



Best Practice

Evidence Based Practice Information Sheets for Health Professionals

Clinical effectiveness of different approaches to peritoneal dialysis catheter exit-site care

Information Source

This *Best Practice* Information Sheet has been derived from a systematic review of research entitled "Clinical effectiveness of different approaches to exit-site care."^{1a} The primary references on which this information sheet is based are available in the systematic review report published by and available from Blackwell Publishing Asia.

Background

Peritoneal dialysis (PD) has been described as a readily available and simple method for selective filtration of excess water, electrolytes and metabolites.¹ It is reported to promote improved well-being and greater personal freedom than haemodialysis through less restrictive life-style changes. It has also been argued that PD should be offered to all appropriate end-stage renal failure patients.¹

Prevention of infection is considered essential for the successful maintenance of PD. Strategies to prevent or reduce the risk of infection are reported to include rigorous exit-site care,

This Information Sheet Covers the Following:

Key Definitions

Antibiotics

Antiseptics

Antimicrobials

Dressings

Recommendations

catheter care and meticulous attention to the use of a clean no-touch technique for dialysis exchanges. In addition to these strategies, other methods reported to prevent infection include reducing the build up of biofilm on catheters and treatment of nasal *Staphylococcus aureus*.⁴ Exit-site care is reported to be integral to PD management. One author has called for increased research activity in this field, as exit-site care has an impact on peritonitis rates, and exit-site infections are as significant a complication of PD as peritonitis.⁵

There is evidence that exit-site infections can tunnel through to the peritoneal space, leading to peritonitis.⁶ The abdominal tunnel through which the dialysis

Levels of Evidence

All studies were categorised according to the strength of the evidence based on the following classification system:^{2a}

Level I Evidence obtained from a systematic review of all relevant randomised controlled trials.

Level II Evidence obtained from at least one properly designed randomised controlled trial.

Level III.1 Evidence obtained from well designed pseudo-randomised controlled trials (alternate allocation or some other method).

Level III.2 Evidence obtained from comparative studies with concurrent controls and allocation not randomised (cohort studies), case-control studies or interrupted time series with a control group.

Level III.3 Evidence obtained from comparative studies with historical control, two or more single arm studies, or interrupted time series without a parallel control group.

Level IV Evidence obtained from case series, either post-test or pre-test and post-test.

catheter passes is a dark, moist, protected environment. As such, there is a risk of tunnel infection arising even in the absence of peritonitis or exit-site infection.^{2,5,7} Either exit-site or tunnel infections may lead to peritonitis or failure of PD therapy.⁵ A review of the literature has found that catheter-related peritonitis occurs in up to 20% of patients undergoing continuous ambulatory peritoneal dialysis (CAPD) and exit-site infection

Table 1: Definitions

Continuous ambulatory peritoneal dialysis (CAPD): dialysate solution instilled into the peritoneum for four to eight hours. During this time solutes, fluid and uraemic metabolites pass into the peritoneal fluid by the process of diffusion and osmosis. The fluid is exchanged four to five times a day, seven days a week. ³
Exit Site Infection: defined as the presence of redness, inflammation and purulent exudate at the catheter site. ⁷
Peritonitis: defined as two positive peritoneal fluid cultures in an asymptomatic person or one positive peritoneal fluid culture in person with symptoms of peritonitis (such as abdominal pain, fever and cloudy peritoneal fluid). ⁷
Blisterfilm®: a 14x15cm polyurethane adhesive dressing with a 7.5x7.5cm central area free of adhesive.
Op-site®: transparent adhesive dressing.
Sodium hypochlorite: is an extensively used antiseptic that when used in concentrations of about 0.005% it has been shown to be germicidal without being cytotoxic. ¹⁸
Chlorhexidine gluconate: antibacterial with broad spectrum activity.
Cover-Roll® dressing: permeable, high tensile strength, translucent adhesive gauze dressing.
Coverlet OR® dressing: a semipermeable, sterile, water resistant cellulose wound dressing.

may be the cause of catheter removal for more than one-fifth of catheters removed.⁶

The focus of the review report of exit-site management was specifically to identify, appraise and summarise the research on measures to prevent exit-site infection. A large number of studies had been conducted that examined a range of techniques. Typically, these involved the use of multifaceted interventions inclusive of cleaning with solutions such as potable tap water through to antibiotic or antiseptic solutions, the application or avoidance of covering dressings and the use of antiseptic devices to assist in maintaining an infection free exit-site.^{2,4,5,7-12}

Although many different approaches to catheter exit-site care have been proposed, few have been rigorously evaluated. Practice guidelines and surveys reported in the literature are equally varied in terms of quality and the methods of how to perform safe, effective exit-site care.^{2,3,7} It has been suggested that some of the limitations to reducing complication rates include the continued use of outdated protocols and reliance on incomplete analysis of current literature.⁸ Patients on all forms of PD self-manage their dialysis routines with visits to health care professionals occurring either for regular check ups or for treatment when complications have arisen. Thus the effectiveness of PD exit-site care in reducing the risk of exit-site infections is a collaborative responsibility with regard to the types and frequency of exit-site care.¹³

Interventions

Based on current evidence, interventions for exit-site care may be placed into one of four categories:

1. Antibiotics
2. Antiseptics
3. Antimicrobial products
4. Dressings

The effects of these interventions for both the early post-operative and long term period have been combined as sufficient information was not available to analyse these separately.

Antibiotics

Mupirocin

Mupirocin is an antibiotic that is active against *Staphylococcus aureus* (*S. aureus*) and is therefore used to treat these infections. The evidence for the effectiveness of mupirocin cream in preventing or ameliorating exit-site infections is limited. (Level III.3)

In one trial with historical controls, CAPD and continuous cyclic PD patients (n=82) were randomised to treatment of the exit-site with either 2% mupirocin calcium ointment daily (n=41) or oral rifampin (300mg) twice per day for 5 days every 3 months (n=41).¹⁰ Infection rates were compared to a historical control group (n=354) and outcomes were expressed as episodes of infection per dialysis year.

This study showed that topical application of mupirocin ointment significantly reduced exit-site infection rates from all organisms (p=0.001), incidence of peritonitis from all organisms (p=0.001), exit-site infections (p=0.001) and peritonitis (p=0.001) due to *S. aureus*. No evaluation of development of

antibiotic resistance was performed.

A second historical controlled trial of 291 PD patients compared the effectiveness of mupirocin ointment (n=143) with usual care (n=148).²⁶ In addition to usual daily care of cleaning the site with soap and water, mupirocin cream was applied with a sterile gauze pad by the treatment group.

There were 36 exit-site infections in the historical control group and 16 in the mupirocin group, with a reported relative risk reduction of 49% ($p < 0.001$). Application of mupirocin cream was shown to reduce the exit-site infection rate from all organisms ($p < 0.001$), the rate of peritonitis from all organisms ($p = 0.003$), as well as the peritonitis rate due to *S. aureus* ($p = 0.05$), when compared with the standard treatment of washing with soap and water only. However, due to bias inherent in the design of these studies and lack of blinding, the effectiveness of topical mupirocin to prevent exit site infections or peritonitis was not proven.

Ciprofloxacin

In a trial of 78 first time CAPD patients, ciprofloxacin (1mg in 0.5mL daily) was applied topically to the exit-site in addition to standard care.⁶ The comparison group was a historical control group (n=86) who performed only the standard care of a daily cleansing with soap and water, drying, then applying a sterile gauze covering.

Daily use of ciprofloxacin reduced the risk of exit-site infections to 15% of controls ($p < 0.00001$). All exit-site infections in the ciprofloxacin group were due to *S. aureus* which showed a significant reduction in the risk of infection due to this organism

($p < 0.00001$). The risk of peritonitis due to *S. aureus* was also significantly reduced ($p = 0.04$). (Level III.3)

Sodium fusidate

Sodium fusidate, a bactericidal antibiotic that is especially active against staphylococci, was evaluated in one small study.

In a single unblinded RCT of 31 CAPD patients over the age of 15 years, the effectiveness of 2% sodium fusidate ointment applied to the exit site and anterior nares twice per day for 5 days (n=9) was compared to a 5-day regimen of oral ofloxacin (n=9) (200 mg/48 h) or placebo tablets (n=13).²⁸ Treatment courses were repeated at monthly intervals for a mean follow-up period of 7.8 months. Patients were monitored for episodes of *S. aureus* exit site and peritoneal infection. No significant differences in the risk of exit-site infection ($p = 0.13$) or peritonitis ($p = 0.22$) due to *S. aureus* were found between the sodium fusidate and the control groups. However, any real difference in effectiveness between the treatments may have been missed due to the small sample size of this RCT. (Level III.1)

Antibiotic resistance

Development of antimicrobial resistance with the prophylactic use of mupirocin, sodium fusidate or ciprofloxacin was neither identified or investigated in these studies. It remains to be seen what would occur with use of these antibiotics for periods longer than 18 months as would be expected in patients on long term PD.

Antiseptics

The most commonly tested antiseptic in identified research was povidone-iodine but other products such as sodium

hypochlorite, hydrogen peroxide and silver rings have also been investigated.

Povidone-iodine

Randomised controlled trials evaluating the effectiveness of povidone-iodine as a treatment to prevent exit-site infections and peritonitis in PD patients have provided mixed results. (Level II)

In a multicentre RCT, new and current adult CAPD patients were randomised to disinfect the exit site 2–3 times per week with a 20 g/L solution of povidone-iodine and then cover the exit-site with a sterile gauze, or cleanse the exit-site daily with non-disinfectant soap on a sterile gauze.²⁹ Results showed a reduction in the rate of exit-site infections with the use of povidone-iodine solution compared to soap and water cleansing ($p = 0.07$).

In an assessor blinded RCT, 117 CAPD or intermittent PD (IPD) patients were randomised to either application of 3.5g of 10% povidone-iodine on gauze at dressing changes or to a group where plain sterile gauze was wrapped around the peritoneal catheter at the exit-site.¹¹ Povidone-iodine treatment did not reduce the risk of overall infection ($p = 0.25$), exit-site infection ($p = 0.48$) or peritonitis ($p = 0.30$). The effect of povidone-iodine was to delay the occurrence of infections for up to 140 days after start of PD, at which time infection rates between groups became similar.

In an unblinded RCT of 149 adult PD patients, the effectiveness of standard dressing changes versus standard dressing changes plus povidone-iodine dry powder spray (2.5%) was assessed for the prevention of exit-site infections and/or peritonitis.³⁰ Again, povidone-iodine did not reduce the number of total

infections, exit-site infections or peritonitis compared to control over the period of the study.

Another unblinded RCT compared the effectiveness of povidone iodine with the use of sodium hypochlorite and chlorhexidine gluconate as antiseptic prophylaxis for PD catheter-related infections.³¹ In group one (chlorhexidine gluconate) 18 patients were followed up for 134 patient months and only one exit-site infection was recorded, giving an infection rate per patient month of 1/134. In group two (sodium hypochlorite) two exit-site infections were recorded, giving an infection rate per patient month of 1/41 for 82 patient observation months. In group three (povidone-iodine) no exit-site infections were recorded in 142 patient observation months. The low rates of infection over the period of the study did not translate into any significant differences in infection rate between any of the study groups.

Randomised controlled trials evaluating the effectiveness of povidone-iodine have provided inconclusive results. Using povidone-iodine spray powder was not found to be any more beneficial than a standard dressing for reduction of exit-site infection, peritonitis or tunnel infection, while a lower quality study found no improved effectiveness of povidone-iodine ointment when compared to two other antibiotics. Therefore, no definitive conclusions regarding the effectiveness of povidone-iodine in reducing the rate of exit-site infection or peritonitis in PD patients can be established on present evidence. There is a substantive need for rigorous studies using concurrent controls and longer periods of follow up.

Antimicrobial products

Silver

There has been some evidence that medical silver devices may reduce local tissue infections. Steady release of molecular quantities of silver are suggested to have an antimicrobial effect.¹²

In an RCT involving 195 PD patients, placing a silver ring around an existing catheter at the skin level of the exit-site was no more effective at preventing exit-site infection, sinus tract/tunnel infection, or peritonitis than not wearing a silver ring. Peritoneal dialysis patients with diabetes were also not protected from exit-site infection when using the silver ring.³² (Level II)

In a small trial, application of a silver ring did not provide any protection from exit-site infection, or peritonitis compared to patients without a silver ring. (Level III.1)

Therefore based on present evidence it would appear that silver is not effective at preventing exit-site infections or peritonitis in PD patients.

Dressings

Dressing types and application techniques have also been examined for use in preventing exit-site infections and peritonitis in PD patients.

OpSite®, gauze dressing or no dressing

In an RCT, 32 existing adult CAPD patients were randomised to one of three groups. A conventional dressing of gauze (n=11), OpSite® (n=7) or no dressing (n=9) was used, and patients were followed for assessment of infection for a period of 6 weeks.³³ Five patients dropped out during the study, four in the OpSite® treatment group and one in the

no dressing group. By intention to treat analysis the OpSite® method may not produce different infection rates to the other treatments but a considerable proportion of patients may not tolerate OpSite® as a dressing due to itching. (Level II)

In a pilot RCT, 13 patients were allocated to a control group (n=10) which used a routine cleaning procedure with a dressing over the exit-site.¹³ The treatment group (n=3) used the same procedure but left the exit-site open. Nine total observations were made in the treatment group and 45 were made in the control group. There was no significant difference in the number of infections as identified by positive culture growth (p=1.0).

Coverlet OR®

In a historically controlled trial, a stepwise care protocol was developed using a sample of 80 adult PD patients receiving new catheters (see table 2).³⁴ The outcomes from each protocol were evaluated and changes incorporated in to the next protocol as indicated. Using purposive sampling every patient who received a new catheter during that specific protocol period was included. The study outcomes showed significantly fewer exit-site infections over the 3 month period for the final protocol compared to the original control protocol (p=0.02). However, the number of changes made between the control and the final intervention group made it difficult to determine whether the reduced infection rates were due to the dressing, surgical procedure or the home care procedure. (Level III.3)

Table 2: Stepwise dressing protocol for PD patients

Historical control group (original protocol)

Pre-operative	antibiotics
Post-operative	gauze dressing applied and secured at the edges with paper tape.
Days 2-4 post-operative	sterile dressing changes using povidone-iodine solution, sterile water and gauze dressings daily.
Days 5-16 post-operative	daily exit-site care performed using povidone-iodine scrub, full strength hydrogen peroxide scrub and gauze dressings.
At home	exit-site cleansed with povidone-iodine scrub in the shower, full strength hydrogen peroxide and then site painted with a povidone-iodine swabaid. No dressing applied. Titanium dressing taped to the skin.

The experimental group (final protocol)

Pre-operative	assessed for nasal <i>S.aureus</i> and treated. Patients started on a multi-vitamin. Hibiclens shower the night before and the day of surgery.
Peri-operative	package containing the peritoneal catheter was opened in the surgery just prior to placement. Cover-Roll® dressing applied over the gauze dressings and remains in place for four days post-operative.
Days 5-9 and 12-16 post-operative	sterile dressing change was made using povidone-iodine swabsticks and a Coverlet OR® dressing (a semi-permeable, sterile, water resistant cellulose wound dressing).
Days 10-11 post-operative	the dressing was not changed.
At home	exit-site cleansed with Ivory soap when showering, the site painted with a povidone-iodine swabstick and covered with a Coverlet OR® dressing. Titanium connector taped to the skin.

Wash and shower technique vs occlusive dressing technique

In a variation of no dressing versus dressing method, a RCT of 60 CAPD patients were randomised into a treatment group that followed a simple wash and shower technique (n=30) where application of a cover dressing was optional or to a protocol requiring an occlusive dressing (n=30) to remain over the exit-site during showering and replacement of the dressing afterwards using a dressing pack and an occlusive dressing to secure

a sterile gauze pad to the exit-site.³⁵ During this 2 year study the outcomes were measured as rates of infection per patient observation months. Independent assessment did not find any significant difference in the rate or risk of infection between the two groups (p=0.17). (Level II)

Blisterfilm® vs gauze

A pseudo-RCT (n=29) using consecutive allocation examined the effectiveness of using Blisterfilm® (n=15) to cover the exit-site compared with gauze covering

(n=14) on reducing the incidence of exit-site infection.³⁶ The Blisterfilm® was changed every 5 days and the gauze covering was changed daily. The results showed no statistically significant difference in the percentage of exit-site infections caused by all organisms experienced by either group (p=0.21). Therefore, on present evidence no one dressing technique can be strongly recommended as being more effective than another at reducing or preventing exit-site infections or peritonitis. (Level III)



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Implications for practice

No one particular dressing technique can be recommended at this time. (Level II)

The results of the review did not strongly point to any one antibiotic, antiseptic, or dressing procedure for use in the prevention or reduction in exit site infection rates or peritonitis. Therefore, until better evidence is available practice will continue to rely primarily on the clinical experience of the attending clinician.

Implications for research

This review has underlined large gaps in the existing knowledge regarding the care of exit-sites in PD patients. Long term randomised controlled trials with sufficient power and blinding are necessary to look at the most effective antibiotics, antiseptics, and dressing methods.

Recommendations

1. Prophylactic therapy using mupirocin ointment at the exit-site may decrease the risk of *S. aureus* exit-site infection. (Level III.3)
2. Povidone-iodine applied to the exit site may be effective in reducing the rate of exit site infections up to 140 days after start of PD, after which the effectiveness of this treatment becomes less clear. (Level II)
3. A silver ring placed around the catheter at the exit site is not recommended for the prevention or reduction in exit site infections or peritonitis. (Level II)

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These additional references have been included for your convenience. Reference numbering has been maintained as cited from the Systematic Review.

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