Preventing Hospital Acquired Clostridium Difficile Infection in ICU Patients: The Efficacy of Theraworx, a Novel Silver-Based Cleanser

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Introduction

Prevention of hospital acquired *clostridium difficile* infection (CDI) continues to be an ongoing concern due to the prevalence, increase in patient morbidity and mortality, and impact on health care costs. It is estimated that 75% of CDI cases are hospital acquired with an estimated annual healthcare cost is $1.5-3.2 billion [5].

Literature has shown a multimodal approach is required for effective transmission prevention. Patient bathing aims to reduce skin contamination and eliminate spores that can survive for up to five months. However, Studies have shown that spores are resistant to the commonly used disinfectants, including Chlorhexidine gluconate (CHG) [5]. A global review of infection prevention strategies revealed significant gaps in consistency and standardization of policies regarding patient bathing techniques [7]. Lack of standardization leaves room for non-compliance and variance, ultimately affecting patient outcomes and increasing the risk of CDI.

Review of literature examining the efficacy of CHG bathing shows gaps in CDI prevention. A study evaluating CHG bathing on the rates of CDI in SICU patients was inconclusive [1]. A review of 17 trials examining CHG bathing against health-care associated infections in ICU patients did show evidence for reduction against CLABSI and CAUTI. However, effectiveness against other HAI, including CDI, were inconclusive [4]. A clinical trial has also showed a concern that CHG bathing may increase microbial resistance and CHG was not effective against multi-drug resistant bacteria [4, 3].

To address the gap in current practice, a study conducted to evaluate the safety and efficacy of Theraworx showed the colloidal silver-based product was non-inferior to the 4% CHG product [2]. Theraworx also has antimicrobial activity against gram positive and gram negative organisms even at low concentrations and has components that supports the skin's innate immune system [2, 6].

Purpose

We planned to explore a non-toxic silver-based skin antiseptic, Theraworx, to address skin contamination and spore eradication with a goal of preventing CDI in our ICU patients.

Methods

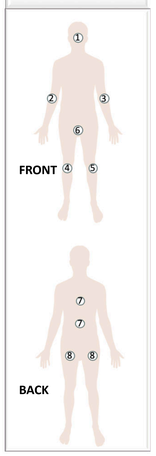
Creation and Implementation of Theraworx Protocol

- Theraworx patient bathing protocol was created by the Department of Infection Prevention at PBMC and was initiated in June 2017 for all ICU patients
- The protocol was communicated to nurses and patient care technicians, who were responsible for patient bathing
- Packet of wipes from warmer (warmer temperature auto regulated not to exceed 115 degrees F) or warm sealed packet under warm water

One packet (8 wipes total) per patient according to protocol

1. Use one cloth to wipe face, neck, chest and abdomen.
2. Use one cloth to wipe right arm and right hand.
3. Use one cloth to wipe left arm and left hand.
4. Use one cloth to wipe right leg and right foot.
5. Use one cloth to wipe left leg and left foot
6. Take one cloth and cleanse perineum. If patient has a foley catheter wipe catheter from meatus down the entire catheter.
7. Proceed to back area and with one wipe cleanse back.
8. Take one wipe, cleanse buttocks.

8 wipes total



Analysis of Results

- Results were analyzed by the Infection Prevention Department comparing data from rates of CDI prior to implementation of protocol (June 2017) and rates after implementation. Data included all patients in the ICU, including those with a prior history of CDI

Theraworx PROTECT

The Theraworx Advantage: A Topical Immunity Health System

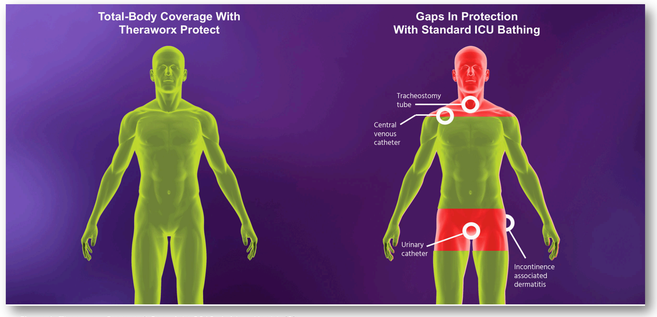
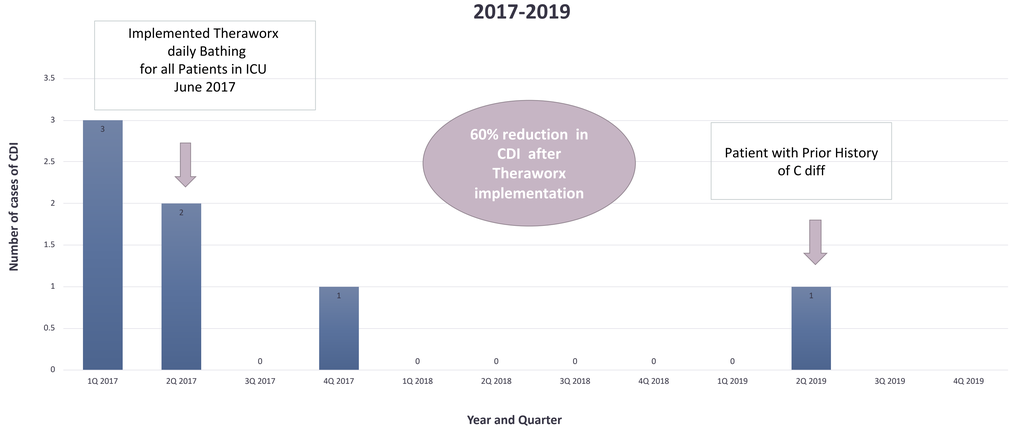
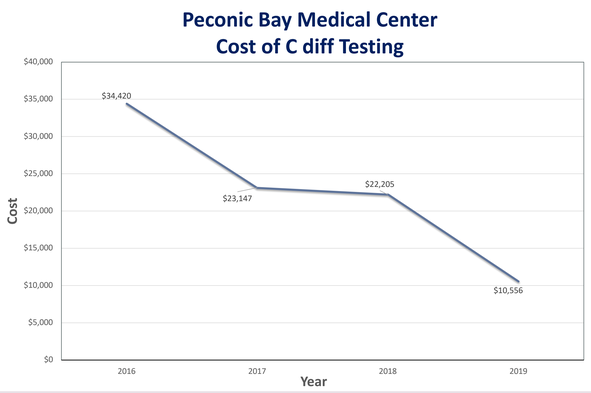


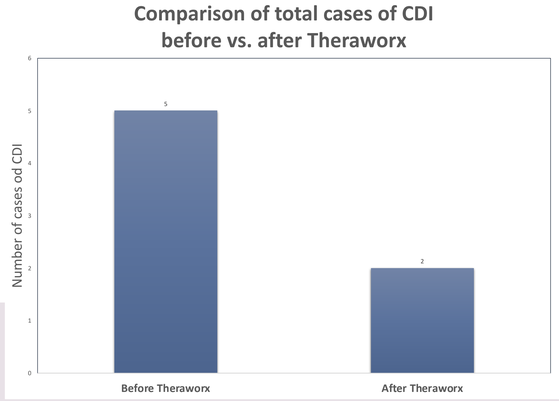
Figure 1: Theraworx Protect ® Copyright 2019, Avidam Health [9]

- Theraworx Protect is a novel silver-based, non-toxic cleanser line that offers numerous benefits that are lacking from the current standard of care:
  - This cleanser can be used on the face, mucosa, and perineum
  - Does not require rinsing after application
  - Acidic pH Supports the natural skin biome and optimizes the stratum corneum, an important barrier which prevents penetration of pathogens into the skin

RESULTS







Discussion

This study demonstrated that Theraworx is a superior cleanser in our ICU patients compared to the standard bathing protocol. In 2016-2017, there were 5 cases of CDI in our ICU. Our study showed that implementing Theraworx daily bathing lead to a 60% reduction in CDI rates. In the second quarter of 2019, there was one incidence of CDI in a patient with a known prior history of C.diff. Colonization by C.diff could have contributed to this occurrence. In addition, there has been an overall reduction in costs related to C.diff testing by more than $12,000.

Theraworx has several benefits in comparison to CHG. The perineum is an area that is commonly colonized by C. diff. Theraworx bath wipes can be applied to the perineum, while CHG bathing cannot. As a silver-based product, Theraworx maintains the normal acidic pH of the skin. It provides nourishment, supports cell growth and skin barrier protection. Overall, Theraworx enhances skin adhesion and integrity to prevent penetration of pathogens (2, 12).

As a no rinse formulation therefore eliminating extra steps which are required in daily bathing thus promoting better compliance.

Conclusion

Daily Theraworx bathing in the ICU has led to a reduction in hospital acquired C. difficile infection rates in these patients. Although our patient population was restricted to the ICU, we believe there is potential that implementing Theraworx in other units may lead to similar results. The benefits of Theraworx can have a great impact on reducing overall healthcare costs by reducing CDI rates.

Our findings of the effectiveness of Theraworx on reducing hospital acquired C. difficile may be helpful in the development of a hospital-wide and perhaps a system-wide standard patient bathing protocol.

Next Steps

Currently, Theraworx bathing is being implemented on inpatient medicine-surgery units who are at high-risk or have a history of C. difficile infection.

We have also seen a reduction in CLABSI and CAUTI rates in the ICU with daily Theraworx bathing used on patients with central indwelling catheters. We plan to further explore the effectiveness of Theraworx on other HAI.

We have also implemented Theraworx bathing for pre-operative and post-operative bathing to further prevent hospital acquired infections.

We hope to implement Theraworx bathing in other hospitals in our system to determine if similar results are attainable. If successful, this research may inform practice changing guidelines for patient bathing protocols.

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