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Catheter type, placement and insertion techniques for preventing peritonitis in peritoneal dialysis patients — Source link \square

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[Intervention Review]

Catheter type, placement and insertion techniques for preventing peritonitis in peritoneal dialysis patients

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ABSTRACT

Background

As many as 15-50% of end-stage kidney disease patients are on peritoneal dialysis (PD), but peritonitis limits its more widespread use. Several PD catheter-related interventions have been purported to reduce the risk of peritonitis in PD.

Objectives

To evaluate the use of catheter-related interventions for the prevention of peritonitis in PD.

Search methods

The Cochrane Renal Group's specialised register (June 2004), The Cochrane CENTRAL Register of Controlled Trials (*The Cochrane Library* Issue 2 2004), MEDLINE (1966-April 2004), EMBASE (1988-April 2004) and reference lists were searched without language restriction

Selection criteria

Trials comparing different catheter insertion techniques, catheter types, use of immobilisation techniques or different break in periods were included. Trials of different PD sets were excluded.

Data collection and analysis

Two reviewers independently assessed trial quality and extracted data. Statistical analyses were performed using a random effects model and the results expressed as risk ratio (RR) with 95% confidence intervals (CI).

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Main results

Seventeen eligible trials (1089 patients) were identified, eight of surgical strategies of catheter insertion, eight of straight versus coiled catheters, one of single cuff versus double cuff catheters and one of an immobiliser device. The methodological quality was suboptimal. There were no significant differences with laparoscopy compared with laparotomy for peritonitis, the peritonitis rate, exit-site/tunnel infection or catheter removal/replacement. Standard insertion with resting but no subcutaneous burying of the catheter versus implantation and subcutaneous burying was not associated with a significant difference in the risk of peritonitis rate, exit-site/tunnel infection. There was no significant difference in the risk of peritonitis, peritonitis rate, exit-site/tunnel infection, exit-site/tunnel infection rate or catheter removal/replacement between straight versus coiled intraperitoneal portion catheters. One trial compared single versus double cuffed catheters and showed no significant difference in the risk of peritonitis, exit-site/tunnel infection or catheter removal/replacement between straight versus coiled intraperitoneal portion catheters. One trial compared single versus double cuffed catheters and showed no significant difference in the risk of peritonitis, exit-site/tunnel infection or catheter removal/replacement. One trial compared immobilisation versus no immobilisation of the PD catheter and showed no significant difference in the risk of difference break-in periods were identified.

Authors' conclusions

No major advantages from any of the catheter-related interventions which have been purported to reduce the risk of PD peritonitis could be demonstrated in this review. The frequency and quality of available trials are suboptimal.

PLAIN LANGUAGE SUMMARY

No reduction in the incidence of peritonitis could be shown from catheter-related interventions for peritoneal dialysis

People with advanced kidney disease may be treated with peritoneal dialysis where a catheter is permanently inserted into the peritoneum (lining around abdominal contents) through the abdominal wall and sterile fluid is drained in and out a few times each day. The most common serious complication is infection of the peritoneum - peritonitis. This may be caused by bacteria accidentally being transferred from the catheter. This review of different catheter types, insertion or immobilisation techniques showed that they do not reduce the incidence of peritonitis.

BACKGROUND

Peritonitis is a major complication of peritoneal dialysis (PD), a major cause of hospitalisation (CANUSA 1996) and is associated with increased morbidity (Luzar 1990) and mortality (Digenis 1990). There is variability in the use of PD across countries. Fifteen percent of the United States end stage kidney disease (ESRD) population is on 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. The incidence of peritonitis depends on age, coexisting diseases (e.g. diabetes), PD modality and interventions (Yishak 2001), catheter design and implantation technique, connection methodology and the presence of nasal reservoirs of Staphylococcus aureus (Schaefer 2003). Although there has been a dramatic decrease in the rates of peritonitis from the inception of continuous ambulatory peritoneal dialysis (CAPD), rates above 0.5 episodes/patient/year are still common (Piraino 2002). These values are even higher in the paediatric population (Oxton 1994; Salusky 1997). In addition, the rate of peritonitis relapse is approximately 0.5 episodes/pa-tient/year (Vas 2001).

Risk factors identified for peritonitis in the absence of prophylactic antibiotic treatment at the time of catheter placement are *S. aureus* nasal carriage, the use of single cuffed (versus doublecuffed) catheters and the upward (versus downward) pointing of the tunnel (Piraino 2002). Particular populations including the immunosuppressed patients, African-American and native American patients are also at increased risk (Fine 1994; Golper 1996; Holley 1993; Piraino 2002).

The prevention of PD peritonitis has primarily focused on antimicrobial prophylaxis. The evaluation of evidence which underlies the use of different anti-microbial strategies to prevent PD has been the subject of an another systematic review (Strippoli 2004). There has also been a systematic review on the use of Y-set compared to double bag systems (Daly 2001) however the impact of

catheter types (straight versus coiled, single versus double-cuffed), types of surgical insertion techniques (laparoscopy versus laparotomy, midline versus lateral insertion, subcutaneous buried versus standard insertion with resting but no subcutaneous burying of the catheter), different break-in periods and catheter immobilisation devices on preventing PD peritonitis have not been systematically assessed.

Many of these interventions are routinely used but guidelines on the topic are rare and indications relating to catheter types and insertion techniques are few. In general guidelines have focused on aspects of connection methodology rather than catheter type and insertion technique (Table 1 - *Published guidelines on catheter related interventions in peritoneal dialysis*).

In this review we focused on the effectiveness of different catheter types, placement and insertion techniques, break-in period and use of immobilisation devices for the prevention of infection in PD patients.

OBJECTIVES

To evaluate the evidence that supports the use of different catheter types and placement and insertion techniques, break in periods and immobilisation devices for the prevention of peritonitis in PD patients.

METHODS

Criteria for considering studies for this review

Types of studies

All randomised controlled trials (RCTs) and quasi-RCTs investigating the effect of different catheter types, placement and insertion techniques for the prevention of peritonitis in PD patients.

Types of participants

Adult and paediatric patients undergoing PD treatment.

Types of interventions

• Surgical catheter insertion techniques (laparoscopy, laparotomy, subcutaneous burying and rest of catheter, standard insertion with resting but no subcutaneous burying of catheter,

Milline insertion, lateral insertion)
Catheter types (straight, coiled, single-cuffed, double-

cuffed)

• Use of immobilisation techniques

• Break-in period

Types of outcome measures

• Peritonitis - number of patients with peritonitis and peritonitis rate (peritonitis defined as dialysate count of > 100 cells/mm³ with > 50% being polymorphonuclear leukocytes)

• Peritonitis relapse (reoccurrence of peritonitis due to the same organism within 2-4 weeks)

• Death due to peritonitis (data on all-cause mortality was also extracted)

• Exit-site and tunnel infection - number of patients with exit-site and tunnel infection and exit-site and tunnel infection rates

• Catheter removal/catheter replacement

• Technique failure (transfer from PD to haemodialysis/ transplant due to peritonitis)

• Time to first peritonitis episode

Search methods for identification of studies

Relevant trials were obtained from the following sources (see Additional Table 2 - *Electronic search strategies* for search terms used)

1. Cochrane Renal Group specialised register of RCTs (June 2004).

2. Cochrane Central Register of Controlled Trials (CENTRAL - Issue 2, 2004) for any "New" records not yet incorporated in the specialised register.

3. MEDLINE and Pre MEDLINE (1966 to April 2004) were searched, combined with the optimally sensitive strategy for the identification of RCTs (Dickersin 1994) (see Cochrane Renal Group Module).

4. EMBASE (1980 to April 2004) was searched using terms similar to those used for MEDLINE and combined with a search strategy for the identification of RCTs (Lefebvre 1996).

5. Reference lists of nephrology textbooks, review articles and relevant trials.

6. Letters seeking information about unpublished or incomplete trials to investigators known to be involved in previous trials.

7. There was no language restriction.

Data collection and analysis

The review was undertaken by five reviewers (GFMS, AT, DJ, FPS, JC). The search strategy described was used to obtain titles and abstracts of studies that might be relevant to the review. The titles and abstracts were screened independently by GFMS and AT, who discarded studies that were not applicable based on the inclusion criteria for this review; however studies and reviews that might include relevant data or information on trials were retained

initially and their full-text version was analysed. Reviewers GFMS and AT independently assessed retrieved abstracts and, if necessary, the full text of these studies to determine study eligibility. Data extraction was carried out independently by the same reviewers using standard data extraction forms. It was planned that studies reported in non-English language journals would be translated before assessment. Where more than one publication of one trial existed, only the publication with the most complete data was included. Any further information or clarification required from the authors was requested by written or electronic correspondence and relevant information obtained in this manner was included in the review. Disagreements were resolved in consultation with DJ and JC.

Study quality

The quality of included studies was assessed independently by GFMS and AT without blinding to authorship or journal using the checklist developed by the Cochrane Renal Group. Discrepancies were resolved by discussion with DJ and JC. The quality items assessed were allocation concealment, blinding of investigators, participants and outcome assessors, intention-to-treat analysis, and the completeness to follow-up.

Quality checklist

Allocation concealment

• *Adequate (A):* Randomisation method described that would not allow investigator/participant to know or influence intervention group before eligible participant entered in the study

• *Unclear* (B): Randomisation stated but no information on method used is available

• *Inadequate* (C): Method of randomisation used such as alternate medical record numbers or unsealed envelopes; any information in the study that indicated that investigators or participants could influence intervention group

Blinding

- Blinding of investigators: Yes/no/not stated
- Blinding of participants: Yes/no/not stated
- Blinding of outcome assessor: Yes/no/not stated
- Blinding of data analysis: Yes/no/not stated

The above are considered not blinded if the treatment group can be identified in > 20% of participants because of the side effects of treatment.

Intention-to-treat analysis

• Yes: Specifically reported by authors that intention-to-treat analysis was undertaken and this was confirmed on study assessment.

• Yes: not specifically stated but confirmed on study assessment

• No: Not reported and lack of intention-to-treat analysis confirmed on study assessment (Patients who were randomised were not included in the analysis because they did not receive the study intervention, they withdrew from the study or were not included because of protocol violation).

- No: Stated, but not confirmed upon study assessment
- Not stated

Completeness to follow-up

Per cent of participants excluded or lost to follow-up.

Statistical assessment

Data from individual trials were analysed using the risk ratio (RR) measure and its 95% confidence intervals (CI). Subgroup analysis was planned to explore potential sources of variability in observed treatment effect where possible (paediatric versus adult population, diabetic versus non-diabetic, trial quality, timing of peritonitis or other outcome). Heterogeneity of treatment effects between studies was formally tested using the Q (heterogeneity χ^2) and the I² statistics. When appropriate, summary estimators of treatment effects were calculated using a random effects model with RR and its 95% CI. Where 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. Where data on the number of episodes were available, then 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. It was also planned that if sufficient RCTs were identified, an attempt would be made to assess for publication bias using a funnel plot (Egger 1997).

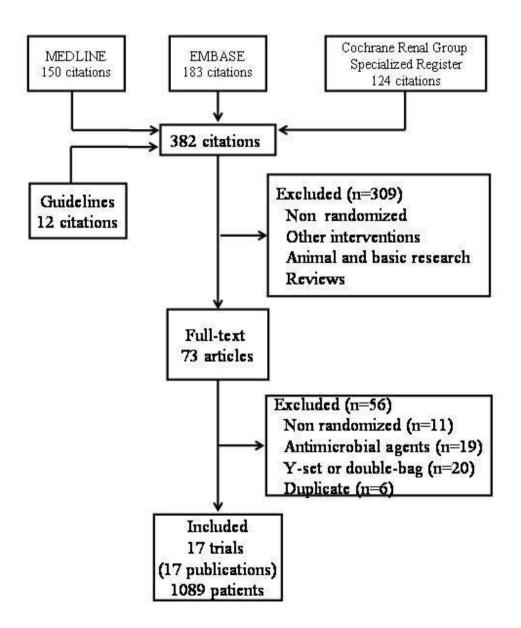
RESULTS

Description of studies

The combined search of MEDLINE, EMBASE, CENTRAL and the specialist registry of the Cochrane Renal Group identified 382 articles. Of these, 309 were excluded. The major reasons for exclusion were 1) studies were not randomised or 2) randomised

trials evaluating other non catheter-related interventions (Figure 1). Full-text assessment of 73 potentially eligible papers identified 17 eligible trials (1089 patients) reported in 40 publications.





There were eight trials in total (601 patients) of surgical approaches for the insertion of the PD catheter. Of these, 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 six weeks versus standard insertion (resting but no subcutaneous burying of catheter) and two (120 patients) compared midline versus lateral insertion (Danielson 2002; Ejlersen 1990; Gadallah 1999; Moncrief 1998; Park 1998; Rubin 1990; Tsimoyiannis 2000; Wright 1998).

A second group of eight studies (405 patients) compared the use of straight versus coiled catheters (Akyol 1990; Dasgupta 2000; Eklund 1994; Eklund 1995; Lye 1995; Nielsen 1995; Rubin 1990; Scott 1994).

The remaining trials compared single-cuff versus double-cuff catheters (Eklund 1997) and an immobiliser device versus the use of tape or no immobilisation (Turner 1992).

Risk of bias in included studies

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 fulfil CONSORT standards for reporting (CONSORT 2001).

Allocation concealment

Allocation concealment was adequate in two trials (Eklund 1994; Nielsen 1995), inadequate in two (Gadallah 1999 - alternate months; Lye 1995 -alternation) and unclear in the remainder of the trials.

Blinding

Blinding was used in 2/17 (12%) trials for participants and investigators (Akyol 1990; Lye 1995). No trial blinded the outcome assessors or data analysts.

Intention-to-treat analysis

Four of 17 trials (24%) used intention-to-treat analysis (Ejlersen 1990; Eklund 1994;Eklund 1995; Lye 1995).

Completeness of follow-up

The proportion of patients lost to follow-up ranged from 1% to 10%.

Effects of interventions

Laparoscopy versus laparotomy

There was no significant difference in the risk of all-cause mortality with laparoscopy compared to laparotomy (Analysis 1.1 (2 trials, 193 patients): RR 1.08, 95% CI 0.52 to 2.26). There was no significant heterogeneity in this analysis (heterogeneity $\chi^2 = 0.33$, P = 0.57, I² = 0%). There were no significant differences with laparoscopy compared with laparotomy for peritonitis (Analysis 1.2 (3 trials, 238 patients): RR 0.68, 95% CI 0.41 to 1.15), the peritonitis rate (Analysis 1.3 (1 trial, 375 patient-months): RR 0.89, 95% CI 0.39 to 2.07), exit-site/tunnel infection (Analysis 1.4 (1 trial, 148 patients): RR 0.11, 95% CI 0.01 to 1.92), catheter removal or replacement (Analysis 1.5 (2 trials, 90 patients): RR 1.02, 95% CI 0.49 to 2.13) and technique failure (Analysis 1.6 (3 trials, 206 patients): RR 0.70, 95% CI 0.45 to 1.08). There was no significant heterogeneity in any of these analyses.

Implantation and subcutaneous burying of the catheter versus standard insertion with resting but no subcutaneous burying of the catheter

Compared to standard insertion with resting but no subcutaneous burying of the catheter, implantation and subcutaneous burying of the catheter for six weeks prior to exposure and initiation of PD was not associated with a significant reduction in all-cause mortality (Analysis 2.1 (2 trials, 119 patients): RR 0.90, 95% CI 0.39 to 2.08), peritonitis rate (Analysis 2.2 (2 trials, 2511 patientmonths): RR 1.16, 95% CI 0.37 to 3.60) and exit-site/tunnel infection rate (Analysis 2.3 (2 trials, 2511 patient-months): RR 1.15, 95% CI 0.39 to 3.42). There was significant heterogeneity (heterogeneity $\chi^2 = 6.25$, I² = 84%) in the analysis of peritonitis rate which may be explained by the different type of catheter used in the trials (Moncrief-Popovich catheter versus standard Tenckhoff catheter). Technique failure was reported in one trial which failed to show any significant difference with the two types of implantation technique (Analysis 2.4 (1 trial, 60 patients): RR 0.33, 95% CI 0.04 to 3.03).

Midline versus lateral insertion of the PD catheter

Midline compared to lateral insertion of the PD catheter was not associated with a statistically significant difference in the risk of peritonitis (Analysis 3.2 (2 trials, 120 patients): RR 0.65, 95% CI 0.32 to 1.33) and exit-site/tunnel infection (Analysis 3.3 (2 trials,

120 patients): RR 0.56, 95% CI 0.12 to 2.58). All-cause mortality was reported in one trial which failed to show any significant difference in the risk (Analysis 3.1 (1 trial, 37 patients): RR 8.50, 95% CI 0.50 to 143.32). Catheter removal or replacement was reported in one trial which showed a significant reduction in the risk with midline catheter insertion (Analysis 3.4 (1 trial, 83 patients): RR 0.57, 95% CI 0.33 to 0.98).

Straight versus coiled PD catheter

There was no significant difference in the risk of peritonitis (Analysis 4.2 (5 trials, 324 patients): RR 1.14, 95% CI 0.73 to 1.79), peritonitis rate (Analysis 4.03 - 4 trials, 2589 patientmonths: RR 0.89, 95% CI 0.63 to 1.26), exit-site/tunnel infection (Analysis 4.4 (6 trials, 332 patients): RR 1.26, 95% CI 0.91 to 1.73) and exit-site/tunnel infection rate (Analysis 4.5 (3 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. There was also no significant difference in the risk of catheter removal or replacement (Analysis 4.6 (5 trials, 275 patients): RR 1.11, 95% CI 0.53 to 2.31) but heterogeneity in this analysis was significant (heterogeneity $\chi^2 = 9.78$, I² = 59.1%) No difference was observed in the risk of technique failure (Analysis 4.7 (1 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 to coiled catheters (Analysis 4.1 (4 trials, 209 patients): RR 0.26, 95% CI 0.07 to 0.99), with no significant heterogeneity. The causes of death were only specified in the trial of Eklund 1995 which reported that three deaths were imputable to complications of diabetes and one to amyloidosis.

Single cuff versus double cuff catheters

Only one trial (60 patients) (Eklund 1997) compared single versus double cuffed catheters and showed no significant difference in the risk of all-cause mortality (Analysis 5.01: RR 0.40, 95% CI 0.08 to 1.90), peritonitis (Analysis 5.2: RR 0.82, 95% CI 0.50 to 1.35), exit-site/tunnel infection (Analysis 5.3: RR 0.79, 95% CI 0.43 to 1.44) and catheter removal or replacement (Analysis 5.4: RR 2.00, 95% CI 0.55 to 7.27).

Use of immobilisation techniques

There was one trial (66 patients) (Turner 1992) comparing the use of immobilisation techniques versus no immobilisation of the PD catheter, which failed to show a significant difference with these approaches in the risk of peritonitis (Analysis 6.1: RR 1.20, 95% CI 0.59 to 2.42) and exit-site/tunnel infection (Analysis 6.2: RR 0.65, 95% CI 0.35 to 1.22).

Break-in period

There were no trials which evaluated the impact of different breakin periods on the risk of PD peritonitis.

DISCUSSION

Our systematic review of PD catheter-related interventions has found that no catheter-related interventions (including surgical catheter insertion technique, straight versus coiled catheters, single cuff versus double cuff, immobiliser devices) have any impact on the risk of peritonitis, exit-site and tunnel infection in PD. The use of straight catheters was found to be associated with a significantly lower risk of all-cause mortality compared to coiled catheters (RR 0.26, 95% CI 0.07 to 0.99), although rates of peritonitis, exit site/ tunnel infections and catheter removal/replacement were comparable between the two catheter types which makes the finding very likely to be spurious.

To the best of our knowledge the present study is the first of its kind in that it represents a comprehensive systematic review of the relative benefits and harms of different catheter-related interventions in PD patients. A previous systematic review of 12 RCTs (991 patients) only focused on the use of disconnect systems in PD (Daly 2001). The analysis demonstrated that conventional spike systems were 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" manoeuvre (Bazzato 1993). Our review demonstrates that no other catheter-related interventions have been proven to significantly impact on patient outcomes. The one exception was the analysis of straight versus coiled catheters (comparison 04.01) 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 (Eklund 1995). Potential alternate explanations include 1) a type 1 statistical error (most likely), or 2) inadequate randomizations, possibly due to sub-optimal 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 for Peritoneal Dialysis guidelines for peritoneal catheter management (Gokal 1998). Our review identified eight RCTs 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 CARI Guidelines (Bannister 2003), which state that no implantation technique has been definitively shown to be superior. On the contrary, no trials of break-in period were identified.

The strength of this investigation is that it represents a comprehensive systematic review based on a previous publication of a detailed protocol, rigid inclusion criteria for RCTs only and a comprehensive search of MEDLINE, EMBASE and the Cochrane Central Register of Controlled Trials. Data extraction, data analysis and method quality assessment were performed by two independent investigators, and consistency was checked with an additional two reviewers. Furthermore, infectious outcomes were separately examined in terms of rates/patient-months and the number of patients affected in order to maximise statistical power and to verify the robustness of statistical analyses.

The main weakness of this study was the relative paucity of quality RCTs. The vast majority of studies evaluated failed to specify whether randomisation and allocation was concealed, outcome assessors were blinded or data were analysed on an intention-totreat basis. Many studies were small and often short in duration, so that 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 (such as for laparoscopy versus laparotomy), which most likely reflected significant intertrial variation (e.g. durations of follow-up, type of catheter). These issues reduce the strength of the conclusions that have been drawn in this review.

AUTHORS' CONCLUSIONS

Implications for practice

This systematic review demonstrates that no clear benefit is observed for different catheter designs and implantation techniques for preventing PD peritonitis. Additionally, judging by the point estimates in our analyses, none of the interventions looked promising. A survival advantage was identified for straight catheters compared with coiled catheters, but these results should be interpreted with caution, since no clear differences were observed with respect to peritonitis, exit site/tunnel infections, catheter removal/replacement or technique survival, i.e. the inability to shown an intervention-related mechanism for reduction in mortality suggests this is a spurious finding.

Implications for research

In terms of clinical research, this review demonstrates that PD catheter-related interventions have been very poorly studied to date. There is an obvious need in this area for well-designed, RCTs, with clear descriptions of trial methodologies.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Akyol 1990

| Methods | Country: Scotland Setting/Design: Single Centre Time frame: October 1986 - July 1987 Randomisation method: Randomly allocated at time of surgery Blinding - Participants: Yes - Investigators: Yes - Outcome assessors: No - Data analysis: Not stated Intention-to-treat: No Follow-up period: 72 weeks Loss to follow-up: 2/40 |
|---------------|---|
| Participants | INCLUSION CRITERIA Consecutive patients for CAPD TREATMENT GROUP - straight Number: 20 Age: mean 49 y (22-70) Sex (M/F): 15/5 Diabetes: 3/20 CONTROL GROUP - coiled Number: 20 Age: mean 45 y (19-73) Sex (M/F): 8/11 Diabetes: 2/20 EXCLUSIONS: None stated |
| Interventions | TREATMENT GROUP Straight tip CONTROL GROUP Coiled tip All catheters were double-cuff Tenckhoff with 4 cm (curled) and 5 cm (straight) between cuffs 1g vancomycin by IV infusion preoperatively on day of surgery. Catheters inserted in an operating theatre with general or local anaesthetic |
| Outcomes | STUDY OUTCOMES (**relevant to this review) 1.Exit-site, wound and tunnel infection (defined as isolation of a pathogenic organism on culture in the presence of local signs of inflammation or infection i.e. swelling, redness, pain or discharge of any nature) **. 2. Peritonitis (defined as either a positive culture form dialysis effluent or a white cell count > 100/mm³ in the effluent associated with clinical evidence of peritonitis)** 3. Mechanical complications** |

Akyol 1990 (Continued)

| Notes | EXCLUSIONS POST RANDOMISATION BUT PRE-INTERVENTION None stated STOP OR END POINT/S Follow-up terminated at the date of catheter removal or at the last clinic visit before the analysis ADDITIONAL DATA REQUESTED FROM AUTHORS None requested |
|--------------|--|
| Risk of bias | |

| Bias | Authors' judgement | Support for judgement |
|-------------------------|--------------------|-----------------------|
| Allocation concealment? | Unclear risk | B - Unclear |

Danielson 2002

| Methods | Country: Sweden Setting/Design: 2 Centres (HS and KS) Time frame: September 1992 - October 1995 Randomisation method: not stated Blinding - Participants: No - Investigators: No - Outcome assessors:No - Data analysis: Not stated Intention-to-treat: No Follow-up period: 0.4-44 months Loss to follow-up: 1/60 |
|---------------|--|
| Participants | INCLUSION CRITERIA ESRD patients scheduled for PD and judged not to need PD for at lease 6 weeks after catheter insertion TREATMENT GROUP (Buried catheter) Number: 30 Age: median 54.6 y (32-80) Sex (M/F): 18/12 Diabetic: 8/30 CONTROL GROUP (Non-buried catheter) Number: 30 Age: median 60.8 y (31-76) Sex (M/F): 16/14 Diabetic: 9/30 EXCLUSIONS: Patients who required PD shortly after catheter insertion |
| Interventions | TREATMENT GROUP - Buried catheter The tip of the catheter was buried in the subcutaneous tissue. Prior to PD the tip was exteriorised through an exit site CONTROL GROUP - Non-buried catheter Moncrief-Popvich catheter used in both groups. |

Danielson 2002 (Continued)

| | All patients were given IV infusion of 2g cloxacillin followed by 1g flucloxacillin orally, twice/day for 5 days. Pocedures performed by one experience nephrologist at HS and one senior surgeon to KS |
|----------|--|
| Outcomes | STUDY OUTCOMES (**relevant to this review) 1. Death** 2. Peritonitis rate (peritonitis defined as any combination of abdominal pain, turbid dialysate, and a dialysate leukocyte count > 100 x 10 (9)/L)** 3. Exit-site/tunnel infection rate (exit site infection defined as pericatheter erythema and/or exudation from the exit site)** 4. Technique failure** |
| Notes | EXCLUSIONS POST RANDOMISATION BUT PRE-INTERVENTION None stated STOP OR END POINT/S None stated ADDITIONAL DATA REQUESTED FROM AUTHORS: |

Support for judgement

B - Unclear

| Bias | Authors' judgement |
|------|--------------------|

| Allocation concealment? | Unclear risk |
|-------------------------|--------------|

Dasgupta 2000

| Methods | Country: Canada Setting/Design: Single centre Time frame: 1994-1997 Randomisation method: not stated Blinding - Participants: Not stated - Investigators: Not stated - Investigators: Not stated - Outcome assessors: Not stated - Data analysis: Not stated Intention-to-treat: Not stated Follow-up period: 23 months Loss to follow-up: Not stated |
|--------------|---|
| Participants | INCLUSION CRITERIA Not stated TREATMENT GROUP (Moncrief-Popovich catheters) Number: 22 Age: not stated Sex (M/F): not stated CONTROL GROUP (Tenckhoff catheters) Number: 19 Age: not stated |

Dasgupta 2000 (Continued)

| | Sex (M/F): not stated EXCLUSIONS: Not stated | |
|-------------------------|---|-----------------------|
| Interventions | TREATMENT GROUP Moncrief-Popovich catheters CONTROL GROUP Tenckhoff catheters | |
| Outcomes | STUDY OUTCOMES (**relevant to this review) 1. Peritonitis/patient/year 2. Exit-site infection/patient/year | |
| Notes | EXCLUSIONS POST RANDOMISATION BUT PRE-INTERVENTION STOP OR END POINT/S ADDITIONAL DATA REQUESTED FROM AUTHORS | |
| Risk of bias | | |
| Bias | Authors' judgement | Support for judgement |
| Allocation concealment? | Unclear risk | B - Unclear |

Ejlersen 1990

| Methods | Country: Denmark Setting/Design: Single centre Time frame: 1 June 1986 - 1 April 1988 Randomisation method: Not stated Blinding - Participants: No - Investigators: No - Outcome assessors: No - Outcome assessors: No - Data analysis: Not stated Intention-to-treat: Yes Follow-up period: 450 days Loss to follow-up: 0/37 |
|--------------|---|
| Participants | INCLUSION CRITERIA All patients with chronic uraemia requiring the insertion of a permanent PD catheter for future CAPD TREATMENT GROUP (Lateral insertion) Number: 16 Age: median 57 y (28-74) Sex (M/F): 9/7 CONTROL GROUP (Midline) Number: 21 Age: median 58 y (28-75) Sex (M/F): 10/11 |

Ejlersen 1990 (Continued)

| | EXCLUSIONS No prior history of extensive peritoneal adherences requiring laparotomy | | |
|-------------------------|---|-----------------------|--|
| Interventions | TREATMENT GROUP - Lateral insertion CONTROL GROUP - Midline insertion Catheter insertions performed by a senior registrar in urology. Right-angled modified Tenckhoff catheter, single-cuff L-catheter Local anaesthetic used for both techniques IV antibiotic prophylaxis just prior to procedure using 2g ampicillin or 2g cefalothin if penicillin allergy suspected CAPD was not initiated until at least 2 weeks after insertion. Patients placed on intermittent PD or HD | | |
| Outcomes | STUDY OUTCOMES (**relevant to this review) 1. Death** 2. Peritonitis** 3. Tunnel infection** 4. Surgical/mechanical failure | | |
| Notes | EXCLUSIONS POST RANDOMISATION BUT PRE-INTERVENTION None stated STOP OR END POINT/S: Surgical or mechanical catheter failure requiring catheter removal - incurable pericatheter leakage, irre- versible displacement and malfunction, pericatheter herniation) ADDITIONAL DATA REQUESTED FROM AUTHORS: None requested | | |
| Risk of bias | Risk of bias | | |
| Bias | Authors' judgement | Support for judgement | |
| Allocation concealment? | Unclear risk | B - Unclear | |

Eklund 1994

| Methods | Country: Finland Setting/Design: Single centre Time frame: August 1987 - February 1989 Randomisation method: Sequentially numbered sealed envelopes containing catheter configurations in random order Blinding - Participants: Yes - Investigators: Yes - Outcome assessors: Not stated - Data analysis: Not stated Intention-to-treat: Yes Follow-up period: 5 years (31 October 1992) Loss to follow-up: 0/40 |
|---------------|--|
| Participants | INCLUSION CRITERIA Consecutive patients selected for CAPD TREATMENT GROUP Number: 20 Age: mean 42.8 y (19.5-61.9) Sex (M/F): 9/11 Diabetes: 3 CONTROL GROUP Number: 20 Age: mean 49.0 y (28.5-65.3) Sex (M/F): 12/8 Diabetes: 10 EXCLUSIONS: None stated |
| Interventions | TREATMENT GROUP Single-cuff, straight Tenckhoff catheter CONTROL GROUP one-bubble, slanted flange, single-cuff Swan neck catheter Catheters inserted surgically by the same surgeon, spinal anaesthesia was the preferred choice. Priot to insertion catheter was soaked in vancomycin 500 mg/10 mL saline solution and rest of antibiotic injected into rectus muscle After implantation peritoneal cavity flushed with 1-3, 1L exchanges until effluent clear. Catheter was then filled with 2 mL saline and 1 mL heparin (5000 U). CAPD training and treatment was started 10-14 days after implantation |
| Outcomes | STUDY OUTCOMES (**relevant to this review) 1. Peritonitis (diagnosed when 2 of the following criteria were fulfilled: abdominal pain; cloudy dialysate with leucocytes > 50/mm³; positive microbiological culture from dialysate)** 2. Peritonitis rate** 3. Exit-site infection (erythema with or without skin induration and/or purulent discharge from exit site) ** 4. Exit-site infection rate** 5 Catheter removal or replacement** 6 Death** |

Eklund 1994 (Continued)

| Risk of bias | |
|--------------|--|
| | None stated DROPOUT DEFINITIONS Catheter removal due to successful transplantation, elective transfer to HD or death from concurrent disease were regarded as lost to follow-up ADDITIONAL DATA REQUESTED FROM AUTHORS None requested |
| Notes | EXCLUSIONS POST RANDOMISATION BUT PRE-INTERVENTION |

| Bias | Authors' judgement | Support for judgement |
|-------------------------|--------------------|-----------------------|
| Allocation concealment? | Low risk | A - Adequate |

Eklund 1995

| Methods | Country: Finland Setting/Design: Single centre Time frame: March 1990 - September 1991 Randomisation method: Sequentially numbered sealed envelopes containing catheter configurations in random order Blinding - Participants: Yes - Investigators: Tes - Outcome assessors: Not stated - Data analysis: Not stated Intention-to-treat: Follow-up period: To 30 September 1994 Loss to follow-up: |
|---------------|--|
| Participants | INCLUSION CRITERIA 40 consecutive patients selected for CAPD TREATMENT GROUP - Tenckhoff Number: 20 Age: mean 48.5 y (26-68) Sex (M/F): 11/9 Diabetes: 6 CONTROL GROUP -Swan neck Number: 20 Age: mean 43.7 y (23-66) Sex (M/F): 11/9 Diabetes: 10 EXCLUSIONS: None stated |
| Interventions | TREATMENT GROUP 2 cuff straight Tenckhoff catheter (straight intraperitoneal segment) CONTROL GROUP 2 cuff Swan neck catheter (straight intraperitoneal segment) |

Eklund 1995 (Continued)

| | Catheters inserted surgically, spinal anaesthesia was used in all instances Priot to insertion catheter was soaked in vancomycin 500 mg/10 mL saline solution and rest of antibiotic injected into rectus muscle |
|----------|---|
| Outcomes | STUDY OUTCOMES (**relevant to this review) 1. Peritonitis (diagnosed when 2 of the following criteria were fulfilled: abdominal pain; cloudy dialysate with leucocyte count of 00 cells/mm³ or more with 50% polymorphonuclear cells; positive microbiological culture from dialysate)** 2. Peritonitis rate** 3. Exit-site infection (erythema with or without skin induration and/or purulent discharge from exit site) ** 4. Exit-site infection rate** 5 Catheter removal or replacement** 6 Death** |
| Notes | EXCLUSIONS POST RANDOMISATION BUT PRE-INTERVENTION None Stated DROPOUT DEFINITIONS Catheter removal due to successful transplantation, elective transfer to HD or death from concurrent disease with functioning catheter were censored at the time of the event ADDITIONAL DATA REQUESTED FROM AUTHORS None requested |

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|-------------------------|--------------------|-----------------------|
| Allocation concealment? | Unclear risk | B - Unclear |

Eklund 1997

| Methods | Country: Finland Setting/Design: Time frame: October 1991 - June 1993 Randomisation method: Allocation concealment: Sealed envelopes Blinding - Participants: No - Investigators:No - Outcome assessors: No - Data analysis: Not stated Intention-to-treat: yes Follow-up period: 1841 days Loss of follow-up: 0/30 |
|--------------|---|
| Participants | INCLUSION CRITERIA Consecutive patients selected for CAPD TREATMENT GROUP - Single-cuff Number: 30 |

Eklund 1997 (Continued)

| Bias Allocation concealment? | Authors' judgement | Support for judgement B - Unclear | |
|------------------------------|---|--------------------------------------|--|
| Risk of bias | Risk of bias | | |
| Notes | EXCLUSIONS POST RANDOMISATION BUT PRE-INTERVENTION: None stated STOP OR END POINT/S: None stated ADDITIONAL DATA REQUESTED FROM AUTHORS: None requested | | |
| Outcomes | STUDY OUTCOMES (**relevant to this review) 1. Peritonitis** (two of the following criteria - abdominal pain, cloudy dialysate with leucocytes > 100/ mm ³ with > 50% polymorphonuclear cells, or positive dialysate culture 2. Exit-site infection** (erythema with or without skin induration and/or purulent discharge for the exit site 3. Death** | | |
| Interventions | TREATMENT GROUP Single-cuff Tenckhoff, straight tip CONTROL GROUP Double-cuff Tenckhoff, straight tip Spinal anaesthesia used for all patients | | |
| | Sex (M/F): 20/10 Diabetes: 6/30 CONTROL GROUP - Double-cuff Number: 30 Age: mean 45.1 y (25-64) Sex (M/F): 20/10 Diabetes: 10/30 EXCLUSIONS: None stated | | |

Gadallah 1999

| Methods | Country: USA Setting/Design: Single Hospital Time frame: October 1992 - October 1995 Randomisation method: Alternate months Blinding - Participants: No - Investigators: No - Outcome assessors: No - Outcome assessors: No - Data analysis: Not stated Intention-to-treat: no Follow-up period: 3 years Loss to follow-up: 5/148 |
|---------------|---|
| Participants | INCLUSION CRITERIA Not stated TREATMENT GROUP (Peritoneoscopic) Number: 76 Age: 45.0 ± 1.8 y (15-75) Sex (M/F): 37/39 Race: White (25), Black (50), Latino (1) CONTROL GROUP (Surgery) Number: 72 Age: 47.2 ± 2.4 y (22-86) Sex (M/F): 22/34 Race: White (17), Black (55), Latino (0) EXCLUSIONS: None stated |
| Interventions | TREATMENT GROUP - Peritoneoscopic placement Performed by the same 3 nephrologists in a special procedure room under local anaesthesia and sterile conditions CONTROL GROUP - surgical placement Performed by the same 3 surgeons in the operating room under general anaesthetic Both groups received 1g vancomycin IV preoperatively Postoperatively both groups had daily irrigation with 200 ml 1.5% dianeal and dialysis was not study until 1 week from the date of surgery |
| Outcomes | STUDY OUTCOMES (**relevant to this review) 1. Early complications 2. Late complications 3. Catheter failure** 4. Death** 5. Pertionitis** 6. Exit site/tunnel infection** |
| Notes | EXCLUSIONS POST RANDOMISATION BUT PRE-INTERVENTION: None stated STOP OR END POINT/S: None stated ADDITIONAL DATA REQUESTED FROM AUTHORS: |

Gadallah 1999 (Continued)

| | None requested | | |
|-------------------------|--|---|--|
| Risk of bias | Risk of bias | | |
| Bias | Authors' judgement | Support for judgement | |
| Allocation concealment? | High risk | C - Inadequate | |
| Lye 1995 | | | |
| Methods | Country: Singapore Setting/Design: Single centre Time frame: January 1993-June 1994 Randomisation method: Alternate randor Blinding - Participants: No - Investigators:No - Outcome assessors: Not stated - Data analysis: Not stated Intention-to-treat: No Follow-up period: 1 year Loss to follow-up: 3/40 | nisation | |
| Participants | INCLUSION CRITERIA Consecutive patients who were commence TREATMENT GROUP - straight Number: 20 Age: 64.2 ± 9.8 y Sex (M/F): not stated Diabetes: 14 CONTROL GROUP - coiled Number: 20 Age: 64.4 ± 10.3 y Sex (M/F): not stated Diabetes: 10 EXCLUSIONS: | ing CAPD for the first time | |
| Interventions | of tip was checked by abdominal radiogra Catheters were flushed using 1 L exchanges saline solution and rested for at least 2 we | tic by the same surgeon and immediately post-surgery position phy. s until effluent was clear. Catheter was then filled with a heparin/ | |

Lye 1995 (Continued)

| Outcomes | STUDY OUTCOMES (**relevant to this review) 1. Peritonitis rate** 2.Exit site infections** 3. Mechanical complications** | |
|--------------------------|---|-----------------------|
| Notes | EXCLUSIONS POST RANDOMISATION BUT PRE-INTERVENTION None stated STOP OR END POINT/S: None stated ADDITIONAL DATA REQUESTED FROM AUTHORS None requested | |
| Risk of bias | | |
| Bias | Authors' judgement | Support for judgement |
| Allocation concealment? | High risk | C - Inadequate |
| Moncrief 1998 Methods | No information available for:Country, Setting/Design, Time frame, Randomisation method, Allocation concealment, Blinding (Participants, Investigators, Outcome assessors, Data analysis), Intention-to-treat, Follow-up period, Completeness of follow-up | |
| Participants | 113 patients included - no data available on number per group, age, M/F or diabetes | |
| Interventions | TREATMENT GROUP Midline insertion CONTROL GROUP Lateral insertion | |
| Outcomes | No outcomes reported | |
| Notes | Conference proceedings/CARI guidelines report. Unable to confirm data with authors | |
| Risk of bias | | |
| Bias | Authors' judgement | Support for judgement |
| Allocation concealment? | Unclear risk | B - Unclear |

Nielsen 1995

| Methods | Country: Denmark Setting/Design: Single centre Time frame: April 1992 - July 1993 Randomisation method: Sequentially number sealed envelopes with catheter type in random order Blinding - Participants: Yes - Investigators: Yes - Outcome assessors: Not stated - Data analysis: Not stated Intention-to-treat: Yes Follow-up period: 15 months Loss to follow-up: 32/72 |
|---------------|---|
| Participants | INCLUSION CRITERIA Consecutive patients selected for CAPD programme TREATMENT GROUP - straight tip Number: 38 Age: mean 50 y (18-79) Sex (M/F): 20/18 Diabetes: 7/38 CONTROL GROUP - coiled tip Number: 34 Age: mean 55 y (29-78) Sex (M/F): 20/14 Diabetes: 6/34 EXCLUSIONS: None stated |
| Interventions | TREATMENT GROUP Straight single cuff Tenckhoff CONTROL GROUP Coiled single cuff Tenckhoff Catheters inserted by 5 nephrologists. All patients received premedication of a minor tranquillizer and morphine. Local anaesthesia used in all cases (lidocaine 1% containing norepinephrine). Immediately after implantation, low volume (1 L) supine intermittent PD was initiated for 24 h (60 L) and continued 1 day/week for the first 3-4 weeks after implantation. All patients started on a disconnect CAPD system |
| Outcomes | STUDY OUTCOMES (**relevant to this review) 1. Drainage failure 2. Tunnel or exit-site infection (defined clinically as an inflammation with or without discharge)** 3. Peritonitis (two of four of the following: cloudy effluent; abdominal pain; leucocyte count above 100 x 10(6)/L (> 50% neutrophils); positive culture)** |
| Notes | EXCLUSIONS POST RANDOMISATION BUT PRE-INTERVENTION None stated STOP OR END POINT/S Results analyses after 60 patients and due to significant difference in catheter outcome, the study was terminated after the inclusion of 72 patients ADDITIONAL DATA REQUESTED FROM AUTHORS |

| | None requested | |
|-------------------------|--|--|
| Risk of bias | | |
| Bias | Authors' judgement | Support for judgement |
| Allocation concealment? | Low risk | A - Adequate |
| Park 1998 | | |
| Methods | Country: Korea Setting/Design: Single centre Time frame: April 1991 - January 1995 Randomisation method: Not stated Blinding - Participants: No - Investigators: No - Investigators: No - Outcome assessors: No - Data analysis: Not stated Intention-to-treat: No Follow-up period: 2 years Loss to follow-up: 1/60 | |
| Participants | INCLUSION CRITERIA Patients commencing CAPD TREATMENT GROUP (Buried catheter) Number: 30 Age: mean 47.8 y (16-69) Sex (M/F): 19/11 Diabetic: 13 CONTROL GROUP (Non-buried catheter) Number: 29 Age: mean 46.2 y (27-71) Sex (M/F): 17/12 Diabetic: 13 EXCLUSIONS Non stated | |
| Interventions | CONTROL GROUP- Non buried cathete | ng exteriorised. Bag exchange commenced the same day er of surgery and 6 weeks were allowed for wound healing before |
| Outcomes | - | review) effluent wit leukocyte count > 100/mm³)** ed as skin over the tunnel red, war, tender and/or if purulent |

Park 1998 (Continued)

| | discharge was observed) 3. Peritonitis rate** 4. Exit-site infection rate** 5. Death** | |
|--------------|---|-----------------------|
| Notes | EXCLUSIONS POST RANDOMISATION BUT PRE-INTERVENTION: None stated STOP OR END POINT/S: ADDITIONAL DATA REQUESTED FROM AUTHORS: | |
| Risk of bias | | |
| Bias | Authors' judgement | Support for judgement |

| Dias | Authors judgement | Support for judgement |
|-------------------------|-------------------|-----------------------|
| Allocation concealment? | Unclear risk | B - Unclear |

Rubin 1990

| Methods | Country: USA Setting/Design: Single centre Time frame: May 1987 - September 1989 Randomisation method: Not stated Blinding - Participants: No - Investigators: No - Outcome assessors: No - Outcome assessors: No - Data analysis: Not stated Intention-to-treat: No Follow-up period: 2 years Loss to follow-up: Unclear |
|---------------|---|
| Participants | INCLUSION CRITERIA All patients undergoing placement of initial PD catheters GROUPS 1 & 3 - straight catheter Number: 50 Age: mean 47 ± 18 y GROUP 2 & 4 - spiral catheter Number: 35 Age: mean 51 ± 17 y EXCLUSIONS: Patients with previous abdominal surgery that precluded randomisation of catheter insertion site |
| Interventions | GROUP 1 & GROUP 3 Midline insertion, straight catheter/Lateral insertion, straight catheter GROUP 2 & GROUP 4 Midline insertion, spiral catheter/Lateral insertion, spiral catheter All procedures performed in an operating room environment. Dialysis was started within 2-3 hours of returning from the operating theatre |

Rubin 1990 (Continued)

| Outcomes | STUDY OUTCOMES (**relevant to this review) 1. Exit site/tunnel infection (Tunnel infection - obvious purulence from the catheter exit site in association with peritonitis; exit site infection - purulence of exit site without peritonitis)** 2. Pertionitis (dialysate becoming turbid and abdominal pain or a positive culture)** 3. Catheter removal/replacement |
|----------|--|
| Notes | EXCLUSIONS POST RANDOMISATION BUT PRE-INTERVENTION None stated STOP OR END POINT/S Non stated ADDITIONAL DATA REQUESTED FROM AUTHORS None requested |

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|-------------------------|--------------------|-----------------------|
| Allocation concealment? | Unclear risk | B - Unclear |

Scott 1994

| Methods | Country: UK Setting/Design: Single centre Time frame: not stated Randomisation method: Not stated Blinding - Participants: Not stated - Investigators: Not stated - Outcome assessors: Not stated - Data analysis: Not stated Intention-to-treat: Not stated Follow-up period: 19 months Loss to follow-up: Not stated |
|--------------|---|
| Participants | INCLUSION CRITERIA Not stated TREATMENT GROUP - straight Number: not stated Age: not stated Sex (M/F): not stated CONTROL GROUP combined (coiled and Oreopoulos) Number: not stated Age: not stated Sex (M/F): not stated EXCLUSIONS: None stated |

Scott 1994 (Continued)

| Interventions | TREATMENT GROUP Double cuff, straight Tenckhoff CONTROL GROUP Group 1 - Standard coiled catheter Group 2 - Oreopoulos (Toronto Western double-disk) Catheters inserted surgically under standard standardised conditions and surgical techniques | |
|---------------|---|-----------------------|
| Outcomes | STUDY OUTCOMES (**relevant to this review) 1. Death** 2.Peritonitis** | |
| Notes | Preliminary report EXCLUSIONS POST RANDOMISATION BUT PRE-INTERVENTION None stated STOP OR END POINT/S None stated ADDITIONAL DATA REQUESTED FROM AUTHORS None requested | |
| Risk of bias | | |
| Bias | Authors' judgement | Support for judgement |

| Allocation concealment? | Unclear risk | B - Unclear |
|-------------------------|--------------|--------------|
| Thiocation conceannent. | Chelear HSK | D - Olicical |

Tsimoyiannis 2000

| Methods | Country: Greece Setting/Design: Hospital Time frame: not stated Randomisation method: Closed envelop containing information regarding placement into group A or B Blinding - Participants: No - Investigators: No - Outcome assessors:No - Outcome assessors:No - Data analysis: No Intention-to-treat: No Follow-up period: 4-36 months (mean 21 ± 10) Loss to follow-up: 5/50 |
|--------------|---|
| Participants | INCLUSION CRITERIA Adult patients undergoing insertion of Tenckhoff catheter LAPAROTOMY GROUP (A) Number: 25 Age: mean 62 y (48-72) Sex (M/F): 16/4 LAPROSCOPY GROUP (B) Number: 25 |

Tsimoyiannis 2000 (Continued)

| | Age: mean 58 y (25-74) Sex (M/F): 18/7 EXCLUSIONS: Problem for general anaesthesia | |
|-------------------------|---|-----------------------|
| Interventions | LAPAROTOMY GROUP (A) Open laparotomy technique with local anaesthesia. No intraabdominal fixation used. CAPD was com- menced 24-48 hours with small amounts of fluid and the full program started several days later LAPROSCOPY GROUP (B) Laproscopic placement with general anaesthesia. Catheter secured to the back wall of the uterus in women or to the peritoneum overlaying the back wall of the bladder in men. Immediately after the end of the procedure CAPD was started | |
| Outcomes | STUDY OUTCOMES (**relevant to this review) 1. Mean operative time 2. Peritonitis** 3. Tip catheter migration 4. Removal of catheter** 5. Fluid leaks 6. Technique failure** | |
| Notes | EXCLUSIONS POST RANDOMISATION BUT PRE-INTERVENTION: Five patients were excluded (group B) because they developed severe cardiovascular or respiratory disease, which contraindicated general anaesthesia STOP OR END POINT/S: none stated ADDITIONAL DATA REQUESTED FROM AUTHORS: none requested | |
| Risk of bias | | |
| Bias | Authors' judgement | Support for judgement |
| Allocation concealment? | Unclear risk | B - Unclear |

Turner 1992

| Methods | Country: UK Setting/Design: Single centre Time frame: March 1990 - March 1991 Randomisation method: Not stated Blinding - Participants: No - Investigators: No - Investigators: No - Outcome assessors: Not stated - Data analysis: Not stated Intention-to-treat: No Follow-up period: 60 weeks Loss to follow-up: None stated |
|---------------|--|
| Participants | INCLUSION CRITERIA All patients who had a Tenckhoff catheter inserted TREATMENT GROUP 1 - immobilisation via device Number: 22 Age: mean 45 ± 15.51 y Sex (M/F): Not stated Diabetes: 4 TREATMENT GROUP 2 - immobilisation via tape Number: 23 Age: mean 40 ± 14.26 y Sex (M/F): Not stated Diabetes: 5 : CONTROL GROUP - NO IMMOBILISATION Number: 21 Age: mean 43 ± 15.8 Sex (M/F): Not stated Diabetes: 4 : EXCLUSIONS: None stated |
| Interventions | TREATMENT GROUP 1 Immobilisation via device Immediately upon insertion of catheter the immobilisation device was placed over the catheter 1-3 inches from the exit site by the surgeon. It was kept in place at all times and replaced daily after showering. A new immobiliser was positioned before removal of the old one TREATMENT GROUP 2 Immobilisation via tape Immediately upon insertion of catheter the tape was placed over the catheter 1-3 inches from the exit site by the surgeon. It was kept in place at all times and replaced daily after showering. A new tape was positioned before removal of the old one CONTROL GROUP No immobilisation CO-INTERVENTIONS |

Turner 1992 (Continued)

| Outcomes | STUDY OUTCOMES (**relevant to this review) 1. Exit-site/tunnel infection (defined as clinically apparent infection - purulent drainage, redness, swelling, warmth and tenderness - at the exit site with/without a positive culture)** 2. Exit-site/tunnel infection rate** 3. Peritonitis** |
|----------|---|
| Notes | EXCLUSIONS POST RANDOMISATION BUT PRE-INTERVENTION None stated STOP OR END POINT/S None stated ADDITIONAL DATA REQUESTED FROM AUTHORS None requested |

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|-------------------------|--------------------|-----------------------|
| Allocation concealment? | Unclear risk | B - Unclear |

Wright 1998

| Methods | Country: UK Setting/Design: Tertiay referral renal unit Time frame: Randomisation method: Sealed enveloped containing cards with 'laparoscopic" or "conventional". Cards stored in theatre anaesthetic room and one envelope opened after each patient was anaesthetized. Blinding - Participants: Yes - Investigators: Yes (ward staff) - Outcome assessors: Not stated - Data analysis: Not stated Intention-to-treat: No Follow-up period: 24 months Loss to follow-up: 5/50 |
|--------------|---|
| Participants | INCLUSION CRITERIA All patients fit enough to undergo general anaesthetic and starting PD TREATMENT GROUP Laproscopic Number: 21 Age: mean 46.4 ± 14.8 y Sex (M/F): 14/7 CONTROL GROUP Conventional Number: 24 Age: mean 49.3 ± 20.2 y Sex (M/F): 15/9 EXCLUSIONS None stated |

Wright 1998 (Continued)

| Interventions | TREATMENT GROUP Laproscopic CONTROL GROUP Conventional/laparotomy One consultant performed all operations All patients received 2g of vancomycin IV prior to surgery as prophylaxis. Dressings were applied to the same position for all patients in order to blind the ward staff to the technique used |
|---------------|--|
| Outcomes | STUDY OUTCOMES (**relevant to this review) 1. Death** 2. Peritonits** 3. Peritonits rate** 4. Catheter removal** 5. Technique failure** 6. Exit site infection** - data was unclear for patient numbers and has been excluded at this stage |
| Notes | EXCLUSIONS POST RANDOMISATION BUT PRE-INTERVENTION Four laparoscopic procedures were converted to conventional in theatre due to technical difficulties (3) and obesity (1) STOP OR END POINT/S ADDITIONAL DATA REQUESTED FROM AUTHORS |

Risk of bias

| Bias | Authors' judgement | Support for judgement |
|-------------------------|--------------------|-----------------------|
| Allocation concealment? | Unclear risk | B - Unclear |

Characteristics of ongoing studies [ordered by study ID]

Rhodes 2000

| Trial name or title | Prospective randomised trial of laparoscopic sutured versus blind (conventional) insertion of Tenckhoff peri- toneal dialysis catheters |
|---------------------|--|
| Methods | |
| Participants | Potential peritoneal dialysis patients |
| Interventions | laparoscopic sutured versus blind (conventional) insertion or Tenckhoff peritoneal dialysis catheters |
| Outcomes | Survival, PD patency, infection rate, morbidity, mortality |
| Starting date | 31 January 2000 |
| Contact information | 31 January 2002 |

| Notes | Project status - complete | | | | |
|---------------------|--|--|--|--|--|
| Sudhindran 2000 | | | | | |
| Trial name or title | Prospective randomised trial of laparoscopic versus closed insertion of Tenckhoff catheters for peritoneal dialysis access | | | | |
| Methods | | | | | |
| Participants | Patients admitted to Addenbrooke's Hospital for insertion of PD catheters | | | | |
| Interventions | Percutaneous closed insertion under local anaesthetic versus laparoscopic insertion under general anaesthetic | | | | |
| Outcomes | Failure rates and complications | | | | |
| Starting date | 11 September 2000 | | | | |
| Contact information | 11 September 2000 | | | | |
| Notes | Project status - complete | | | | |

DATA AND ANALYSES

| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|-------------------------------------|-------------------|------------------------|----------------------------------|---------------------|
| 1 All-cause mortality | 2 | 193 | Risk Ratio (M-H, Random, 95% CI) | 1.08 [0.52, 2.26] |
| 2 Peritonitis | 3 | 238 | Risk Ratio (M-H, Random, 95% CI) | 0.68 [0.41, 1.15] |
| 3 Peritonitis rate (patient-months) | 1 | | Risk Ratio (M-H, Random, 95% CI) | Totals not selected |
| 4 Exit-site/tunnel infection | 1 | | Risk Ratio (M-H, Random, 95% CI) | Totals not selected |
| 5 Catheter removal or replacement | 2 | 90 | Risk Ratio (M-H, Random, 95% CI) | 1.02 [0.49, 2.13] |
| 6 Technique failure | 3 | 206 | Risk Ratio (M-H, Random, 95% CI) | 0.70 [0.45, 1.08] |

Comparison 1. Laparoscopy versus laparotomy

Comparison 2. Buried (subcutaneous) versus non-buried catheter

| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|---|-------------------|------------------------|----------------------------------|---------------------|
| 1 All-cause mortality | 2 | 119 | Risk Ratio (M-H, Random, 95% CI) | 0.90 [0.39, 2.08] |
| 2 Peritonitis rate (patient-months) | 2 | 2511 | Risk Ratio (M-H, Random, 95% CI) | 1.16 [0.37, 3.60] |
| 3 Exit-site/tunnel infection rate (patient-months) | 2 | 2511 | Risk Ratio (M-H, Random, 95% CI) | 1.15 [0.39, 3.42] |
| 4 Technique failure | 1 | | Risk Ratio (M-H, Random, 95% CI) | Totals not selected |

Comparison 3. Midline versus lateral insertion

| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|-----------------------------------|-------------------|------------------------|----------------------------------|---------------------|
| 1 All-cause mortality | 1 | | Risk Ratio (M-H, Random, 95% CI) | Totals not selected |
| 2 Peritonitis | 2 | 120 | Risk Ratio (M-H, Random, 95% CI) | 0.65 [0.32, 1.33] |
| 3 Exit-site/tunnel infection | 2 | 120 | Risk Ratio (M-H, Random, 95% CI) | 0.56 [0.12, 2.58] |
| 4 Catheter removal or replacement | 1 | | Risk Ratio (M-H, Random, 95% CI) | Totals not selected |

Comparison 4. Straight versus coiled

| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|--|-------------------|------------------------|----------------------------------|---------------------|
| 1 All-cause mortality | 4 | 209 | Risk Ratio (M-H, Random, 95% CI) | 0.26 [0.07, 0.99] |
| 2 Peritonitis | 5 | 324 | Risk Ratio (M-H, Random, 95% CI) | 1.14 [0.73, 1.79] |
| 3 Peritonitis rate (patient-months) | 4 | 2589 | Risk Ratio (M-H, Random, 95% CI) | 0.89 [0.63, 1.26] |
| 4 Exit-site/tunnel infection | 6 | 332 | Risk Ratio (M-H, Random, 95% CI) | 1.26 [0.91, 1.73] |
| 5 Exit-site/tunnel infection rate (patient-months) | 3 | 1993 | Risk Ratio (M-H, Random, 95% CI) | 1.04 [0.73, 1.47] |
| 6 Catheter removal or replacement | 5 | 275 | Risk Ratio (M-H, Random, 95% CI) | 1.11 [0.53, 2.31] |
| 7 Technique failure | 1 | | Risk Ratio (M-H, Random, 95% CI) | Totals not selected |

Comparison 5. Single versus double cuff

| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|-----------------------------------|-------------------|------------------------|----------------------------------|---------------------|
| 1 All-cause mortality | 1 | | Risk Ratio (M-H, Random, 95% CI) | Totals not selected |
| 2 Peritonitis | 1 | | Risk Ratio (M-H, Random, 95% CI) | Totals not selected |
| 3 Exit-site/tunnel infection | 1 | | Risk Ratio (M-H, Random, 95% CI) | Totals not selected |
| 4 Catheter removal or replacement | 1 | | Risk Ratio (M-H, Random, 95% CI) | Totals not selected |

Comparison 6. Immobilisation versus no immobilisation

| Outcome or subgroup title | No. of studies | No. of participants | Statistical method | Effect size |
|------------------------------|-------------------|------------------------|----------------------------------|---------------------|
| 1 Peritonitis | 1 | | Risk Ratio (M-H, Random, 95% CI) | Totals not selected |
| 2 Exit-site/tunnel infection | 1 | | Risk Ratio (M-H, Random, 95% CI) | Totals not selected |

Analysis I.I. Comparison I Laparoscopy versus laparotomy, Outcome I All-cause mortality.

Review: Catheter type, placement and insertion techniques for preventing peritonitis in peritoneal dialysis patients

Comparison: I Laparoscopy versus laparotomy

Outcome: I All-cause mortality

| Study or subgroup | Laparoscopy | Laparotomy | Risk Ratio M- H,Random,95% | Weight | Risk Ratio M- H,Random,95% |
|------------------------------|--|-----------------------------|----------------------------------|---------|----------------------------------|
| | n/N | n/N | CI | | ĊI |
| Gadallah 1999 | 9/76 | 9/72 | | 71.7 % | 0.95 [0.40, 2.25] |
| Wright 1998 | 4/21 | 3/24 | | 28.3 % | 1.52 [0.38, 6.04] |
| Total (95% CI) | 97 | 96 | - | 100.0 % | 1.08 [0.52, 2.26] |
| Total events: 13 (Laparos | scopy), 12 (Laparotomy) | | | | |
| Heterogeneity: $Tau^2 = 0$. | .0; Chi ² = 0.33, df = 1 (P | $r = 0.57$); $ ^2 = 0.0\%$ | | | |
| Test for overall effect: Z | = 0.22 (P = 0.83) | | | | |
| | | | | | |

0.1 0.2 0.5 1 2 5 10

Favours laparoscopy Favours laparotomy

Analysis I.2. Comparison I Laparoscopy versus laparotomy, Outcome 2 Peritonitis.

Review: Catheter type, placement and insertion techniques for preventing peritonitis in peritoneal dialysis patients

Comparison: I Laparoscopy versus laparotomy

Outcome: 2 Peritonitis

| Study or subgroup | Lararoscopy | Laparotomy | | | isk Ratio M- | | Weight | Risk Ratio M- |
|------------------------------|-----------------------------------|-------------------------------|----------------|--------|-----------------|----------|---------|---------------------|
| | n/N | n/N | | H,Ran | dom,95% Cl | | | H,Random,95% Cl_ |
| Gadallah 1999 | 11/76 | 16/72 | - | - | _ | | 54.9 % | 0.65 [0.32, 1.31] |
| Tsimoyiannis 2000 | 3/20 | 5/25 | | | | | 15.7 % | 0.75 [0.20, 2.77] |
| Wright 1998 | 5/21 | 8/24 | | - | | | 29.4 % | 0.71 [0.28, 1.85] |
| Total (95% CI) | 117 | 121 | | - | - | | 100.0 % | 0.68 [0.41, 1.15] |
| Total events: 19 (Lararosc | opy), 29 (Laparotomy) | | | | | | | |
| Heterogeneity: $Tau^2 = 0.0$ |); $Chi^2 = 0.05$, $df = 2$ (P = | = 0.98); l ² =0.0% | | | | | | |
| Test for overall effect: Z = | = 1.44 (P = 0.15) | | | | | | | |
| | | | | | 1 | | | |
| | | | 0.2 | 0.5 I | 2 | 5 | | |
| | | | Favours laparo | oscopy | Favours la | parotomy | | |

Analysis 1.3. Comparison I Laparoscopy versus laparotomy, Outcome 3 Peritonitis rate (patient-months).

Review: Catheter type, placement and insertion techniques for preventing peritonitis in peritoneal dialysis patients

Comparison: I Laparoscopy versus laparotomy

Outcome: 3 Peritonitis rate (patient-months)

| Study or subgroup | Laparoscopy | Laparotomy | Risk Ratio M- H,Random,95% | Risk Ratio M- H,Random,95% |
|-------------------|-------------|------------|--|----------------------------------|
| | n/N | n/N | Cl | Cl |
| Wright 1998 | 9/171 | 12/204 | | 0.89 [0.39, 2.07] |
| | | | | |
| | | | 0.2 0.5 I 2 5 | |
| | | | Favours laparoscopy Favours laparotomy | |

Analysis I.4. Comparison I Laparoscopy versus laparotomy, Outcome 4 Exit-site/tunnel infection.

Review: Catheter type, placement and insertion techniques for preventing peritonitis in peritoneal dialysis patients

Comparison: I Laparoscopy versus laparotomy

Outcome: 4 Exit-site/tunnel infection

| Study or subgroup | Laparoscopy | Laparotomy | Risk Ratio M- H,Random,95% | Risk Ratio M- H,Random,95% |
|-------------------|-------------|------------|--|----------------------------------|
| | n/N | n/N | CI | CI |
| Gadallah 1999 | 0/76 | 4/72 | | 0.11 [0.01, 1.92] |
| | | | | |
| | | | 0.005 0.1 1 10 200 | |
| | | | Favours laparoscopy Favours laparotomy | |

Analysis 1.5. Comparison I Laparoscopy versus laparotomy, Outcome 5 Catheter removal or replacement.

Review: Catheter type, placement and insertion techniques for preventing peritonitis in peritoneal dialysis patients

Comparison: I Laparoscopy versus laparotomy

Outcome: 5 Catheter removal or replacement

| Study or subgroup | Laparoscopy | Laparotomy | | Risk Ratio | | Weight | Risk Ratio M- |
|------------------------------|-----------------------------------|-------------------------------|----------|--------------------|----|---------|---------------------|
| | n/N | n/N | | H,Random,95% Cl |) | | H,Random,95% Cl |
| Tsimoyiannis 2000 | 1/20 | 3/25 | | - | | 11.4 % | 0.42 [0.05, 3.71] |
| Wright 1998 | 8/21 | 8/24 | | | | 88.6 % | 1.14 [0.52, 2.51] |
| Total (95% CI) | 41 | 49 | | + | | 100.0 % | 1.02 [0.49, 2.13] |
| Total events: 9 (Laparosco | opy), II (Laparotomy) | | | | | | |
| Heterogeneity: $Tau^2 = 0.0$ |); $Chi^2 = 0.76$, $df = 1$ (P = | = 0.38); l ² =0.0% | | | | | |
| Test for overall effect: Z = | = 0.05 (P = 0.96) | | | | | | |
| | | | | | 1 | | |
| | | | 0.02 0.1 | I I0 | 50 | | |

Favours laparoscopy Favours laparotomy

Analysis I.6. Comparison I Laparoscopy versus laparotomy, Outcome 6 Technique failure.

Review: Catheter type, placement and insertion techniques for preventing peritonitis in peritoneal dialysis patients

Comparison: I Laparoscopy versus laparotomy

Outcome: 6 Technique failure

| Study or subgroup | Laparoscopy | Laparotomy | | lisk Ratio M- | Weight | Risk Ratio M- |
|------------------------------|----------------------------------|----------------------------------|---------------------|--------------------|---------|---------------------|
| | n/N | n/N | H,Ran | dom,95% Cl | | H,Random,95% Cl_ |
| Gadallah 1999 | 19/58 | 32/58 | | | 69.0 % | 0.59 [0.38, 0.92] |
| Tsimoyiannis 2000 | 1/20 | 3/25 | i | | 3.9 % | 0.42 [0.05, 3.71] |
| Wright 1998 | 8/21 | 8/24 | - | - | 27.1 % | 1.14 [0.52, 2.51] |
| Total (95% CI) | 99 | 107 | • | | 100.0 % | 0.70 [0.45, 1.08] |
| Total events: 28 (Laparoso | copy), 43 (Laparotomy) | | | | | |
| Heterogeneity: $Tau^2 = 0.0$ | D2; $Chi^2 = 2.24$, $df = 2$ (F | P = 0.33); ² = % | | | | |
| Test for overall effect: Z = | = 1.61 (P = 0.11) | | | | | |
| | | | | | | |
| | | | 0.02 0.1 | 10 50 | | |
| | | | Favours laparoscopy | Favours laparotomy | | |

Analysis 2.1. Comparison 2 Buried (subcutaneous) versus non-buried catheter, Outcome 1 All-cause mortality.

Review: Catheter type, placement and insertion techniques for preventing peritonitis in peritoneal dialysis patients

Comparison: 2 Buried (subcutaneous) versus non-buried catheter

Outcome: I All-cause mortality

| Study or subgroup | Buried | Non-buried | Risk Ratio M- H,Random,95% | Weight | Risk Ratio M- H.Random.95% |
|------------------------------|----------------------------------|------------------------------------|----------------------------------|---------|----------------------------------|
| | n/N | n/N | Cl | | CI |
| Danielson 2002 | 6/30 | 5/30 | | 60.8 % | 1.20 [0.41, 3.51] |
| Park 1998 | 3/30 | 5/29 | | 39.2 % | 0.58 [0.15, 2.21] |
| Total (95% CI) | 60 | 59 | - | 100.0 % | 0.90 [0.39, 2.08] |
| Total events: 9 (Buried), I | 10 (Non-buried) | | | | |
| Heterogeneity: $Tau^2 = 0.0$ | 0; Chi ² = 0.69, df = | I (P = 0.4I); I ² =0.0% | | | |
| Test for overall effect: Z = | = 0.24 (P = 0.81) | | | | |
| | | | <u> </u> | | |
| | | | 0.1 0.2 0.5 1 2 5 10 | | |

Favours buried Favours non-buried

Analysis 2.2. Comparison 2 Buried (subcutaneous) versus non-buried catheter, Outcome 2 Peritonitis rate (patient-months).

Review: Catheter type, placement and insertion techniques for preventing peritonitis in peritoneal dialysis patients

Comparison: 2 Buried (subcutaneous) versus non-buried catheter

Outcome: 2 Peritonitis rate (patient-months)

| Study or subgroup | Buried | Non-buried | | Risk Ratio M- H,Random,95% | Weight | Risk Ratio M- H,Random,95% |
|------------------------------|-----------------------------------|-----------------------------------|-----|----------------------------------|---------|----------------------------------|
| | n/N | n/N | | ĊI | | CI |
| Danielson 2002 | /475 | 2/ 33 | | | 45.3 % | 2.19 [0.97, 4.92] |
| Park 1998 | 37/493 | 45/410 | | | 54.7 % | 0.68 [0.45, 1.04] |
| Total (95% CI) | 968 | 1543 | | | 100.0 % | 1.16 [0.37, 3.60] |
| Total events: 48 (Buried), | 57 (Non-buried) | | | | | |
| Heterogeneity: $Tau^2 = 0.5$ | 57; Chi ² = 6.25, df = | I (P = 0.01); I ² =84% | | | | |
| Test for overall effect: Z = | = 0.25 (P = 0.80) | | | | | |
| | | | | | | |
| | | | 0.2 | 0.5 I 2 5 | | |

Favours buried

Favours non-buried

Analysis 2.3. Comparison 2 Buried (subcutaneous) versus non-buried catheter, Outcome 3 Exit-site/tunnel infection rate (patient-months).

Review: Catheter type, placement and insertion techniques for preventing peritonitis in peritoneal dialysis patients

Comparison: 2 Buried (subcutaneous) versus non-buried catheter

Outcome: 3 Exit-site/tunnel infection rate (patient-months)

| Study or subgroup | Buried | Non-buried | Risk Ratio M- H.Random,95% | Weight | Risk Ratio M- H,Random,95% |
|------------------------------|-----------------------------------|-------------------------------------|-----------------------------------|---------|----------------------------------|
| | n/N | n/N | Cl | | CI |
| Danielson 2002 | 5/475 | 5/1133 | | 36.7 % | 2.39 [0.69, 8.20] |
| Park 1998 | 39/493 | 43/410 | | 63.3 % | 0.75 [0.50, 1.14] |
| Total (95% CI) | 968 | 1543 | | 100.0 % | 1.15 [0.39, 3.42] |
| Total events: 44 (Buried), | 48 (Non-buried) | | | | |
| Heterogeneity: $Tau^2 = 0.4$ | 14; Chi ² = 3.00, df = | : I (P = 0.08); I ² =67% | | | |
| Test for overall effect: Z = | = 0.25 (P = 0.80) | | | | |
| | | | | | |
| | | | 0.1 0.2 0.5 1 2 5 10 | | |
| | | | Favours buried Favours non-buried | | |

Analysis 2.4. Comparison 2 Buried (subcutaneous) versus non-buried catheter, Outcome 4 Technique failure.

Review: Catheter type, placement and insertion techniques for preventing peritonitis in peritoneal dialysis patients

Comparison: 2 Buried (subcutaneous) versus non-buried catheter

Outcome: 4 Technique failure

| Study or subgroup | Buried | Non-buried | Risk Ratio M- H,Random,95% Cl | Risk Ratio M- H,Random,95% Cl |
|-------------------|--------|------------|---|--|
| Danielson 2002 | 1/30 | 3/30 | | 0.33 [0.04, 3.03] |
| | | | | |
| | | | 0.02 0.1 I I0 50 Favours buried Favours non-buried | |

Analysis 3.1. Comparison 3 Midline versus lateral insertion, Outcome I All-cause mortality.

Review: Catheter type, placement and insertion techniques for preventing peritonitis in peritoneal dialysis patients

Comparison: 3 Midline versus lateral insertion

Outcome: I All-cause mortality

| Study or subgroup | Midline n/N | Lateral n/N | Risk Ratio M- H,Random,95% Cl | Risk Ratio M- H,Random,95% Cl |
|-------------------|----------------|----------------|---|--|
| Ejlersen 1990 | 5/21 | 0/16 | | 8.50 [0.50, 143.32] |
| | | | 0.005 0.1 I 10 200 Favours midline Favours lateral | |

Analysis 3.2. Comparison 3 Midline versus lateral insertion, Outcome 2 Peritonitis.

Review: Catheter type, placement and insertion techniques for preventing peritonitis in peritoneal dialysis patients

Comparison: 3 Midline versus lateral insertion

Outcome: 2 Peritonitis

| Study or subgroup | Midline | Lateral | Risk Ratio M- | Weight | Risk Ratio M- |
|------------------------------|------------------------------|----------------------------------|---------------------------------|---------|---------------------|
| | n/N | n/N | H,Random,95% Cl | | H,Random,95% Cl |
| Ejlersen 1990 | 1/21 | 3/16 | | 11.0 % | 0.25 [0.03, 2.22] |
| Rubin 1990 | 10/48 | 10/35 | - | 89.0 % | 0.73 [0.34, 1.56] |
| Total (95% CI) | 69 | 51 | • | 100.0 % | 0.65 [0.32, 1.33] |
| Total events: 11 (Midline), | 13 (Lateral) | | | | |
| Heterogeneity: $Tau^2 = 0.0$ |); $Chi^2 = 0.82$, $df = 1$ | (P = 0.36); I ² =0.0% | | | |
| Test for overall effect: Z = | = 1.18 (P = 0.24) | | | | |
| | | | <u> </u> | | |
| | | | 0.02 0.1 1 10 50 | | |
| | | | Favours midline Favours lateral | | |

Analysis 3.3. Comparison 3 Midline versus lateral insertion, Outcome 3 Exit-site/tunnel infection.

Review: Catheter type, placement and insertion techniques for preventing peritonitis in peritoneal dialysis patients

Comparison: 3 Midline versus lateral insertion

Outcome: 3 Exit-site/tunnel infection

| Study or subgroup | Midline | Lateral | Risk Ratio M- H,Random,95% | Weight | Risk Ratio M- H.Random,95% |
|------------------------------|----------------------------------|--------------------------------|----------------------------------|---------|----------------------------------|
| | n/N | n/N | CI | | CI |
| Ejlersen 1990 | 1/21 | 0/16 | | 23.0 % | 2.32 [0.10, 53.42] |
| Rubin 1990 | 2/48 | 4/35 | | 77.0 % | 0.36 [0.07, 1.88] |
| Total (95% CI) | 69 | 51 | - | 100.0 % | 0.56 [0.12, 2.58] |
| Total events: 3 (Midline), 4 | ł (Lateral) | | | | |
| Heterogeneity: $Tau^2 = 0.0$ | 9; Chi ² = 1.06, df = | (P = 0.30); I ² =5% | | | |
| Test for overall effect: Z = | 0.75 (P = 0.45) | | | | |
| | | | | | |
| | | | 0.01 0.1 1 10 100 | | |
| | | | Favours midline Favours lateral | | |

Analysis 3.4. Comparison 3 Midline versus lateral insertion, Outcome 4 Catheter removal or replacement.

Review: Catheter type, placement and insertion techniques for preventing peritonitis in peritoneal dialysis patients

Comparison: 3 Midline versus lateral insertion

Outcome: 4 Catheter removal or replacement

| Study or subgroup | Midline n/N | Lateral n/N | Risk Ratio M- H,Random,95% Cl | | Risk Ratio M- H,Random,95% Cl |
|-------------------|----------------|----------------|--|---------|--|
| Rubin 1990 | 4/48 | 18/35 | | | 0.57 [0.33, 0.98] |
| | | | | | |
| | | | 0.2 0.5 I 2 | 5 | |
| | | | Favours midline Favours | lateral | |

Analysis 4.1. Comparison 4 Straight versus coiled, Outcome 1 All-cause mortality.

Review: Catheter type, placement and insertion techniques for preventing peritonitis in peritoneal dialysis patients

Comparison: 4 Straight versus coiled

Outcome: I All-cause mortality

| Study or subgroup | Straight | Coiled | Risk Ratio | Weight | Risk Ratio M- |
|------------------------------|------------------------------------|---------------------------|---------------------------------|---------|---------------------|
| | n/N | n/N | H,Random,95% Cl | | H,Random,95% Cl_ |
| Akyol 1990 | 0/20 | 0/20 | | | Not estimable |
| Eklund 1994 | 0/20 | 4/20 | | 21.6 % | 0.11[0.01, 1.94] |
| Eklund 1995 | 1/20 | 3/20 | | 37.2 % | 0.33 [0.04, 2.94] |
| Scott 1994 | 1/30 | 6/59 | | 41.2 % | 0.33 [0.04, 2.60] |
| Total (95% CI) | 90 | 119 | - | 100.0 % | 0.26 [0.07, 0.99] |
| Total events: 2 (Straight), | 13 (Coiled) | | | | |
| Heterogeneity: $Tau^2 = 0.0$ |); Chi ² = 0.45, df = 2 | $(P = 0.80); I^2 = 0.0\%$ | | | |
| Test for overall effect: Z = | = 1.98 (P = 0.048) | | | | |
| | | | | | |
| | | | 0.005 0.1 1 10 200 | | |
| | | | Favours straight Favours coiled | | |

Analysis 4.2. Comparison 4 Straight versus coiled, Outcome 2 Peritonitis.

Review: Catheter type, placement and insertion techniques for preventing peritonitis in peritoneal dialysis patients

Comparison: 4 Straight versus coiled

Outcome: 2 Peritonitis

| Study or subgroup | Straight | Coiled | Risk Ratio M- | Weight | Risk Ratio M- |
|--------------------------------|-----------------------------------|---------------------------|--------------------|---------|---------------------|
| | n/N | n/N | H,Random,95% Cl | | H,Random,95% Cl |
| Eklund 1994 | 3/20 | 4/20 | | 10.9 % | 0.75 [0.19, 2.93] |
| Eklund 1995 | 9/20 | 8/20 | | 38.8 % | 1.13 [0.55, 2.32] |
| Nielsen 1995 | 2/38 | 2/34 | | 5.6 % | 0.89 [0.13, 6.01] |
| Rubin 1990 | 12/42 | 8/41 | | 33.0 % | 1.46 [0.67, 3.21] |
| Scott 1994 | 3/30 | 6/59 | _ | 11.7 % | 0.98 [0.26, 3.66] |
| Total (95% CI) | 150 | 174 | + | 100.0 % | 1.14 [0.73, 1.79] |
| Total events: 29 (Straight), | 28 (Coiled) | | | | |
| Heterogeneity: $Tau^2 = 0.0$; | Chi ² = 0.87, df = 4 (| $(P = 0.93); I^2 = 0.0\%$ | | | |
| Test for overall effect: Z = | 0.57 (P = 0.57) | | | | |
| | | | | | |

0.1 0.2 0.5 I 2 5 I0 Favours straight Favours coiled

Analysis 4.3. Comparison 4 Straight versus coiled, Outcome 3 Peritonitis rate (patient-months).

Review: Catheter type, placement and insertion techniques for preventing peritonitis in peritoneal dialysis patients

Comparison: 4 Straight versus coiled

Outcome: 3 Peritonitis rate (patient-months)

| Study or subgroup | Straight | Coiled | Risk Ratio M- | Weight | Risk Ratio M- |
|------------------------------|------------------------------------|----------------------------------|--------------------|---------|---------------------|
| | n/N | n/N | H,Random,95% Cl | | H,Random,95% Cl |
| Akyol 1990 | 14/266 | 17/255 | | 25.4 % | 0.79 [0.40, 1.57] |
| Eklund 1994 | 10/327 | 11/381 | _ | 16.8 % | 1.06 [0.46, 2.46] |
| Eklund 1995 | 15/476 | 13/342 | | 22.5 % | 0.83 [0.40, 1.72] |
| Lye 1995 | 20/267 | 22/275 | _ | 35.3 % | 0.94 [0.52, 1.68] |
| Total (95% CI) | 1336 | 1253 | • | 100.0 % | 0.89 [0.63, 1.26] |
| Total events: 59 (Straight) | , 63 (Coiled) | | | | |
| Heterogeneity: $Tau^2 = 0.0$ |); Chi ² = 0.35, df = 3 | (P = 0.95); I ² =0.0% | | | |
| Test for overall effect: Z = | 0.66 (P = 0.51) | | | | |
| | | | | | |
| | | | 0.2 0.5 I 2 5 | | |

Favours straight Favours coiled

Analysis 4.4. Comparison 4 Straight versus coiled, Outcome 4 Exit-site/tunnel infection.

Review: Catheter type, placement and insertion techniques for preventing peritonitis in peritoneal dialysis patients

Comparison: 4 Straight versus coiled

Outcome: 4 Exit-site/tunnel infection

| Study or subgroup | Straight | Coiled | Risk Ratio M- | Weight | Risk Ratio M- |
|--|----------|--------|---------------------------------|---------|----------------------|
| | n/N | n/N | H,Random,95% Cl | | H,Random,95% Cl_ |
| Akyol 1990 | 3/20 | 3/20 | | 4.8 % | 1.00 [0.23, 4.37] |
| Eklund 1994 | /20 | 9/20 | + | 26.4 % | 1.22 [0.65, 2.29] |
| Eklund 1995 | 12/20 | 10/20 | + | 32.4 % | 1.20 [0.68, 2.11] |
| Lye 1995 | 14/20 | 9/20 | | 32.7 % | 1.56 [0.89, 2.73] |
| Rubin 1990 | 1/42 | 5/41 | | 2.3 % | 0.20 [0.02, 1.60] |
| Scott 1994 | 1/30 | 1/59 | | 1.4 % | 1.97 [0.13, 30.36] |
| Total (95% CI)152180Total events: 42 (Straight), 37 (Coiled)Heterogeneity: Tau ² = 0.0; Chi ² = 4.07, df = 5 (P = 0.54); I ² = 0.0%Test for overall effect: $Z = 1.39$ (P = 0.17) | | | * | 100.0 % | 1.26 [0.91, 1.73] |
| | | | | | |
| | | | 0.02 0.1 I I0 50 | | |
| | | | Favours straight Favours coiled | | |

Analysis 4.5. Comparison 4 Straight versus coiled, Outcome 5 Exit-site/tunnel infection rate (patientmonths).

Review: Catheter type, placement and insertion techniques for preventing peritonitis in peritoneal dialysis patients

Comparison: 4 Straight versus coiled

Outcome: 5 Exit-site/tunnel infection rate (patient-months)

| Study or subgroup | Straight | Coiled | Risk Ratio M- | Weight | Risk Ratio M- |
|------------------------------|-----------------------------------|---------------------------|---------------------------------|---------|---------------------|
| | n/N | n/N | H,Random,95% Cl | | H,Random,95% Cl_ |
| Akyol 1990 | 21/266 | 16/255 | | 30.8 % | 1.26 [0.67, 2.36] |
| Eklund 1994 | 21/327 | 19/327 | _ | 33.5 % | . [0.6 , 2.02] |
| Eklund 1995 | 23/476 | 20/342 | | 35.7 % | 0.83 [0.46, 1.48] |
| Total (95% CI) | 1069 | 924 | + | 100.0 % | 1.04 [0.73, 1.47] |
| Total events: 65 (Straight), | 55 (Coiled) | | | | |
| Heterogeneity: $Tau^2 = 0.0$ | ; Chi ² = 0.99, df = 2 | $(P = 0.61); I^2 = 0.0\%$ | | | |
| Test for overall effect: Z = | 0.20 (P = 0.84) | | | | |
| | | | | | |
| | | | 0.2 0.5 I 2 5 | | |
| | | | Favours straight Favours coiled | | |

Analysis 4.6. Comparison 4 Straight versus coiled, Outcome 6 Catheter removal or replacement.

Review: Catheter type, placement and insertion techniques for preventing peritonitis in peritoneal dialysis patients

Comparison: 4 Straight versus coiled

Outcome: 6 Catheter removal or replacement

| Study or subgroup | Straight | Coiled | Risk Ratio M- | Weight | Risk Ratio M- |
|------------------------------|-------------------------------------|---------------------------------|--------------------|---------|---------------------|
| | n/N | n/N | H,Random,95% Cl | | H,Random,95% Cl |
| Akyol 1990 | 1/20 | 6/20 | | 9.8 % | 0.17 [0.02, 1.26] |
| Eklund 1994 | 3/20 | 4/20 | | 16.7 % | 0.75 [0.19, 2.93] |
| Eklund 1995 | 2/20 | 2/20 | | 11.1 % | 1.00 [0.16, 6.42] |
| Nielsen 1995 | 24/38 | 8/34 | | 30.0 % | 2.68 [1.40, 5.16] |
| Rubin 1990 | 17/42 | 15/41 | - | 32.3 % | . [0.64, .9] |
| Total (95% CI) | 140 | 135 | + | 100.0 % | 1.11 [0.53, 2.31] |
| Total events: 47 (Straight) | , 35 (Coiled) | | | | |
| Heterogeneity: $Tau^2 = 0.3$ | 36; Chi ² = 9.78, df = 4 | (P = 0.04); I ² =59% | | | |
| Test for overall effect: Z = | = 0.28 (P = 0.78) | | | | |
| | | | | | |
| | | | 0.02 0.1 1 10 50 | | |

Favours straight Favours coiled

Analysis 4.7. Comparison 4 Straight versus coiled, Outcome 7 Technique failure.

Review: Catheter type, placement and insertion techniques for preventing peritonitis in peritoneal dialysis patients

Comparison: 4 Straight versus coiled

Outcome: 7 Technique failure

| Study or subgroup | Straight n/N | Coiled | Risk Ratio M- H,Random,95% Cl | Risk Ratio M- H,Random,95% Cl |
|-------------------|-----------------|--------|--|--|
| Lye 1995 | 0/20 | 1/20 | | 0.33 [0.01, 7.72] |
| | | | 0.01 0.1 1 10 100 | |
| | | | Favours straight Favours coiled | |

Analysis 5.1. Comparison 5 Single versus double cuff, Outcome 1 All-cause mortality.

Review: Catheter type, placement and insertion techniques for preventing peritonitis in peritoneal dialysis patients

Comparison: 5 Single versus double cuff

Outcome: I All-cause mortality

| Study or subgroup | Single cuff | Double cuff | Risk Ratio M- H.Random.95% | | Risk Ratio M- H,Random,95% |
|-------------------|-------------|-------------|-----------------------------------|-----------------------------|----------------------------------|
| | n/N | n/N | r iji tario. | Cl | Cl |
| Eklund 1997 | 2/30 | 5/30 | | _ | 0.40 [0.08, 1.90] |
| | | | | | |
| | | | 0.05 0.2 I Favours single cuff | 5 20 Favours double cuff | |

Analysis 5.2. Comparison 5 Single versus double cuff, Outcome 2 Peritonitis.

Review: Catheter type, placement and insertion techniques for preventing peritonitis in peritoneal dialysis patients

Comparison: 5 Single versus double cuff

Outcome: 2 Peritonitis

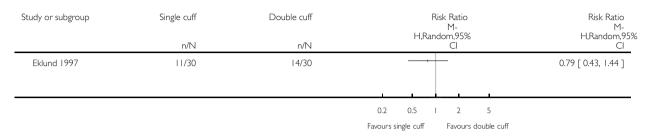
| Study or subgroup | Single cuff n/N | Double cuff n/N | Risk Ratio M- H,Random,95% Cl | Risk Ratio M- H,Random,95% Cl |
|-------------------|--------------------|--------------------|---|--|
| Eklund 1997 | 14/30 | 17/30 | | 0.82 [0.50, 1.35] |
| | | | 0.5 0.7 1 1.5 2 | |
| | | | Favours single cuff Favours double cuff | |

Analysis 5.3. Comparison 5 Single versus double cuff, Outcome 3 Exit-site/tunnel infection.

Review: Catheter type, placement and insertion techniques for preventing peritonitis in peritoneal dialysis patients

Comparison: 5 Single versus double cuff

Outcome: 3 Exit-site/tunnel infection



Analysis 5.4. Comparison 5 Single versus double cuff, Outcome 4 Catheter removal or replacement.

Review: Catheter type, placement and insertion techniques for preventing peritonitis in peritoneal dialysis patients

Comparison: 5 Single versus double cuff

Outcome: 4 Catheter removal or replacement

| Study or subgroup | Single cuff | Double cuff | Risk Ratio M- | Risk Ratio M- |
|-------------------|-------------|-------------|----------------------|---------------------|
| | n/N | n/N | H,Random,95% Cl | H,Random,95% Cl |
| Eklund 1997 | 6/30 | 3/30 | | 2.00 [0.55, 7.27] |
| | | | | |
| | | | 0.1 0.2 0.5 1 2 5 10 | |

Favours single cuff Favours double cuff

Analysis 6.1. Comparison 6 Immobilisation versus no immobilisation, Outcome I Peritonitis.

Review: Catheter type, placement and insertion techniques for preventing peritonitis in peritoneal dialysis patients

Comparison: 6 Immobilisation versus no immobilisation

Outcome: I Peritonitis

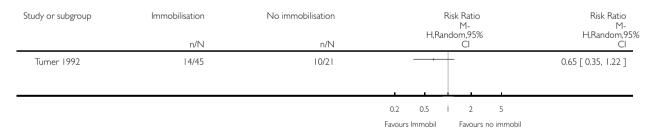
| Study or subgroup | Immobilisation | No immobilisation | Risk Ratio M- H,Random,95% | Risk Ratio M- H.Random,95% |
|-------------------|----------------|-------------------|----------------------------------|----------------------------------|
| | n/N | n/N | Cl | Cl |
| Turner 1992 | 18/45 | 7/21 | | 1.20 [0.59, 2.42] |
| | | | | |
| | | | 0.2 0.5 I 2 5 | |
| | | | Favours Immobil Favours no imm | obil |

Analysis 6.2. Comparison 6 Immobilisation versus no immobilisation, Outcome 2 Exit-site/tunnel infection.

Review: Catheter type, placement and insertion techniques for preventing peritonitis in peritoneal dialysis patients

Comparison: 6 Immobilisation versus no immobilisation

Outcome: 2 Exit-site/tunnel infection



ADDITIONAL TABLES

Table 1. Published guidelines on catheter related interventions in peritoneal dialysis

| Guideline | Country | Year | Recommendation |
|--|--------------------------|------|---|
| Kidney Diseasese Outcome Quality Initiative (K-DOQI) | United States of America | 2000 | No guideline |
| British Renal Association (BRA) | United Kingdom | 2002 | Catheter type: No peritoneal dialysis catheter has proven to be superior to the standard double cuff Tenckhoff catheter. In pae- diatric populations, no peritoneal dialysis catheter has proven to be superior to the standard double cuff Tenckhoff catheter. Swan neck tunnel, two cuff and downward pointing exit-site may have an advantage. No guideline on catheter placement |
| Canadian Society of Nephrol- ogy (CSN) | Canada | 2003 | No guideline |
| European Best Practice Guide- lines (EBPG) | Europe | 2003 | No guideline |
| International Society of Peri- toneal Dialysis (ISPD) | Not applicable | 2000 | No catheter appears to be superior to the standard two cuff Tenckhoff catheter. Double cuff catheters are recommended to reduce peritonitis and improve catheter survival time. Peri- toneal entry should be lateral or paramedian. Exit-site should be facing downwards or be directed laterally. Upward-directed exit sites should in general be avoided |
| Caring for Australians with re- nal Impairment (CARI) | Australia | 2003 | No peritoneal dialysis catheter has proven to be superior in the prevention of peritonitis (level III evidence). There is no tech- nique of insertion of a peritoneal dialysis catheter that has con- sistently proven to be superior in the prevention of peritonitis (level II evidence) |

Table 2. Electronic search strategies

| Database searched | Search terms |
|------------------------------|--|
| CENTRAL (Issue 2 2004) | #1 peritoneal next dialysis #2 PERITONEAL DIALYSIS (MeSH explode)) #3 pd or capd or ccpd #4 #1 or #2 or #3 #5 PERITONITIS (MeSH) #6 periton* #7 #5 or #6 #8 #4 and #7 |
| MEDLINE (1966 to April 2004) | 1 exp Peritoneal Dialysis/ 2 peritoneal dialysis.tw. |

Table 2. Electronic search strategies (Continued)

| 3 (PD or CAPD or CCPD).tw. |
|---------------------------------|
| 4 or/1-3 |
| 5 Catheters, Indwelling/ |
| 6 catheter\$.tw. |
| 7 or/5-6 |
| 8 Peritonitis/ |
| 9 peritonitis.tw. |
| 10 (periton\$ and infect\$).tw. |
| 11 or/8-10 |
| 12 and/4,7,11 |
| 13 pc.fs. |
| 14 (plac\$ or insert\$).tw. |
| 15 (break-in or immobil\$).tw. |
| 16 surg\$.tw. |
| 17 or/13-16 |
| 18 12 and 17 |
| 19 and/4,11,13 |
| 20 18 or 19 |
| |

WHAT'S NEW

Last assessed as up-to-date: 2 August 2004.

| Date | Event | Description |
|-----------------|---------|--------------------------|
| 14 January 2010 | Amended | Contact details updated. |

HISTORY

Protocol first published: Issue 1, 2004

Review first published: Issue 4, 2004

| Date | Event | Description |
|-------------------|---------|---------------------------------|
| 13 May 2009 | Amended | Contact details updated. |
| 22 September 2008 | Amended | Converted to new review format. |

CONTRIBUTIONS OF AUTHORS

- Designing the Review; GFMS, DJ, JCC
- Coordinating the review; JCC
- Data Collection for the review was carried out independently by GFMS and AT, and included the following components:
- Developing search strategy
- Undertaking searches
- Screening search results
- Organising retrieval of papers
- Screening retrieved papers against inclusion criteria
- Appraising quality of papers
- Abstracting data from papers (Renal Group data extraction form)
- Searching for additional data in unpublished studies
- Data management for the review
- Entering data into RevMan; GFMS, AT
- Analysis of data; GFMS, DJO, JCC
- Interpretation of data: GFMS, DJO, JCC
- Providing a methodological perspective
- Providing a clinical perspective
- Providing a policy perspective
- Providing a consumer perspective
- Writing the review; GFMS, DJO, JCC
- Providing general advice on the review; JCC, DJO, FPS

DECLARATIONS OF INTEREST

Associate Professor David Johnson is a consultant for Baxter Healthcare Pty Ltd and has previously received research funds from this company. He has received speakers' honoraria from Fresenius Medical Care.

INDEX TERMS

Medical Subject Headings (MeSH)

*Peritoneal Dialysis [instrumentation]; Catheterization [*methods]; Catheters, Indwelling; Peritonitis [*prevention & control]; Randomized Controlled Trials as Topic

MeSH check words

Humans