Please note: These studies may involve findings that exceed the claims currently cleared by the FDA for the product. Bravida Medical is not intending to make performance claims about its product. The intent is to disseminate the scientific literature on these products. We encourage you to read these studies to understand the strengths and limitations of the data. For some claims, Bravida is seeking to broaden the indications with the FDA in the future using data, such as these studies, to provide the substantiation.

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Clinicians identify ways to prevent peritoneal dialysis catheter exit site infections



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# Clinicians identify ways to prevent peritoneal dialysis catheter exit site infections

Studies have shown patients with end-stage kidney disease treated with peritoneal dialysis perceive they have a higher quality of life than those who receive in-center hemodialysis.

In addition, PD has been noted to be a significantly less expensive modality than in-center hemodialysis (ICHD). In the absence of complications, an individual can live a healthy, active life on PD for many years. It benefits the patient and society to have patient start with PD as their first modality and to remain on PD as long as possible.

Peritonitis is the most frequent reason for catheter removal and patient dropout from PD. The relationship between PD catheter exit site infections (ESI) and peritonitis was first noted in the 1980s, when it was found that patients with an ESI were more likely to develop peritonitis than patients who did not have an ESI.

Current recommended practice for the prevention of PD catheter-related infections is routine catheter exit site care, including a daily cleansing of the catheter exit site using liquid pump soap followed by prophylactic topical application of gentamicin 0.1% cream or mupirocin 2% ointment.

# **Antibiotic resistance**

Antibiotic resistance is a significant problem in health care, and there is a growing concern about the potential for increasing antibiotic resistance with long-term prophylactic use of topical antibiotics at the PD catheter exit site.

The PD community is now reporting cases of patients using prophylactic topical gentamicin who developed ESIs with organisms that are found to be gentamicin resistant. Other organisms, such as the emerging fungus Candida auris, have been found to be difficult to identify with standard laboratory methods and are often resistant to all three available classes of antifungals, posing serious global health threats.

Antibiotic stewardship is of the upmost importance as a way to prevent the development of antibiotic resistance, improve patient outcomes and reduce health care costs. It has been shown that even a moderate reduction in antibiotic usage can reduce the transmission of multidrug-resistant organisms. Growing concerns about resistance have led to a quest for alternatives to topical antibiotics.

#### Modified sodium hypochlorite

Modified sodium hypochlorite 0.057% has been tested and proven to kill the pathogens that are the most common causes of ESI. Although modified sodium hypochlorite liquid is also available at higher concentrations, kill studies have shown it to be effective at the 0.057% concentration, eliminating the need to expose the skin to a higher concentration product.

In liquid and gel forms, the commercially available modified sodium hypochlorite 0.057% has exceptionally rapid broad-spectrum fungicidal, sporicidal, virucidal and bactericidal properties. These include the pathogens Candida auris, SARS-Cov 2, HIV-type 1, Clostridium difficile spores and the antibiotic-resistant strains carbapenem-resistant Escherichia coli, MRSA and vancomycin-resistant Enterococcus faecalis.

Clinical studies report that it produces a significant reduction in both aerobic and anaerobic wound bioburden, dissolves necrotic tissue remnants, does not interfere with the mechanisms responsible for wound re-epithelialization and is effective in wound odor control.

Sodium hypochlorite 0.057% has a 2-year shelf life when stored at room temperature.

The Southern California Permanente Medical Group Home Dialysis Program currently has more than 225 patients on PD. The patients are provided with daily PD catheter exit site care (see <u>Table</u>).

#### Gently wash the exit site and catheter with mild liquid soap and Table. Daily exit site care your fingers. Do not scrub the exit site area. Do not remove any for patients using PD 5. Rinse thoroughly. Pat dry the exit site area and the catheter with a clean towel or Materials paper towels. Anasept (Anacapa Technologies) antimicrobial skin and wound Apply one to two sprays of antimicrobial skin and wound cleanser to the exit site area. Anasept antimicrobial skin and wound gel After 2 minutes, blot the cleanser from the exit site area with a 3x3 catheter immobilization device liquid pump soap Apply a small amount (pea size) of antimicrobial skin and wound 3x3 gauze around site, including underneath the catheter. dressing 10. Apply an air-permeable dressing to the exit site. A 3x3 gauze crisscrossed with paper tape or a self-adhesive non-adherent **Procedure** dressing may be used. Wash hands per WHO guidelines. 11. Immobilize the catheter by taping it to the abdomen. Make certain to allow the catheter to loop loosely before securing to the Remove the old dressing from the catheter exit site. Secure the catheter abdomen to minimize the risk tugging at the exit site. For added by taping it to the abdomen or by using an immobilization device. Do not safety, an immobilization device may be used. allow the catheter to dangle Inspect the catheter exit site area for signs of redness, swelling, These instructions may be adjusted by specific nephrologist preferences drainage or bleeding. If any are present, report observation to the or patient needs. PD nurse as directed

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### Results

All of the patients apply the sodium hypochlorite 0.057% spray, but many are instructed to apply gentamicin 0.1% cream. Our program from 2015 to 2020 included 13,825.2 patient treatment months. During that time, we saw 235 episodes of peritonitis (frequency of 1:58.8 patient months). This is 27% lower than the national average.

We did see 156 ESIs with a frequency of 1:88.6 patient months. This is significantly better than the reported ESI range of 1:29.3 to 1:57.1 patient months.

Modified sodium hypochlorite 0.057% spray has been noted to effectively remove any dried exudate from the exit site area. Applied via a pump spray bottle, the product covers an area of several square inches surrounding the exit site, effectively disinfecting the entire area of skin and catheter that will be covered by the air permeable dressing. We have rarely seen any local skin irritation after prolonged use.

Modified sodium hypochlorite 0.057% gel remains effective for 24 hours, providing continuous antimicrobial protection between dressing changes. The gel is also effective in debriding the immediate exit site area. The clear hydrogel softens the dry crust and scabs that often form around the catheter. We have observed that daily use of gentamicin 0.1% cream often creates a buildup of dried white product in the exit site surrounding the catheter. The clear, modified sodium hypochlorite 0.057% hydrogel dries without leaving a visible residue and does not occlude the exit site.

#### **Conclusion**

Our 20-plus years of experience using modified sodium hypochlorite 0.057% for daily exit site care has shown that healthy, infection-free PD catheter exit sites can be maintained in a cost-effective way, even without the use of additional topical antibiotics. In addition, using the sodium hypochlorite gel instead of topical antibiotics can provide long-acting,

broad-spectrum antimicrobial coverage while meeting the recommended Antibiotic Stewardship guidelines.

### For more information:

Talha H. Imam, MD, is a nephrologist with the Southern California Permanente Medical Group. He can be reached at talha.h.imam@kp.org.

Alan Falcioni, MSN, RN, CNN, was the peritoneal dialysis coordinator at Kaiser Permanente Southern California Ontario Medical Center. He can be reached at <a href="mailto:alanfalcioni@yahoo.com">alanfalcioni@yahoo.com</a>.

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**Disclosures:** Imam reports no relevant financial disclosures. Falcioni reports he is a renal clinical consultant at Anacapa Technologies in San Dimas, California, which manufactures the Anasept antimicrobial skin and wound cleanser and antimicrobial skin and wound gel.

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