Comparison of a New and Innovative 2% Chlorhexidine Gluconate (CHG) Impregnated Preparation Cloth with the Standard 4% CHG Surgical Skin Preparation

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OVERVIEW

It is estimated that 750,000 surgical site infections (SSIs) occur in the USA each year. This results in increased patient morbidity and mortality and costs more than $1.6 billion in excess hospital charges.[1] Effective and persistent skin antisepsis is one of the key measures to reduce the risk of SSI.

The peri-operative nurse can help meet the challenges of reducing SSI through his or her role in complete skin antisepsis. Choosing an effective skin preparation product can mean the difference between an uneventful surgical recovery and a multi-drug resistant SSI for your patient. CHG is a commonly used skin antiseptic that is effective and persists on the skin to provide prolonged antisepsis.[2] An alcohol-free 2% CHG preparation is now available in a no-rinse, preoperative skin preparation, offering a one-step method for presurgical preparation.

CHG, one of the most commonly used skin antiseptics, offers the benefit of prolonged activity on the surface of the skin.[3] This is of particular benefit during long surgical procedures or in body areas with high humidity and high bacterial counts, such as the inguinal region. A product that incorporates 2% CHG into a polyester, no-rinse, alcohol-free skin prepping cloth is now available.

The FDA requires antiseptic skin products to demonstrate rapid reduction in transient and resident microbes in the surgical field prior to incision. The antiseptic must also maintain its effectiveness (a 3.0 Log_{10} reduction from baseline) for at least 6 hours post application.[4] With these requirements in mind, this study sought to compare the efficacy of this new alcohol-free 2% CHG prepping cloth (PC) to the standard 4% CHG surgical skin prep (SP).

> "The non-abrasive texture of the 2% CHG preoperative skin prepping cloth most likely promotes a gentle exfoliation of skin cells within the prepped area, allowing for a more thorough antiseptic effect within the immediate post-application period."

This study found that the 2% CHG PC treatment led to a significantly greater log_{10} microbial count reduction in inguinal areas compared to the 4% CHG SP at all testing times (10 minutes, 30 minutes, 6 hours; $P<0.05$). The non-abrasive texture of the 2% CHG preoperative skin prepping cloth most likely promotes a gentle exfoliation of skin cells within the prepped area, allowing for a more thorough antiseptic effect within the immediate post-application period.

In addition to superior reduction in inguinal microbial counts, the 2% CHG PC was easier to use because it required no blotting or removal of excess CHG. This would be particularly useful (with or without assistance) for patients, such as orthopedic patients who are immobilized, who find it difficult to comply with early preoperative skin preparation (night before, morning of) to reduce preoperative microbial contamination prior to hospital admission and surgery.

METHODS

An open-label, matched-pair, parallel, phase-III clinical study was done on 30 volunteers. The subjects were screened with baseline skin sampling bilaterally on the abdomen near the umbilicus and at the inguinal crease of the inner-most aspect of the upper thigh. Those subjects with bacterial counts of a minimum of 5.0 log_{10} CFU/cm2 at the inguinal site and 2.4 log_{10} CFU/cm2 at the abdominal site were entered into the study.

One product was applied to one side of each subject and the second product to the other side. Computer randomization was used to determine sampling sites for each of 3 post-treatment sampling times of 10 minutes, 30 minutes, and 6 hours.

The 2% CHG PC was applied with vigorous wiping motion for 1.5 minutes, then turned to the unused side and used for an additional 1.5 minutes (total treatment time: 3 minutes). The 4% CHG SP solution was applied liberally with gauze for 2 minutes and blotted with sterile gauze; this was repeated as a second application for an additional 2 minutes followed by blotting with sterile gauze (total treatment time: 4 minutes).

Sites were sampled at 10 minutes, 30 minutes, and 6 hours after treatment. The skin was sampled using a CHG neutralizer combined with a sterile stripping fluid. After the 30-minute sample was done, the sampling area of the skin was protected with sterile gauze to prevent contamination before the 6 hour sampling time. The samples were immediately processed for culturing and incubation.

Confidence intervals were determined for baseline and post-application microbial recovery between study materials from calculated descriptive statistics. The confidence intervals were calculated using the MINITAB® (Version 14) statistical computer package. Matched-pair t-tests were used to compare the 2% CHG PC and 4% CHG SP treatments directly.

RESULTS

- **There were no adverse events in either treatment group.**
- **Baseline microbial counts from the inguinal sites were equivalent.**
- **At 10 minutes, 30 minutes, and 6 hours post-application, the 2% CHG PC demonstrated statistically significant reductions** in microbial counts ($P<.05$) in both the inguinal and abdominal sites.
- **The reduction in microbial counts at the abdominal sites with both preparations exceeded the FDA requirements.** (Table 2)
- **The 2% CHG PC exceeded the FDA requirements** for reduction in microbial counts in the inguinal area at all sample times. (Table 1)
- **The 4% CHG SP failed to meet the FDA requirements** for reduction in microbial counts in the inguinal area at 10 minutes. (Table 1)

Soft fibers gently exfoliate while evenly distributing 2% CHG

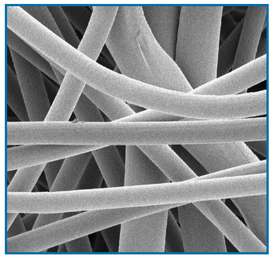


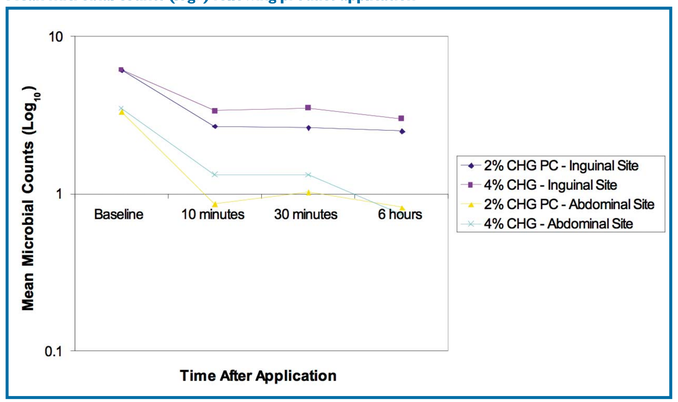
Table 1: Reductions in bacterial counts at inguinal sites after skin preparation

Results – Inguinal sites	Baseline inguinal microbial counts (log_{10} cfu/cm²)	Mean reductions in bacterial counts (log_{10} cfu/cm²): By time lapsed after prepping Inguinal sites			Meets or exceeds FDA Standards for skin prep
		10 minutes	30 minutes	6 hours	
2% CHG PC	6.15	3.45	3.50	3.64	✓
4% CHG SP	6.16	2.78	2.63	3.15	—

Table 2: Reductions in bacterial counts at abdominal sites after skin preparation

Results – Abdominal sites	Baseline abdominal microbial counts (log_{10} cfu/cm²)	Mean reductions in bacterial counts (log_{10} cfu/cm²): By time lapsed after prepping Abdominal sites			Meets or exceeds FDA Standards for skin prep
		10 minutes	30 minutes	6 hours	
2% CHG PC	3.36	2.50	2.33	2.54	✓
4% CHG SP	3.51	2.18	2.19	2.77	✓

Mean microbial counts (log_{10}) following product application



LESSONS LEARNED

- **The alcohol-free 2% CHG PC is a new, 500 mg equivalent CHG product that allows preoperative skin prep in one step** without blotting or removal of excess CHG.
- **The alcohol-free 2% CHG PC demonstrated significantly greater log_{10} microbial reduction** in the inguinal site for the entire testing period compared to the 4% CHG SP.
- **The amount of preparation time required for microbial reduction was less with the 2% CHG product** compared to the 4% CHG solution (3 minutes vs 4 minutes).
- **The antimicrobial effects from the 2% CHG product persisted on the skin for a full 6 hours** after application.
- **The non-abrasive, polyester skin preparation cloth most likely promotes a gentle exfoliation of skin cells** that allows for a more thorough antiseptic effect immediately after application.
- **The ease of use may make it easier for patients to comply** with early preoperative skin preparation (night before, morning of) to reduce microbial contamination.

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