

Evolução e segurança na antissepsia cirúrgica de mãos

Resultados de ensaios clínicos com métodos padrões de testes



Enf^a Deborah Abdo

Lead
the Way

3M

Método:	Escovação x Fricção Escovação x Fricção sem lavagem
Antisséptico:	CHG x PVPI x Álcool
Resultados:	Taxa de infecção; Coleta Microbiológica
Conclusão:	Não há diferença estatística significativa Método de fricção: melhor adesão à técnica Melhor condição da pele

1990- Estudos comparativos de protocolos de mãos para avaliar a eficácia dos métodos com escova x fricção.

Eficácia de três métodos de degermação das mãos utilizando gluconato de clorexidina degermante (GCH 2%)

O objetivo deste estudo foi avaliar três métodos para degermação cirúrgica utilizando a formulação degermante de gluconato de clorexidina – GCH 2%: com escova, com esponja e sem artefato.

EFFICACY OF THREE HAND ASEPSIS TECHNIQUES USING CHLORHEXIDINE GLUCONATE (CHG 2%)

EFICÁCIA DE TRES MÉTODOS DE DESINFECCIÓN DE LAS MANOS UTILIZANDO GLUCONATO DE CLORHEXIDINA ANTISÉPTICA (GHC 2%)

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SUMÁRIO

A degermação cirúrgica das mãos e dos braços é um procedimento que integra as atividades de paramentação cirúrgica como uma medida de prevenção de infecção do sítio cirúrgico. Com o advento dos princípios antissépticos degermantes, a necessidade do uso de escovas para a degermação cirúrgica tem sido questionada.

ABSTRACT

The scrubbing of hands and forearms using antiseptic agents has been the standard pre-operative procedure to prevent surgical site infection. With the introduction of antiseptic agents, the need to use brushes for pre-operative disinfection has been questioned and it has been recommended that the procedure be abandoned due to the injuries it

RESUMEN

La desinfección quirúrgica de manos y antebrazos es un procedimiento que integra las actividades prequirúrgicas como medida de prevención contra infección del sitio quirúrgico. Con el advenimiento de la antisepsia desinfectante, se cuestiona y se recomienda dejar de lado el uso de cepillos debido a lesiones provocadas en piel. Para

As

análises estatísticas comprovaram não haver diferenças estatísticas significantes na redução microbiana entre os três métodos analisados ($p=0,148$), o que teoricamente descarta a necessidade da continuidade do uso de escovas e esponjas para a realização da degermação das mãos.

tática de la técnica de desinfección sin uso de cepillos se evaluó tres métodos de desinfección quirúrgica, usando gluconato de clorexidina 2% con cepillo, con esponja y sin artefacto. Fueron evaluados los niveles de bacterias antes y después de la desinfección, usándose el método de recuento por placa para recolección de muestras. El análisis estadístico no mostró diferencias significativas entre los tres métodos, lo que teóricamente descarta la necesidad del uso de cepillos y esponjas para la desinfección de manos.

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Recommendations and Reports


Guideline for Hand Hygiene in Health-Care Settings
Recommendations of the Healthcare Infection Control Practices Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force

Vol. 23 No. 12, Suppl. INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY S3

GUIDELINE FOR HAND HYGIENE IN HEALTH-CARE SETTINGS: RECOMMENDATIONS OF THE HEALTHCARE INFECTION CONTROL PRACTICES ADVISORY COMMITTEE AND THE HICPAC/SHEA/APIC/IDSA HAND HYGIENE TASK FORCE

John M. Boyce, MD; Didier Pittet, MD

SUMMARY
The Guideline for Hand Hygiene in Health-Care Settings provides health-care workers (HCWs) with a review of data regarding handwashing and hand antisepsis in health-care settings. In addition, it provides specific recommendations to promote improved hand-hygiene practices and reduce transmission of pathogenic microorganisms to patients and personnel in health-care settings. This report reviews studies published since the 1965 CDC guideline (Garner JS, Favore MS. CDC guideline for handwashing and hospital environmental control, 1965. *Infect Control* 1966;7:231-41) and the 1995 APIC guideline (Larson EL, APIC Guideline Committee. APIC guideline for handwashing and hand antisepsis in health care settings. *Am J Infect Control* 1996;23:251-60) were issued and provides an in-depth review of recommended handwashing practices, and factors adversely affecting adherence. New studies of the in vivo efficacy of alcohol-based hand rubs and the low incidence of dermatitis associated with their use are reviewed. Recent studies demonstrating the potential role of alcohol-based hand rubs in improving hand-hygiene practices are summarized. Recommendations concerning lotions or creams, and wearing of artificial fingernails are also included (*Infect Control Hosp Epidemiol* 2002;27[suppl]:S3-S40).



AST Standards of Practice for Surgical Attire, Surgical Scrub, Hand Hygiene and Hand Washing

Introduction
The following recommended standards of practice were researched and authored by the AST Education and Professional Standards Committee and have been approved by the AST Board of Directors. They are effective April 13, 2008.

AST developed the Recommended Standards of Practice to support healthcare facilities

Recommended Practices for Preoperative Patient Antisepsis

The act of washing and rinsing removes microorganisms from the skin. Some organisms may be difficult or impossible to kill with the application of CHG alone.

Staphylococcus aureus is the most common organism causing surgical site infections.²⁴ In 2003, 64.4% of health care-associated *Staphylococcus aureus* infections were from methicillin-resistant *Staphylococcus aureus* (MRSA).⁴⁴ Many surgical site infections result from colonization of the surgical site with the patient's own flora; and colonization with *Staphylococcus aureus* is a known risk factor for the use of proper antiseptic showers to reduce the number of microorganisms on the skin, including *Staphylococcus aureus*.⁴⁴ In 1999, the Centers for Disease Control and Prevention recommend requiring patients to "shower or bathe with an antiseptic agent at least the night before the operative day" (Category IB).⁴

Unless contraindicated, patients should be instructed or assisted to perform two proper preoperative baths or showers with CHG before surgery to reduce the number of microorganisms on the skin and reduce the risk of subsequent contamination of the surgical wound. (PB, IAB, I123, I104, I50, I36, I106)

Four percent CHG is more effective than povidone-iodine or soap, and more showers are necessary to achieve the same antiseptic effectiveness.⁴⁴ An antiseptic shower with 4% CHG is found to be twice as effective as skin bacterial flora as shown in nonmedicated soap. Two studies found 4% CHG were found to reduce microbial counts than soap, medicated soap, iodine.⁴⁴ This greater reduction in bacterial counts persisted for 48 hours. One randomized study found two consecutive showers with 4% CHG resulted in a 12.8% reduction in site infection rates compared with 12.8% reduction with 4% CHG wash. A 20-fold reduction in bacterial counts at the end of the procedure.

National Collaborating Centre for Women's and Children's Health

Surgical site infection
prevention and treatment of surgical site infection



Perioperative Standards and Recommended Practices
2013 Edition

Association of periOperative Registered Nurses

Manager, Standards and Recommended Practices
Ramona Connor, MSN, RN, CNOR

Recommendation I
Patients undergoing open Class I surgical procedures below the chin should have two preoperative showers with chlorhexidine gluconate (CHG) before surgery, when appropriate.²

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Guidelines sobre Higienização de Mãos- Antissepsia Cirúrgica

	CDC	AORN	SHEA	APIC	WHO
Artefatos não são necessários	✓	✓	✓	✓	✓
Associação c/ CHG desejável	✓	✓	✓	✓	✓
Atividade residual	✓	✓	✓	✓	✓
Waterless	✓	✓	✓	✓	✓
Características antisséptico	✓	✓			

FALHAS NA ANTISSEPSE CIRÚRGICA DAS MÃOS

- Micro-perfurações nas luvas
 - 15% a 82%
 - 80% dos casos os microfuros não são percebidos pela equipe cirúrgica
 - Após 3 horas de cirurgia, 35% das luvas com microperfurações
 - 57% em cirurgias ortopédicas

**Antissepsia cirúrgica de mãos é uma medida essencial para redução de ISC.
Esta prática necessita garantir segurança e eficácia.**

Rabussay D, Korniewicz DM. The risks and challenges of surgical glove failure. AORN J. 1997; 66:867–888.

Glove Punctures and Postoperative Skin Flora of Hands in Cardiac Surgery

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Teste com 400 luvas
154 (39%) apresentou perfurações
Cir. até 3 horas
65% em cir. acima de 5 horas
Obs: Contagem bacteriana das
mãos em cir. prolongadas

Background. Surgical gloves are frequently perforated during operations, including heart operations. This infection risk factor is inadequately studied.

Methods. After preoperative hand disinfection and at the end of 116 heart operations, bacterial samples from hands of surgeons, altogether 800 samples, were taken. Glove punctures were examined with water test.

Results. Surgeons changed 70 gloves because of breakage during operations. Additionally, 154 of 400 (39%) gloves had holes in postoperative testing. The breakage rate of gloves increased from 30% in operations shorter than 3 hours to 65% when operations were longer than 5 hours. High bacterial counts of the hands were also more common after prolonged operations.

The lowest possible level is essential in heart surgery in which deep wound infections or prosthetic valve endocarditis lead to prolonged hospital stay and increased morbidity and mortality. One possible contamination route is a perforated glove. The purpose of surgical gloves is to create a barrier between the operating staff and the patient and thus to protect them both from microbial infections. In unused surgical gloves the puncture rate varies between 1.4% and 5.5% [1-3]. Studies conducted during surgical procedures have demon-

strated that the gloves used in heart surgery consisted mostly of coronary artery bypass grafting operations with cardiopulmonary bypass. One hundred six procedures were done through median sternotomy incision. Ten operations were redo procedures with previous heart operations. In total, 200 pairs of gloves from



Standard Test Method for Evaluation of Surgical Hand Scrub Formulations¹

This standard is issued under the fixed designation E1115; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ϵ) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This test method is designed to measure the reduction of microbial flora on the skin. It is intended for determining both immediate and persistent (continuing antimicrobial effect) microbial reductions, after single or repetitive treatments, or both. It may also be used to measure cumulative antimicrobial activity after repetitive treatments.

1.2 A knowledge of microbiological techniques is required for these procedures.

1.3 Performance of this procedure requires the knowledge of regulations pertaining to the protection of human subjects (21 CFR, Parts 50 and 56)

1.4 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.4.1 In this test method, SI units are used for all applications, except for distance, in which case inches are used and SI units follow in parentheses.

1.5 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 ASTM Standards:²

D1193 Specification for Reagent Water

E1054 Test Methods for Evaluation of Inactivators of Antimicrobial Agents

E2180 Test Method for Determining the Activity of Incorporated Antimicrobial Agent(s) In Polymeric or Hydrophobic Materials

2.2 Other Documents:

21 CFR Parts 50 and 56³

AATCC 147-2004 Antibacterial Assessment of Textile Materials: Parallel Streak Method⁴

JIS Z 2801 :2000, Antimicrobial Products—Test for Antimicrobial Activity and Efficacy⁵

USP 32 United States Pharmacopeia, Chapter 61 “Microbial Limits Test”, 2009⁶

3. Terminology

3.1 Definitions:

3.1.1 *active ingredient*—a substance added to a formulation specifically for the inhibition or inactivation of microorganisms.

3.1.2 *cleansing wash*—a non-antimicrobial wash intended to remove gross soil or residues from the hands.

3.1.3 *cleansing wash formulation*—a liquid castile soap or other liquid soap with neutral pH which does not contain an antimicrobial.

3.1.4 *cumulative effect*—a progressive decrease in the number of microorganisms recovered following repeated applications.

3.1.5 *internal reference formulation*—a formulation with demonstrated performance characteristics within the laboratory.

3.1.6 *neutralization*—a process that results in quenching or inactivation of the antimicrobial activity of a formulation. This may be achieved through dilution of the formulation or through the use of chemical agents called neutralizers.

3.1.7 *persistence*—prolonged or extended antimicrobial activity that prevents or inhibits the proliferation or survival of microorganisms after treatment.

¹ This test method is under the jurisdiction of ASTM Committee E35 on Pesticides, Antimicrobials, and Alternative Control Agents and is the direct responsibility of Subcommittee E35.15 on Antimicrobial Agents.

Current edition approved Aug. 1, 2011. Published August 2011. Originally approved in 1986. Last previous edition approved in 2010 as E1115 – 10. DOI: 10.1520/E1115-11.

² For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For Annual Book of ASTM Standards volume information, refer to the standard's Document Summary page on the ASTM website.

³ Available from U.S. Government Printing Office, 732 N. Capitol St., Washington, DC 20401, U.S. Government Bookstore, <http://bookstore.gpo.gov/baskets/crl-listing.jsp>.

⁴ Technical Manual of the American Association of Textile Chemists and Colorists (AATCC), 2009, Vol. 82, P.O. Box 12215, Research Triangle Park, NC 27709, <http://www.aatcc.org>.

⁵ Available from Japanese Industrial Standards Committee, Divisional Council on Consumer Life, Japanese Standards Association (JSA), 4-1-24 Akasaka Minato-Ku, Tokyo, 107-8440, Japan, <http://www.jsa.or.jp>.

⁶ Available from U.S. Pharmacopeia (USP), 12601 Twinbrook Pkwy., Rockville, MD 20852-1790, <http://www.usp.org>.

5.1 Este método de teste deverá ser usado para avaliar a atividade da formulação do produto em teste na:

- redução da população bacteriana das mãos
- imediatamente após uma única utilização
- determinar a atividade persistente (inibição do crescimento) depois de 6 h.



Análise comparativa dos Métodos de Testes

Método de teste	ASTM 1115	EN12791
Local testado	Mão inteira (Caldo de luvas)	Pontas dos dedos (Placa de Petri)
Número de aplicações	11	4 (1x semana)
Duração do teste	5 dias	4 x com intervalos
Tempo de coleta	1 min e 6 horas	1 min e 3 horas
Organismo testado	Microbiota Residente	Microbiota Residente
Teste controle	Um produto aprovado pelo FDA	N-propanol (12 a 15ml)
Requisitos de Redução Imediata	1 min no 1º dia, após a primeira aplicação, redução de 1 Log	Em 1 minuto o produto de teste tem que ser menor que o controle
Atividade persistente ou sustentada	Até 6 horas após a 1º aplicação	3 horas, deve ser melhor

3M Avagard™ CHG



Aprovado pelo FDA
Aprovado pela ANVISA

Antisséptico cirúrgico para mãos
sem escovação e sem enxague

- Álcool etílico a 61% p/p
- Gluconato de Clorexidina a 1%
- Emolientes e umectantes



2 ingredientes ativos presentes no *Avagard* de ação bastante conhecida

MÉTODO SEM ESCOVAÇÃO E SEM ENXÁGUE

O conceito da antissepsia cirurgica de mãos sem água e sem enxague é consolidado ha mais de 15 anos e difundido em vários países do mundo, inclusive no continente americano.

- Menor agressão a pele
- Facilidade no preparo
- Menor tempo de aplicação
- Segurança e eficácia

3M AVAGARD™ CHG - ESTUDOS DE EFICÁCIA E ATIVIDADE MICROBIANA

(estudo in vitro) MIC- 1058 cepas

Morte microbiana maior do que 99% em 15 segundos

- Atividade bactericida:
 - Bactérias gram positivas e negativas
- Cepas resistentes a antibióticos:
 - *S. aureus* resistente a meticilina (MRSA),
 - *Staphylococcus epidermidis* resistente a meticilina (MRSE),
 - *Enterococcus faecium* resistente a diversas drogas (MDR)
 - *Enterococcus faecalis* resistente a vancomicina (VRE)

(estudo In vivo)

Avagard satisfaz e excede os critérios do FDA

- 1 Aplicação
 - Redução maior do que 99% das bactérias semeadas nas mãos de 2,5 log
- 10 Aplicações
 - Redução maior do que 99.9% das bactérias de 3,7log

Estudo In Vitro de Tempo de Morte

Micro-organismos	% de Morte Microbiana (15 Segundos)
<i>Staphylococcus aureus</i> (ATCC 29213)	99.99
<i>Staphylococcus aureus</i> (ATCC 6538)	99.99
<i>Staphylococcus aureus</i> (MRSA) (ATCC 33592)	99.98
<i>Escherichia coli</i> (ATCC 11229)	99.96
<i>Escherichia coli</i> (ATCC 25922)	99.99
<i>Pseudomonas aeruginosa</i> (ATCC 15442)	99.91
<i>Pseudomonas aeruginosa</i> (ATCC 27853)	99.99
<i>Serratia marcescens</i> (ATCC 14756)	99.99
<i>Staphylococcus epidermidis</i> (ATCC 12228)	99.99*
<i>Staphylococcus epidermidis</i> (MRSE) (ATCC 51625)	99.99
<i>Micrococcus luteus</i> (ATCC 7468)	99.56
<i>Enterococcus faecalis</i> (ATCC 29212)	99.95
<i>Enterococcus faecalis</i> (VRE) (ATCC 51299)	99.48
<i>Enterococcus faecium</i> (MDR) (ATCC 51559)	99.81
<i>Candida albicans</i> (ATCC 10231)	99.98

Estudos Clínicos

Eficácia entre o método waterless x métodos tradicionais

**Avagard (waterless)
Eficácia**

**CHG4% e PVPI 7,5%
(Tradicional)**

Eficácia entre os métodos waterless

**Avagard (waterless)
Eficácia**

**Veículo alcóolico
(Waterless)**

Comparison of a Waterless, Scrubless CHG/Ethanol Surgical Scrub to Traditional CHG and Povidone-Iodine Surgical Scrubs

Comparison of a Waterless, Scrubless CHG/Ethanol Surgical Scrub to Traditional CHG and Povidone-Iodine Surgical Scrubs

Abstract

A new waterless surgical hand scrub product containing 1% chlorhexidine gluconate (CHG) and 61% ethanol in an emollient-rich lotion base (CHG/ethanol-emollient hand preparation) was assessed. This clinical study was based on the Tentative Final Monograph for Health Care Antiseptic Drug Products1 (TFM); Proposed Rule and ASTM E 1115-912, Standard Test Method for Evaluation of Surgical Hand Scrub Formulations.

A randomized, single center, blinded, well-controlled clinical study involving 124 healthy subjects evaluated the antimicrobial effectiveness in producing an immediate and persistent reduction in the normal bacterial flora of the hands. The CHG/ethanol-emollient hand preparation was applied without scrubbing or the use of water. The marketed products, 4% CHG (Hibiclens® Antiseptic Skin Cleanser) and 7.5% povidone-iodine (Betadine® Surgical Scrub), were applied using scrub brushes in two 3-minute or 5-minute surgical scrubs, respectively. Over a 5-day period, each subject performed a series of 11 surgical scrubs using one of the products. After the first treatment on Days 1, 2 and 5, surgical gloves were worn on one hand for 6 hours. Bacterial samples were taken using the glove juice technique at 1 minute and 6 hours after treatment.

The immediate bactericidal effect of the CHG/ethanol-emollient hand preparation after a single application resulted in a 2.8 log reduction in normal flora (compared to 1.1 log for Betadine Scrub and 1.2 log for Hibiclens cleanser). This bactericidal effect persisted throughout the study, and eventually increased to a 3.2 log reduction after the eleventh scrub on Day 5. The log reductions of the CHG/ethanol-emollient hand preparation proved to be significantly better ($p<0.0001$) than that of Hibiclens cleanser at each sampling interval on Days 1 and 2, and of Betadine scrub at all sampling intervals.

Introduction

- To assess the bacterial reductions achieved within 1 minute and at 6 hours post-treatment, comparing the CHG/ethanol-emollient hand preparation versus Hibiclens cleanser and Betadine scrub.
- To compare the hand skin condition resulting from the use of the CHG/ethanol-emollient hand preparation, Hibiclens cleanser and Betadine scrub based on subject self-assessment.

Methods

Study Design

A prospective, randomized, partially-blinded, parallel-group trial:

- 14-day pretreatment washout period for stabilization of hand bacterial flora, during which subjects refrained from using any topical antimicrobials, systemic antibiotics, or medicated soaps, lotions, shampoos, etc.
- 5 to 7 days of baseline bacterial evaluations where three baseline samples of hand bacterial flora were taken.
- Subjects with baseline bacterial populations $\geq 1.0 \times 10^4$ colony forming units (CFU) per hand at the first and second baseline samplings were eligible to be enrolled in the treatment period.
- 5-day treatment period during which subjects performed a series of 11 simulated surgical hand scrubs using one of the test products as follows:
 - Once daily on Treatment Days 1 and 5, and
 - Three times daily on Treatment Days 2, 3, and 4

Treatments

Subjects were randomized to receive one of the following three treatments:

- CHG/ethanol-emollient hand preparation (6 mL, 3 x 2 mL; until dry)

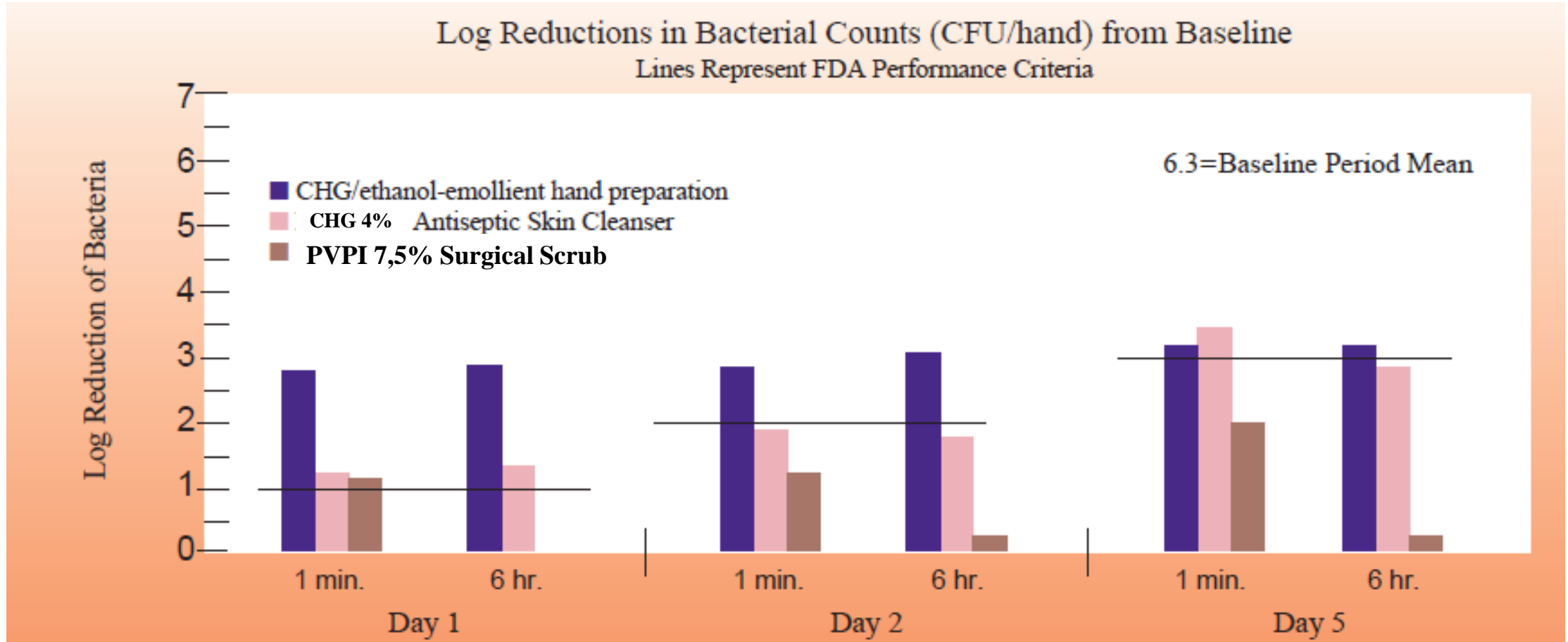
Waterless x Tradicional

Table 2

Log Reductions in Bacterial Counts (CFU/Hand) from Baseline

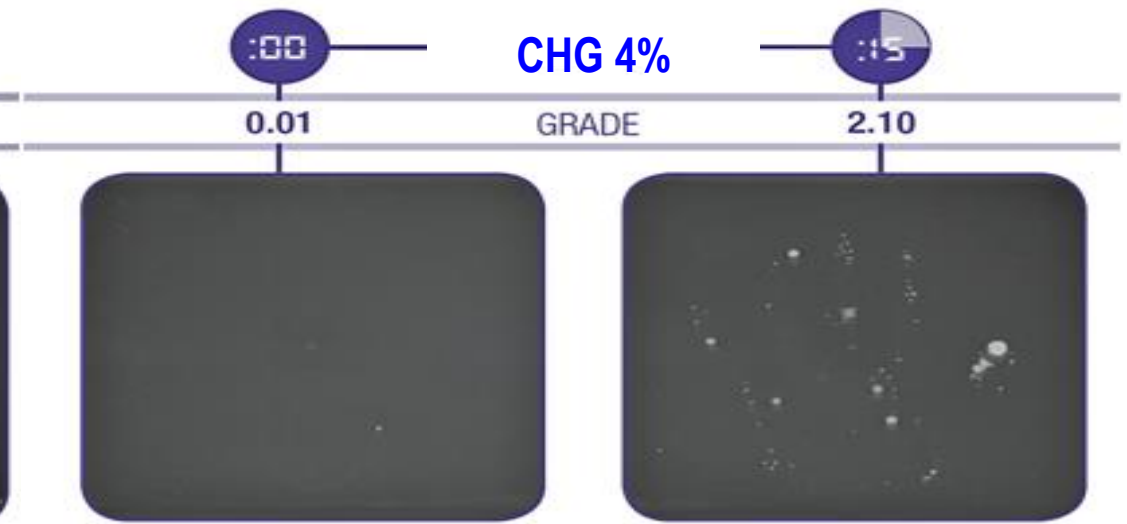
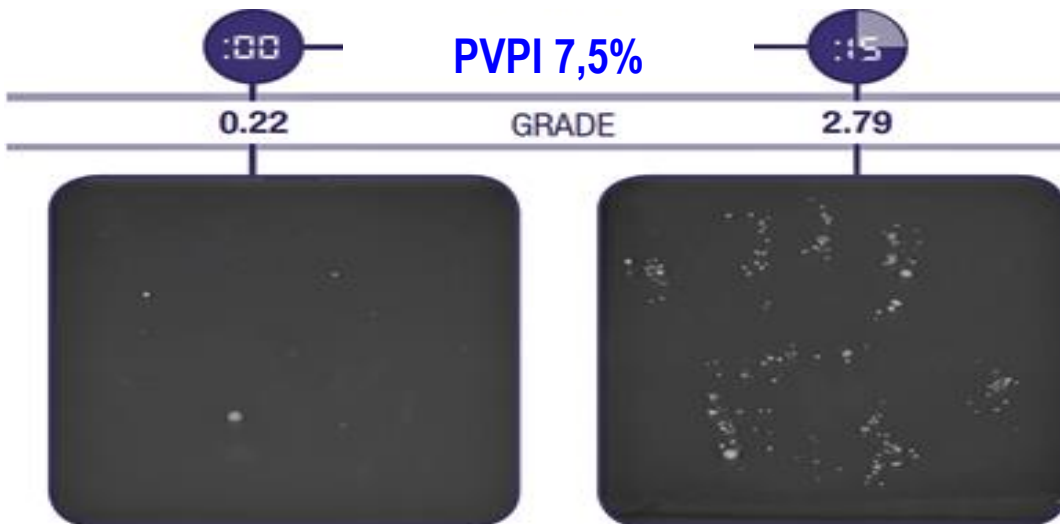
Date/Time point	CHG/ethanol-emollient hand preparation	CHG 4% Antiseptic Skin Cleanser	PVPI 7,5% Surgical Scrub
Baseline Period Mean	6.3	6.3	6.3
Day 1 Log Reduction			
1 minute	2.8	1.2	1.1
6 hours	2.9	1.4	0.0
Day 2 Log Reduction			
1 minute	2.9	1.8	1.4
6 hours	3.1	1.7	0.4
Day 5 Log Reduction			
1 minute	3.2	3.4	2.0
6 hours	3.2	2.9	0.4

Comparison of a Waterless, Scrubless CHG/Ethanol Surgical Scrub to Traditional CHG and Povidone-Iodine Surgical Scrubs



Results of a Timed Study to Determine Persistence of Three Hand Antiseptics

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Evaluation of a waterless, scrubless chlorhexidine gluconate/ethanol surgical scrub for antimicrobial efficacy

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 Janine Pyrek, MSc
 Julie Stahl, BSc
 Miamiville, Ohio, and Minneapolis and St Paul, Minnesota

Table 4. Study B: log reductions in bacterial counts (CFU/hand)

Day/time point	Treatment group			P value*
	CHG/ethanol combination (n = 34)	4% CHG treatment (n = 31)	61% ethanol vehicle (n = 20)	
Baseline period mean	6.1	6.0	6.0	ns ns
Day 1 log reduction				
1 min	2.6	1.6	1.1	.0602 .0032
3 h	3.1	1.8	1.4	.0002 .0001
6 h	2.8	1.4	0.5	.0003 .0001
Day 2 log reduction				
1 min	3.2	2.4	2.0	.0034 .0001
3 h	3.7	2.3	1.3	.0001 .0001
6 h	3.6	2.3	0.5	.0001 .0001
Day 5 log reduction				
1 min	3.5	3.6	1.5	ns .0001
3 h	3.9	3.6	1.4	ns .0001
6 h	3.5	3.0	0.5	ns .0001

*First P value represents CHG/ethanol hand preparation vs 4% CHG treatment; second P value represents CHG/ethanol hand preparation vs 61% ethanol vehicle.

Associação dos 2 antissépticos

Conclusão

Álcool

Amplo espectro de ação
Atividade Imediata



**Redução significativa
da carga microbiana**

+

CHG

Amplo espectro de ação
Atividade residual ou
persistente



**Mantêm ação em condições
de perfuração de luvas**

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Análise qualitativa- Dados de 3 hospitais no Brasil

Especialidade	Realizaram o teste
Cir. Geral	24%
Cir. Plástica	17%
Anestesiologista	14%
Instrumentador	11%
Neurocirurgia	7%
Ortopedia	6%
Cardíaca	6%
Cir. cardiovascular	5%
Gineco	2%
Cir. Vascular	2%
Otorrino	2%
Buco maxilo	1%
Colorectal	1%
Torácica	1%
Cir. Ped	1%

Índice de Aprovação



Muito obrigada

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