
Ejlertsen <i>et al.</i> 1990 (23)	NA	Midline <i>versus</i> lateral	37	3
Rubin <i>et al.</i> 1990 (24) <sup>b</sup>	24	Midline <i>versus</i> lateral	83	NA
<b>Straight <i>versus</i> coiled catheter</b>				
Akyol <i>et al.</i> 1990 (25)	12	Tenckhoff (straight) <i>versus</i> Tenckhoff (curled) catheter	40	13
Dasgupta <i>et al.</i> 2000 (26)	NA	Tenckhoff (straight) <i>versus</i> Moncrief-Popovich (curled) catheter	41	NA
Eklund <i>et al.</i> 1994 (27)	13	Single-cuff straight Tenckhoff <i>versus</i> one-bubble slanted flange single-cuff Swan Neck (coiled) catheter	40	NA
Eklund <i>et al.</i> 1995 (28)	16	Two-cuff straight Tenckhoff catheter <i>versus</i> two-cuff Swan neck (coiled) catheter	40	NA
Lye <i>et al.</i> 1996 (29)	35	Double-cuffed Swan-neck (coiled) <i>versus</i> double-cuffed Tenckhoff (straight) catheter	40	12
Nielsen <i>et al.</i> 1995 (30)	18	Tenckhoff (straight) <i>versus</i> permanently bent Swan neck (curled) catheter	72	6
Rubin <i>et al.</i> 1990 (24) <sup>b</sup>	24	Straight <i>versus</i> coiled catheter	83	NA
Scott <i>et al.</i> 1994 (31) <sup>c</sup>	NA	Double-cuffed Tenckhoff (straight) <i>versus</i> Toronto Western (curled) <i>versus</i> standard coiled Oreopoulos	89	12
<b>Y-set <i>versus</i> conventional spike catheter or modified Y-set</b>				
Cheng <i>et al.</i> 1994 (32)	15	O-set <i>versus</i> conventional spike <i>versus</i> UVXD <sup>d</sup>	100	>12
Churchill <i>et al.</i> 1989 (33)	NA	Y-set plus sodium hypochlorite <i>versus</i> standard system	124	12
Dryden <i>et al.</i> 1992 (34)	15	Y-set (Freeline solo) <i>versus</i> standard system	80	3–36
Li <i>et al.</i> 1996 (35)	20	Y-set (ultraset) <i>versus</i> conventional spike	40	12
Lindholm <i>et al.</i> 1988 (36)	28	5F take-off system <i>versus</i> conventional	58	9
Maiorca <i>et al.</i> 1983 (37)	NA	Y-set plus sodium hypochlorite <i>versus</i> standard system	62	18–24
Owen <i>et al.</i> 1992 (38)	NA	O-set <i>versus</i> standard	60	>12
Rottembourg <i>et al.</i> 1987 (39)	22	Y-set (Y-set or O-set or 5F safe-lock) <i>versus</i> conventional	55	33
Viglino <i>et al.</i> 1989 (40)	1	Y-set <i>versus</i> Travenol Advanced Bystem (TAB)	60	13
Viglino <i>et al.</i> 1993 (41)	20	Y-set <i>versus</i> T-set	122	15
<b>Y-set <i>versus</i> double bag</b>				
Harris <i>et al.</i> 1996 (42)	15	Y-set (standard) <i>versus</i> double bag (Freeline solo)	66	18
Kiernan <i>et al.</i> 1995 (43)	25	Ultra Y-set <i>versus</i> Ultra Twin Bag	83	4.5
Li <i>et al.</i> 1999 (44)	24	Y-set (ultraset) <i>versus</i> double bag (ultrabag) system	120	16
Monteon <i>et al.</i> 1998 (45) <sup>c</sup>	50	Y-set <i>versus</i> double bag <i>versus</i> straight spike	147	12
<b>Miscellaneous</b>				
De Fijter <i>et al.</i> 1991 (46)	NA	Y-set CAPD <i>versus</i> CCPD	56	18
Bro <i>et al.</i> 1999 (47)	4	Y-set CAPD <i>versus</i> APD (NIPD or CCPD)	34	6
Eklund <i>et al.</i> 1997 (48)	26	Single cuff <i>versus</i> double cuff Tenckhoff catheter	60	20
Li <i>et al.</i> 2002 (49)	38	Ultrabag <i>versus</i> Stay Safe	102	>12
Pommer <i>et al.</i> 1998 (50)	20	Silver ring <i>versus</i> none	195	4.5
Trooskin <i>et al.</i> 1990 (51)	NA	Antibiotic treated catheter <i>versus</i> none	86	NA
Turner <i>et al.</i> 1992 (52) <sup>c</sup>	20	Immobilizer device <i>versus</i> tape <i>versus</i> no immobilization	66	0.25–15

<sup>a</sup> Trials all were in adult populations. UVXD, ultraviolet irradiation connection box machine; NA, not available.

<sup>b</sup> Trial with four arms.

<sup>c</sup> Trial with three arms.



1.02; 95% CI, 0.49 to 2.13), technique failure (three trials, 206 patients; RR, 0.70; 95% CI, 0.45 to 1.08), and all-cause mortality (two trials, 193 patients; RR, 1.08; 95% CI, 0.52 to 2.26) with laparoscopy compared with laparotomy (Figure 2). There was no significant heterogeneity in any of these analyses. Other outcomes were reported only in individual trials that failed to show any significant difference in peritonitis rate (one trial, 375 patient months; RR, 0.89; 95% CI, 0.39 to 2.07) and exit-site/tunnel infection (one trial, 148 patients; RR, 0.11; 95% CI, 0.01 to 1.92).

Compared with standard insertion with resting but no subcutaneous burying of the catheter, implantation and subcutaneous burying of the catheter for 6 wk before exposure and initiation of PD was not associated with a significant reduction of the peritonitis rate (two trials, 2511 patient-months; RR, 1.16; 95% CI, 0.37 to 3.60), exit-site/tunnel infection rate (two trials, 2511 patient-months; RR, 1.15; 95% CI, 0.39 to 3.42), and all-cause mortality (two trials, 119 patients; RR, 0.90; 95% CI, 0.39 to 2.08; Figure 3). There was significant heterogeneity in these analyses that may be explained by the different types of catheter used in the trials (Moncrief-Popovich *versus* standard Tenckhoff catheter). Technique failure was reported in one trial that failed to show any significant difference with the two types of implantation technique (one trial, 60 patients; RR, 0.33; 95% CI, 0.04 to 3.03).

Midline compared with lateral insertion of the PD catheter was not associated with a statistically significant difference in the risk of peritonitis (two trials, 120 patients; RR, 0.65; 95% CI, 0.32 to 1.33) and exit-site/tunnel infection (two trials, 120 patients; RR, 0.56; 95% CI, 0.12 to 2.58; Figure 4). Catheter removal or replacement was reported in one trial that showed a significant reduction in the risk with midline catheter insertion (one trial, 83 patients; RR, 0.57; 95% CI, 0.33 to 0.98). All-cause mortality was reported in one trial that failed to show any significant difference in the risk (one trial, 37 patients; RR, 8.50; 95% CI, 0.50 to 143.32).

**Type of PD Catheter.** There was no significant difference in the risk of peritonitis (five trials, 324 patients; RR, 1.14; 95% CI, 0.73 to 1.79), peritonitis rate (four trials, 2589 patient-months; RR, 0.89; 95% CI, 0.63 to 1.26), exit-site/tunnel infection (six trials, 332 patients; RR, 1.26; 95% CI, 0.91 to 1.73), and exit-site/tunnel infection rate (three trials, 1993 patient-months; RR, 1.04; 95% CI, 0.73 to 1.47) between catheters with a straight *versus* a coiled intraperitoneal portion. There was no significant heterogeneity in any of these analyses (Figure 5). There was also no significant difference in the risk of catheter removal or replacement (five trials, 275 patients; RR, 1.11; 95% CI, 0.53 to 2.31), but heterogeneity in this analysis was significant (heterogeneity  $\chi^2 = 9.78$ ,  $I^2 = 59.1\%$ ). No difference was observed in the risk of technique

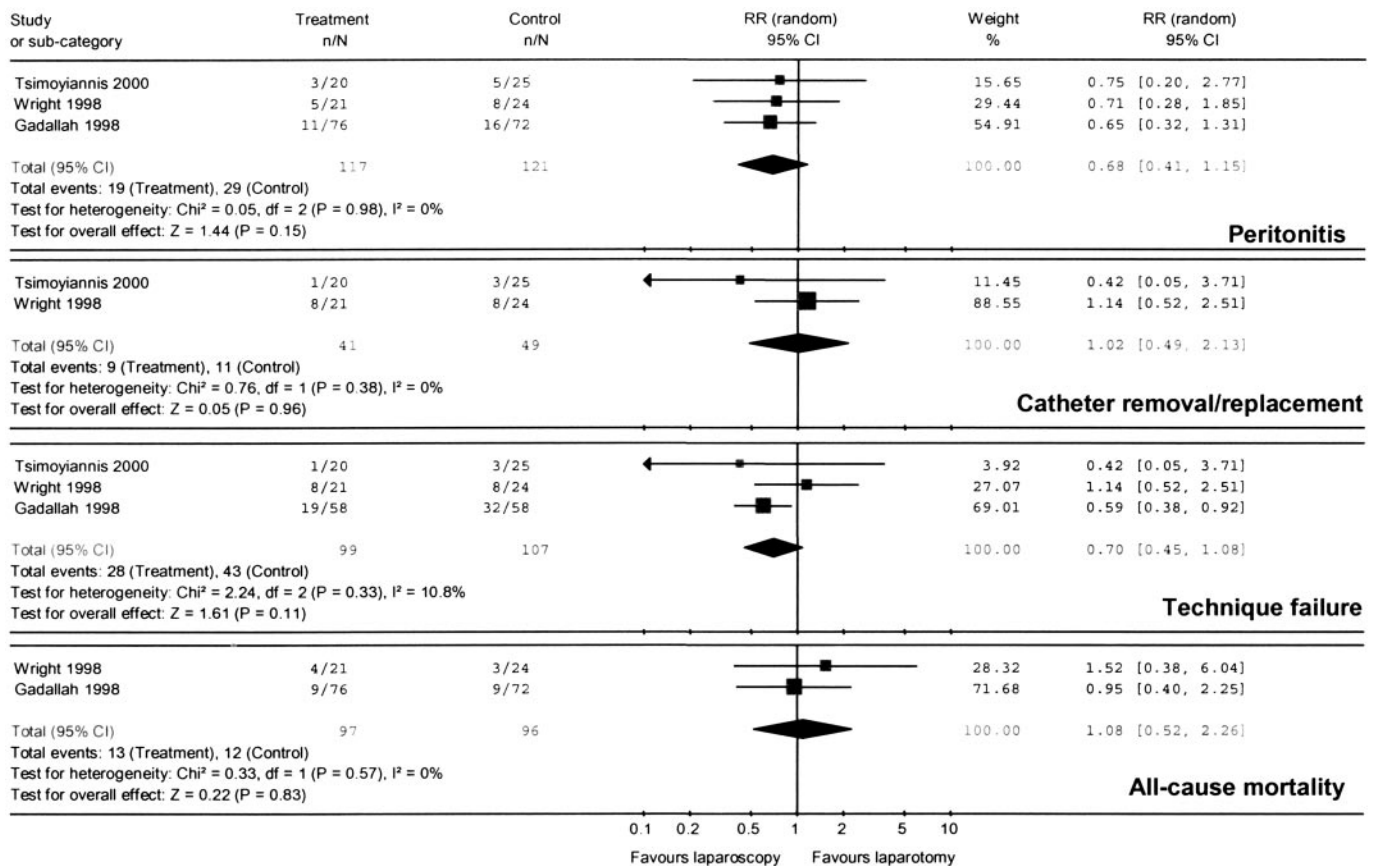


Figure 2. Catheter insertion by laparoscopy *versus* laparotomy in peritoneal dialysis (PD): Effect on peritonitis, catheter removal/replacement, technique failure, and all-cause mortality.

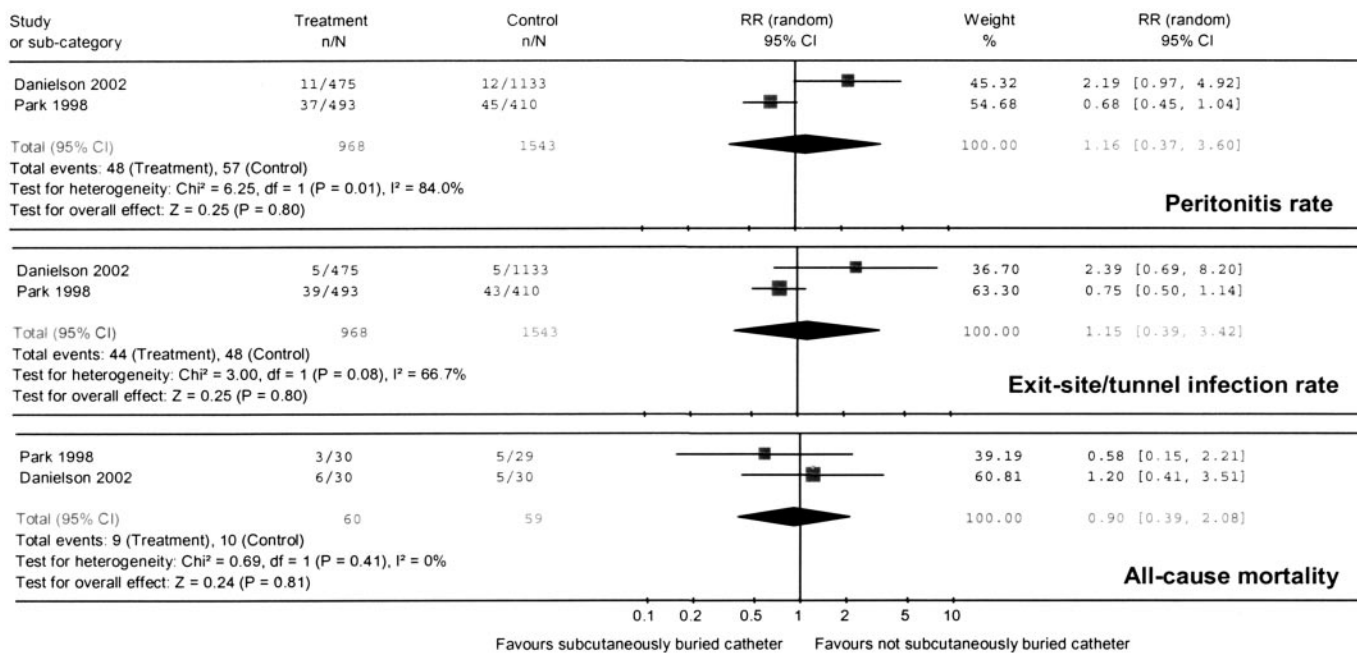


Figure 3. Subcutaneously buried versus standard insertion and immediate use of catheter in PD: Effect on peritonitis rate, exit-site/tunnel infection rate, and all-cause mortality.

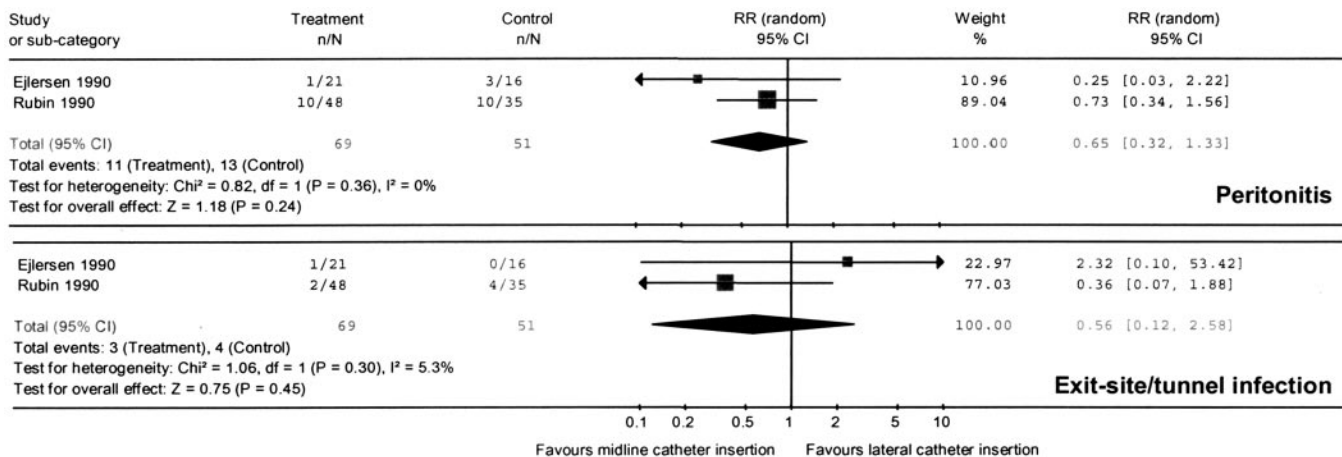


Figure 4. Midline versus lateral insertion of PD catheter: Effect on peritonitis and exit-site/tunnel infection.

failure (one trial, 40 patients; RR, 0.33; 95% CI, 0.01 to 7.72). There was a significantly lower risk of all-cause mortality with the use of straight compared with coiled catheters (four trials, 209 patients; RR, 0.26; 95% CI, 0.07 to 0.99), with no significant heterogeneity (Figure 6). The causes of death were not specified in these trials, except for the trial of Eklund *et al.* (28), which reported that three deaths were imputable to complication of diabetes and one to amyloidosis. Only one trial (60 patients) comparing single- versus double-cuffed catheters was available showing no significant difference in the risk of peritonitis, exit-site/tunnel infection, catheter removal/replacement, and all-cause mortality (48).

**Type of PD Set.** The use of the Y-set compared with standard spike systems was associated with a significantly lower risk of peritonitis (seven trials, 485 patients; RR, 0.64;

95% CI, 0.53 to 0.77) and peritonitis rate (eight trials, 7417 patient-months; RR, 0.49; 95% CI, 0.40 to 0.61) but no difference in exit-site/tunnel infection (three trials, 226 patients; RR, 1.00; 95% CI, 0.70 to 1.43) and rate (two trials, 2841 patient-months; RR, 1.24; 95% CI, 0.91 to 1.69; Figure 7). There was also no difference in catheter removal/replacement (two trials, 126 patients; RR, 0.80; 95% CI, 0.40 to 1.63) and all-cause mortality (five trials, 386 patients; RR, 0.96; 95% CI, 0.47 to 1.95). Technique failure was reported in only one trial (60 patients) that showed a significant increase in the risk with the Y-set (RR, 2.00; 95% CI, 1.14 to 3.52) (38).

There was no statistically significant difference with double-bag systems compared with Y-set for peritonitis (three trials, 292 patients; RR, 0.59; 95% CI, 0.35 to 1.01), peritonitis rate (four trials, 4319 patients-months; RR, 0.90; 95% CI, 0.49 to

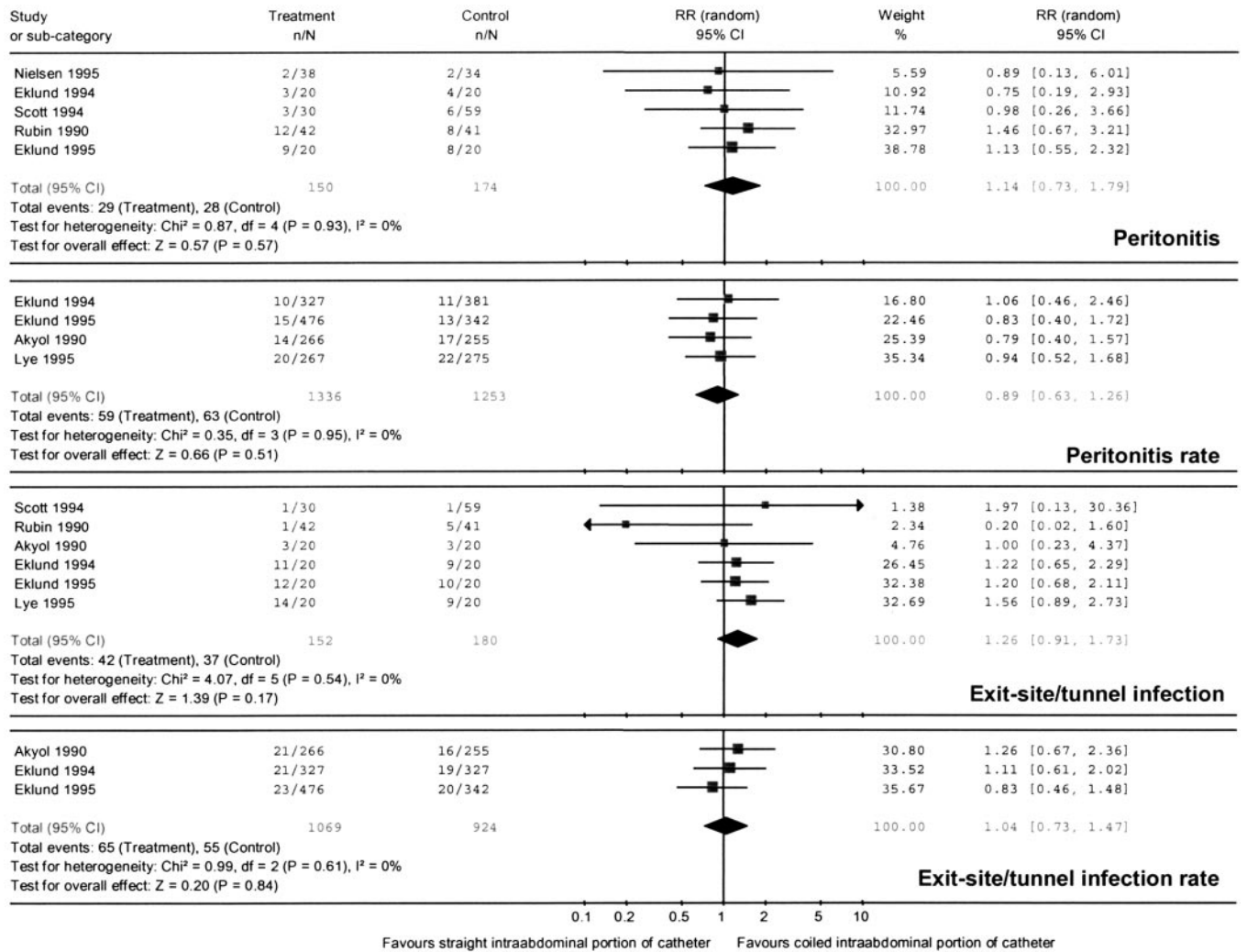


Figure 5. Straight versus coiled PD catheters: Effect on peritonitis, peritonitis rate, exit-site/tunnel infection, and exit-site/tunnel infection rate.

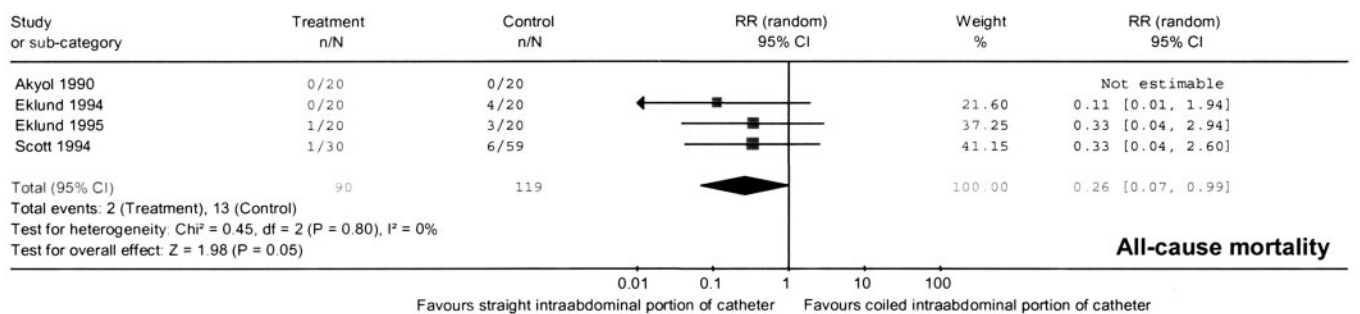


Figure 6. Straight versus coiled PD catheters: Effect on all-cause mortality.

1.66), and exit-site/tunnel infection rate (two trials, 2319 patient months; RR, 1.04; 95% CI, 0.52 to 2.06; Figure 8). There was also no difference in catheter removal/replacement (three trials, 321 patients; RR, 0.83; 95% CI, 0.40 to 1.73) and all-cause mortality (two trials, 174 patients; RR, 1.58; 95% CI, 0.48 to 5.26). The analysis of peritonitis rate showed significant heterogeneity (heterogeneity  $\chi^2 = 12.24$ ,  $I^2 = 75.5\%$ ), which is imputable to the trial of Kiernan *et al.* (43). This trial

had a shorter follow-up duration compared with all others. There were also two trials that compared the standard Y-set and modified Y systems (the TAB set and the T system) and showed no significant difference in the risk of any outcomes with these modified sets (40,41).

**Other Interventions.** Other interventions that were tested in published trials included the use of single-cuff versus double-cuff Tenckhoff catheter, the Ultrabag versus the Stay Safe



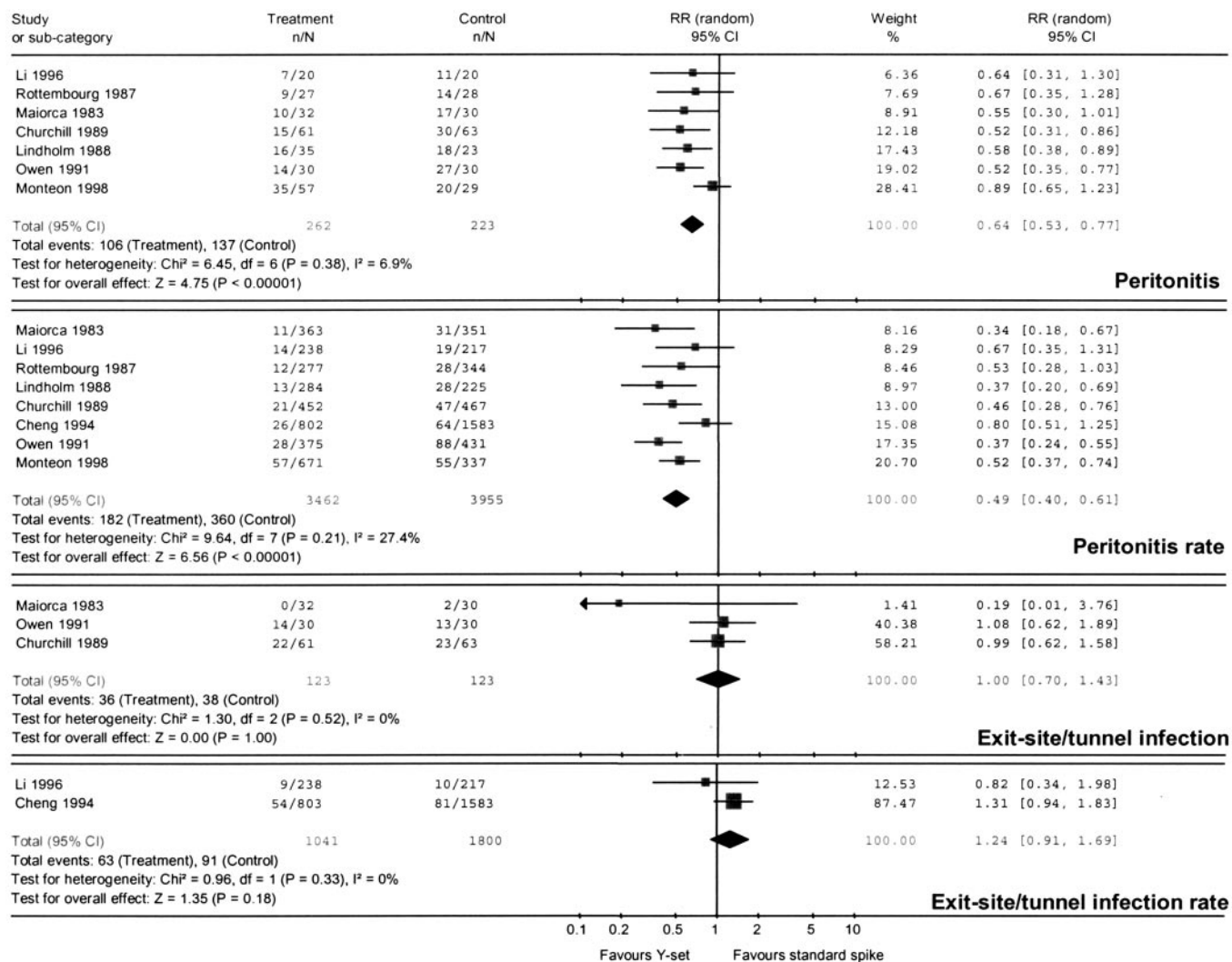


Figure 7. Y-set versus standard spike systems: Effect on peritonitis, peritonitis rate, exit-site/tunnel infection, and exit-site/tunnel infection rate.

set, the use of a silver ring at the catheter insertion compared with a standard straight catheter, the use of antibiotic-treated catheters compared with normal ones, and the use of immobilization devices. There was also one trial that compared CAPD with a Y set and CCPD with a normal set and one of APD versus CAPD. None of these trials showed significant differences for any of the outcomes of interest.

**Discussion**

Our systematic review of PD catheter-related interventions has demonstrated that disconnect (double-bag and Y-connection) systems are superior to conventional spike (or luer lock) connect systems for the prevention of peritonitis. There was no statistically significant advantage of twin-bag systems compared with Y-systems, although the former were associated with a trend toward fewer affected patients with peritonitis ( $P = 0.05$ ). The use of straight catheters was associated with a significantly lower risk of all-cause mortality than coiled catheters (RR, 0.26; 95% CI, 0.07 to 0.99), but rates of peritonitis, exit-site/tunnel infections, and catheter removal/replacement

were comparable between the two catheter types. No other catheter-related interventions (surgical catheter insertion technique, single versus double cuff, Ultrabag versus Staysafe, silver ring catheters, antibiotic-treated catheters, immobilizer devices, or automated PD versus CAPD) were shown to be beneficial.

To our knowledge, the present study represents the most comprehensive systematic review of the relative benefits and harms of different catheter-related interventions in PD patients. One previous meta-analysis of 12 randomized controlled trials (991 patients) compared double-bag, Y-connection, and conventional spike systems (54). In keeping with the findings of our present larger review (12 trials and 991 patients versus 37 trials and 2822 patients), conventional spike systems were found to be associated with significantly increased peritonitis rates compared with the disconnect systems. The most likely reason for this observation is a reduction of inadvertent peritoneal microbial contamination during connections with Y-set and twin-bag systems as a result of the “flush before fill” maneuver (55). Although the elimination of one connection



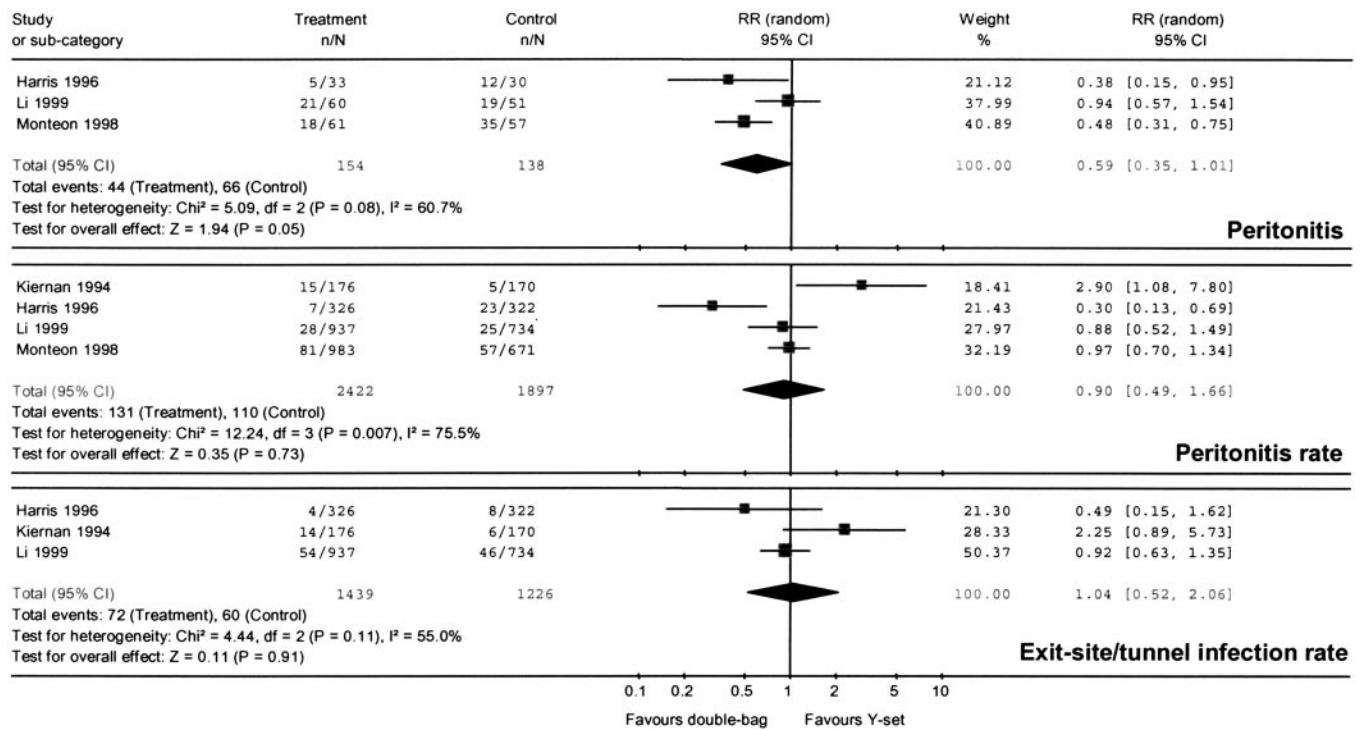


Figure 8. Double-bag versus Y-set systems: Effect on peritonitis, peritonitis rate, and exit-site/tunnel infection rate.

procedure by twin-bag systems theoretically should further reduce peritonitis episodes beyond that achieved by Y-connection systems, this was unable to be demonstrated in our study. In contrast, the systematic review by Daly *et al.* (54) reported a significantly lower risk of experiencing peritonitis episodes with double-bag systems compared with Y-systems (odds ratio, 0.44; 95% CI, 0.27 to 0.71). This apparent disparity may be partly explained by the more conservative statistical approach adopted in our meta-analysis (random effects model) compared with that used by Daly *et al.* (54) (fixed effects model). To assess better the robustness of our statistical findings, we additionally evaluated peritonitis rates as episodes per month (rather than just number of patients experiencing peritonitis) and again demonstrated no statistically significant differences between the two disconnect systems. Similar findings were observed for the other outcome measures evaluated, including exit-site/tunnel infections, catheter removal/replacement, technique survival, and all-cause mortality.

These results support the recommendations of the British Renal Association and the Caring for Australians with Renal Impairment guidelines against the use of conventional spike connection systems. Although the International Society of Peritoneal Dialysis and Kidney Disease Outcomes Quality Initiative clinical practice guidelines make no specific recommendations about connection method, spike and luer lock connect system usage has generally been declining in recent years. In the United Kingdom, the use of connect PD systems has decreased from 22% in 1998 to <1% in 2002 (56). A similar experience has been reported in Australia and New Zealand (57).

Apart from connection systems, no other catheter-related interventions seemed to have a significant impact on patient outcomes. The one exception was the meta-analysis of four randomized, controlled trials that compare straight and coiled catheters, which demonstrated a reduction in all-cause mortality associated with straight catheters. This result was unexpected and largely unexplained, particularly in view of the similar rates of peritonitis, exit-site/tunnel infections, and catheter removal/replacement observed with the two catheter types. Causes of death were not reported to clarify further on this finding. Only one trial reported that three deaths were associated with complications of diabetes and one with amyloidosis (28). Potential alternative explanations include a type 1 statistical error (most likely) or inadequate randomization, possibly as a result of suboptimal allocation concealment. In any case, this result should be interpreted with caution.

An appreciable number of PD catheter implantation techniques have been proposed to reduce the risk of catheter-associated infections. These methods have been described in detail in the International Society of Peritoneal Dialysis guidelines for peritoneal catheter management (58). Our review identified eight randomized, controlled trials of PD catheter insertion techniques (laparoscopy versus laparotomy or subcutaneous buried versus standard insertion or midline versus lateral placement) but found no evidence that any particular technique resulted in enhanced clinical outcomes. These findings support the recommendations of the Caring for Australians with Renal Impairment guidelines (59), which state that no implantation technique has been shown definitively to be superior.

Several retrospective, observational cohort studies have suggested that automated PD (APD) is associated with a reduced risk of peritonitis compared with CAPD (60–62) and have speculated that this may reflect the reduced number of connections (and therefore opportunities for intraluminal contamination) involved with APD. However, interpretation of these findings is potentially confounded by the possibility of selection and recall biases. We could identify only two small, relatively short-duration, randomized, controlled trials of APD *versus* CAPD (46,47). No differences in PD outcomes were observed, but the possibility of a type 2 statistical error could not be excluded.

The strength of this investigation is that it represents a comprehensive systematic review based on a previous publication of a detailed protocol (63); rigid inclusion criteria for randomized, controlled trials only; and a comprehensive MEDLINE, EMBASE, and Cochrane Controlled Trial Registry search. Data extraction, data analysis, and method quality assessments were performed by two independent investigators, and consistency was checked with an additional two reviewers. Furthermore, infectious outcomes were examined separately in terms of rates per patient-month and the number of patients affected to maximize statistical power and to verify the robustness of statistical analyses. Several studies reported peritonitis incidence as an outcome with the limitation that the presence of two or more episodes in one patient were not statistically independent events; we considered the outcome of number of patients affected by peritonitis (one or more episodes) to overcome this limitation and in conjunction also analyzed the outcome of peritonitis rate given by the rate of episodes over total patient-months on PD.

The main weakness of this study was the relative paucity of quality randomized, controlled trials. The vast majority of studies evaluated failed to specify whether randomization allocation was concealed, outcome assessors were blinded, or data were analyzed on an intention-to-treat basis. Many studies were small and often short in duration, so the possibility of a type 2 statistical error for some of the less frequently observed outcome measures (*e.g.*, catheter loss) could not be excluded. Moreover, evidence of trial heterogeneity was found in some analyses of peritonitis rates (*e.g.*, for laparoscopy *versus* laparotomy and twin-bag *versus* Y-set), which most likely reflected significant intertrial variation in durations of follow-up. These issues reduce the strength of the conclusions that have been drawn in this review.

In conclusion, this systematic review demonstrates that disconnect (twin-bag and Y-set) systems are clearly superior to conventional spike systems with respect to the prevention of peritonitis. No clear advantage of twin-bag over Y-set systems could be shown, although available trials were limited. Similarly, no clear benefit was observed for different catheter designs, implantation techniques, or APD. Judging by the point estimates, none of the interventions looked promising, although further study may be necessary to compare laparoscopy with laparotomy for insertion of PD catheters, as wide CI around the point estimates for peritonitis and technique failure are also suggestive of a lack of statistical power. A survival

advantage was identified for straight catheters compared with coiled catheters, but these results should be interpreted with caution, because no clear differences were observed with respect to peritonitis, exit-site/tunnel infections, catheter removal/replacement, or technique survival, *i.e.*, the inability to show an intervention-related mechanism for reduction in mortality suggests that this is a spurious finding. This review also demonstrates that PD catheter-related interventions have been very poorly studied to date. It should be emphasized that because of the paucity and suboptimal quality of available studies, there is an obvious need in this area for well-designed, randomized, controlled studies, involving experts in trial methodology, based on clear descriptions of trial methods and choice of appropriate outcome measures (*e.g.*, first peritonitis episode *versus* peritonitis rates).

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