

## Surgical Hand Antisepsis—A Pilot Study comparing Povidone Iodine Hand Scrub and Alcohol-based Chlorhexidine Gluconate Hand Rub

Kah Weng Lai,<sup>1</sup> Dip AvMed, MRCSEd, MMed (Ortho), Tun Lin Foo,<sup>1</sup> MBBS, Wilson Low,<sup>2</sup> BSc, MSc (Epidemiology), Ganesan Naidu,<sup>1</sup> MRCSEd, MMed (Surg), FRCS (Ortho & Trauma)

### Abstract

**Introduction:** The surgeon uses different methods of surgical hand antisepsis with the aim of reducing surgical site infections. To date, there are no local studies comparing the efficacy of iodine hand scrub against newer alcohol-based hand rubs with active ingredients. Our pilot study compares a traditional aqueous hand scrub using 7.5% Povidone iodine (PVP-I) against a hand rub using Avagard: 61% ethyl alcohol, 1% chlorhexidine gluconate. The outcome measure is the number of Colony Forming Units (CFU) cultured from 10-digit fingertip imprints on agar plates. **Materials and Methods:** Ten volunteers underwent 2 hand preparation protocols, with a 30-minute interval in between—Protocol A (3-minute of aqueous scrub using PVP-I) and Protocol B (3-minute of hand rub, until dry, using Avagard). In each protocol, fingertip imprints were obtained immediately after hand preparation ( $t_0$ ). The volunteers proceeded to don sterile gloves and performed specific tasks (suturing). At one hour, the gloves were removed and a second set of imprints was obtained ( $t_1$ ). **Results:** Four sets of fingertip imprints were obtained. All 10 participants complied with the supervised hand preparation procedures for each protocol. CFUs of initial fingertip imprints ( $t_0$ ): The median CFU counts for initial imprint was significantly higher in the PVP-I treatment (median = 6, Inter Quartile Range (IQR) = 33) compared to the Avagard treatment (median = 0, IQR = 0,  $P < 0.001$ ). CFUs of fingertip imprint at 1 hour ( $t_1$ ): The median CFU counts for second imprint ( $t_1$ ) was significantly higher in the PVP-I treatment (median = 0.5, IQR = 11) compared to the Avagard treatment (median = 0, IQR = 0,  $P = 0.009$ ). Our results suggest that the Avagard was more efficacious than aqueous PVP-I scrub at reducing baseline colony counts and sustaining this antisepsis effect. **Conclusion:** Alcohol hand rub with an active compound, demonstrated superior efficacy in CFU reduction. Based on our results, and those pooled from other authors, we suggest that alcohol-based hand rubs could be included in the operating theatre as an alternative to traditional surgical scrub for surgical hand antisepsis.

Ann Acad Med Singapore 2012;41:12-16

**Key words:** Alcohol-based, Hand rub, Hand scrub, Surgical hand antisepsis, Surgical site infection

### Introduction

Surgical site infection (SSI) is a globally recognised problem that results in significant morbidity<sup>1</sup> (delayed healing, wound breakdown, sepsis) and negative economic impact<sup>2</sup> (prolonged hospital stays, revision surgery). Hand antisepsis remains a cornerstone of the overall aseptic technique in surgery, to eliminate transient micro-organisms and reduce resident skin flora. Despite significant advances in glove manufacturing techniques and development in surgical instruments design, glove perforation rates have been reported to be as high as 17%,<sup>3</sup> reiterating the

importance of good hand antisepsis.

Traditional surgical hand antisepsis consists of an aqueous scrub with or without brush, using povidone iodine (PVP-I) or chlorhexidine-based detergents. Some institutions in Singapore have recently started using alcohol-based hand rub as an alternative to the traditional aqueous scrub, whilst continental Europe has used such alcohol-based hand rubs for more than 30 years.

The increasing use of alcohol-based hand rubs have led to trials studying its efficacy as an alternative to traditional hand scrubbing for hand antisepsis in surgery.<sup>4-8</sup> The current

<sup>1</sup>Department of Orthopaedic Surgery, Tan Tock Seng Hospital, Singapore

<sup>2</sup>Clinical Research Unit, Tan Tock Seng Hospital, Singapore

Address for Correspondence: Dr Lai Kah Weng, Department of Orthopaedic Surgery, Tan Tock Seng Hospital, 11 Jalan Tan Tock Seng, Singapore 308433.

Email: laikahweng@gmail.com

evidence for surgical hand antisepsis suggests that alcohol-based hand rubs performed better than aqueous hand scrubs (including PVP-I) at reducing colony forming units (CFU), which serves as a surrogate predictor of SSIs.<sup>4</sup> However, this did not necessarily translate into significant reduction of surgical morbidity.<sup>5</sup>

Previous studies compared alcohol rubs with other active compounds (chlorhexidine gluconate, mectronium, zinc) against each other and against aqueous scrubs (chlorhexidine, PVP-I). These found that alcohol hand rubs with additional active compounds were as-or-more effective than aqueous scrubs at reducing CFUs,<sup>6</sup> cost 67% less,<sup>7</sup> and have a sustained bactericidal activity. Chlorhexidine's property of adhering to the stratum corneum of the skin allows it to exert a residual antimicrobial effect of up to 6 hours. Nonetheless, between the additive active compounds within the alcohol rubs, none were noted to be significantly better.

Currently in Singapore's restructured hospitals, alcohol-based hand rubs are not routinely used for surgical hand antisepsis. As there have been no local studies comparing aqueous hand scrubs against alcohol hand rubs with other active ingredients, the aim of this pilot study compares the standard 7.5% Povidone iodine aqueous hand scrub against the alcohol-based hand rub Avagard [1% chlorhexidine gluconate, 61% ethyl alcohol (3M, MN, USA)] to determine the feasibility of using alcohol-based hand rubs as a viable alternative for surgical hand antisepsis in local operating theatres. CFU is used as the outcome measure to enable quantitative analysis of the results.

## Materials and Methods

### *Study Design*

Ten volunteers were recruited in this non-randomised within-subject cohort study conducted during a suture practice workshop held at a clean experimental surgical laboratory equipped with standard operating facilities and hand scrub stations. The workshop consisted of 2 distinct suture practice sessions (lasting an hour each), where the subjects underwent a supervised hand preparation protocol prior to commencement of each suture practice. The subjects' fingertip imprints were sampled for CFU counts before and after each practice session.

Inclusion criteria for the subjects were practising doctors who had prior experience of surgical hand scrub in an operating theatre environment. The subjects had no known history of upper limb infections or recent trauma to the fingers and hands. All subjects were informed of the risks and benefits involved in this study and informed consent to participate in this study was obtained.

Participants were briefed and underwent rehearsal of the study procedures on the same day of the workshop.

A familiarisation hand scrub/rub was demonstrated to the subjects, and they performed a 'dry' scrub/rub, i.e. no solutions were used. Prior to each hand preparation protocol, all participants underwent 1 minute of hand washing with a neutral soap and a sponge-bristle brush to remove gross contaminants.

### *Detailed Hand Preparation Protocol*

The study participants underwent 2 sequential hand preparation protocols:

**Protocol A:** Three minutes of traditional scrub (PVP-I) followed by 1 hour of basic suture practice.

**Protocol B:** Three minutes of hand rubbing, until dry (Avagard) followed by 1 hour of suture practice.

After general cleansing with neutral soap, participants commenced Protocol A with a timed 3-minute hand scrubbing with 15 ml (3 full squirts) of PVP-I. Hands were dried with sterile towels and the initial sets of 2 x 5-digit fingertip imprint were obtained, applying gentle pressure of finger pulps onto 2 blood agar plates (1 plate for each hand) for 5 seconds. Thereafter, gloves were donned using a no-touch technique and participants proceeded to perform specific tasks (suturing, knot-tying) as part of a suturing workshop. After one hour, the gloves were removed, also via a no-touch technique. The subsequent sets of 2 x 5-digit imprints were then obtained.

A 30-minute interval was mandated, where participants were allowed to use their hands normally with no restriction.

After the break, a similar sequence for Protocol B was repeated. Cleansing began with neutral hand wash. Thereafter, 15ml (3 full squirts) of Avagard was dispensed onto each participant's hands, and covered completely before rubbing commenced. Sterile towels were not required as rubbing continued until solution evaporated and hands were dry. 2 x 5-fingertip imprints were obtained before and after donning and doffing gloves respectively for the second suture practice session.

Compliance officers (operating theatre scrub nurses, authors – KWL, TLF) were present at every station (neutral hand wash, surgical hand preparation, hand drying, gloving, suture practice and removal of gloves) to ensure proper technique and adherence to sterile procedures.

The agar plates were delivered to the hospital's Microbiology Department for incubation upon collection. After 48 hours of incubation, colony counts were obtained. Species identification was not performed because the primary focus is to obtain a quantitative rather than a qualitative analysis.

*Statistical Analysis*

The distribution of the CFU counts was expressed as median and interquartile range (IQR). Comparison of median for paired data was performed using Wilcoxon signed-rank test. All statistical analysis was conducted using STATA (version 10; Stata, College Station, TX), Statistical significance was assumed as  $P < 0.05$ .

**Results**

Four sets (PVP-I:  $t_0, t_1$ ; Avagard:  $t_0, t_1$ ) of fingertip imprints (20 hands in each set) were obtained (Table 1). All 10 participants complied with the standard operating procedure for each station and protocol. One participant (Subject 8) had to repeat the steps for Protocol A due to a breach in sterility 10 minutes into the suture practice.

*CFU Counts at Immediately after Hand Preparation Protocols ( $t_0$ )*

The median CFU counts per 5 fingers tips were 6 (IQR = 33) at immediately after the PVP-I protocol while the counts were statistically significantly lower at 0 (IQR = 0,  $P < 0.001$ ) at immediately after the Avagard protocol (Fig. 1).

Table 1. CFU Counts per 5 Finger Tips per Hand at Immediately after ( $t_0$ ) and at 1 hour ( $t_1$ ) among Study Subjects by Hand Preparation Protocols

Subject	Hand*	PVP-I (A)		Avagard (B)	
		$t_0$	$t_1$	$t_0$	$t_1$
1	R	1	0	0	0
1	L	0	4	0	0
2	R	1	7	1	0
2	L	1	0	0	0
3	R	21	0	0	0
3	L	107	0	0	0
4	R	1	0	0	0
4	L	5	0	0	0
5	R	2	0	2	21
5	L	1	0	0	0
6	R	7	1	0	0
6	L	50	9	0	0
7	R	0	0	0	0
7	L	0	0	0	0
8	R	8	13	0	0
8	L	67	69	0	0
9	R	26	64	0	2
9	L	58	102	0	3
10	R	14	1	0	0
10	L	42	27	0	0

\*R: Right, L: Left

*CFU Counts at 1 hour after Hand Preparation Protocols ( $t_1$ )*

The median CFU counts per 5 fingers tips were 0.5 (IQR = 11) at 1 hour after the PVP-I protocol while it was statistically significantly lower at 0 (IQR = 0,  $P = 0.009$ ) at 1 hour after the Avagard protocol (Fig. 1).

*Comparing CFU Counts between at Immediately ( $t_0$ ) and at 1 hour after ( $t_1$ ) within and between Hand Preparation Protocols*

The median change in CFU counts per 5 fingers tips between  $t_0$  to  $t_1$  was -1 (IQR = 12.5) and 0 (IQR = 0) for PVP-I and Avagard protocol respectively. However, the median change in CFU counts per 5 fingers tips between  $t_0$  to  $t_1$  was not statistically different within the PVP-I ( $P = 0.29$ ) and Avagard protocol ( $P = 0.28$ ) respectively. Between the PVP-I and Avagard protocol, the difference in the median change in CFU counts per 5 fingers tips was not statistically significant ( $P = 0.24$ )

The overall results suggest that the Avagard was more efficacious than aqueous PVP-I scrub at reducing baseline colony counts and sustaining its antiseptic effect.

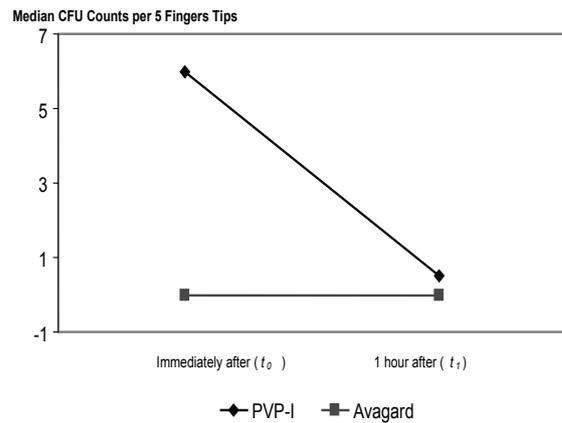


Fig. 1. Median CFU Counts per 5 Finger Tips at Immediately after Hand Preparation ( $t_0$ ) and at 1 hour ( $t_1$ ) by Hand Preparation Protocols

**Discussion**

As Singapore does not have its own standards for assessing surgical hand antiseptics, either the European standard EN12971 or US standard ASTM E-1115 could have been used as reference documents for the above study. Of the 2 standards, the EN12971 entails a more complete microbial reduction protocol and appears closer to clinical practice. However, the investigating team had planned the study as a pilot trial, and therefore had not used the above references for a comprehensive assessment of the 2 products. The limitation from this omission is also extended to the study design and

protocol, which negated the determination of pre-values. The lack of pre-values precluded the determination of the true reduction factor (from before, to after surgical hand antisepsis), which would be an important consideration if this small feasibility study is to be later expanded to a formal comparison between the 2 methods of hand antisepsis.

PVP-I was selected for the aqueous scrub as it was the one of the most commonly used solutions in our operating theatres. It was prioritised for the first practice session because its ability to exert a residual effect is less established compared to chlorhexidine.<sup>9</sup> Although it may be better to compare the 2 antiseptic protocols on different days and in different suture practice sessions (e.g. in a cross-over design), the nature of a small-scale feasibility study had imposed conditions on the authors to perform the study within a single session.

Avagard's 61% alcohol content is at the lower end of the antimicrobial activity spectrum of alcohol (60% to 90%), and it is known that products with 70% to 80% alcohol generally perform better against microbes than those with less than 70% alcohol. Nonetheless, Avagard was chosen due to its better skin tolerance profile and availability at the time of study. In addition, the more established residual antimicrobial property of chlorhexidine in Avagard compared to PVP-I mandates that it should be studied during the second protocol. This could have affected the outcome should the residual activity of PVP-I be significant. Also, the recovery of the microbial counts during the interval between protocols may not have reached pre-values – which were not determined.

For contact time with skin, Tanner *et al* had suggested that 3 minutes of surgical hand preparation was adequate for both aqueous scrub and alcohol hand rub.<sup>10</sup> This duration was followed in the hand preparation protocols for both solutions. The WHO 2009 guidelines recommended a sequential application of 3 x 5ml of solution for alcohol hand rubs, but the authors decided on a 1 x 15ml application at the start based on the usage guidelines for Avagard. A one-time application at the start also provides consistency with the PVP-I protocol and this maintains simplicity in ensuring compliance.

The most appropriate outcome measure for the study of surgical hand antisepsis is post-operative surgical site infection (SSI). However, due to its low incidence, a prohibitively large sample size is required to sufficiently power a study using SSI as an outcome measure. In contrast, the numbers of CFUs on hands are high, and this can be employed as a reasonable surrogate outcome for SSIs. For the quantification of CFU counts, the fingertip imprints on agar dish method was chosen over the alternative method of using 'glove juice' for ease in test administration. This

method was used by at least 1 other author<sup>11</sup> with significant results.

The authors were surprised by the marked difference of median CFUs between the 2 study treatments ( $P < 0.001$ ), and confirms a significantly more efficacious effect of the alcohol hand rub in reducing CFUs.

There was a reduction in CFU between  $t_0$  and  $t_1$  samples of subjects 3, 6 and 10 from the PVP-I study treatment. The decreasing CFUs of these 3 participants may be explained by an error during the sampling process—where their initial sampling of finger imprints was deeper and may have included their nail folds. Alternatively, these 3 participants may not have adhered to the guidelines of not using chlorhexidine-based hand cleansers during the morning ward rounds prior to the suture workshop. The residual effect of chlorhexidine from the ward hand cleansers on these 3 subjects could have contributed to the effect of declining CFU counts during the first suture session. Finally, the findings could also be due to a possible persistent activity of PVP-I, which has not been refuted conclusively. Nonetheless, the overall reductions between  $t_0$  and  $t_1$  samples within each protocol were shown not to be statistically significant.

The ideal study design would have included a randomised crossover protocol, where each subject could have served as his own control. Due to logistical limitations, the study had to be completed within a single suture practice workshop. Consequently, a crossover design became technically impossible because the known residual effect of chlorhexidine mandates that it should only be used sequentially after PVP-I. A PVP-I carryover effect could have occurred, but this was addressed by instituting a standard neutral soap hand wash performed to remove any traces of PVP-I before commencement of the Avagard protocol. In the end, the lack of a concurrent control group and the absence of pre-values had restricted the interpretation of the results.

In a multicentre randomised control trial (RCT), Parienti *et al*<sup>5</sup> showed that alcohol hand rubs were as efficacious as traditional aqueous hand scrubs with surgical site infection (SSI) as the endpoint. The rates of SSIs for patients from various surgical specialties, including implantation of metallic prosthesis, were 2.48% for the aqueous scrub group and 2.44% in the alcohol hand rub group. A firm conclusion could not be drawn from this RCT as it was designed to show equivalence. In addition, the causal link between CFU and SSI could not be conclusively established. The heterogeneity of the data on CFU and SSI may suggest that both strict aseptic technique and good hand antisepsis are equally important in preventing SSI. This seems logical: if a higher CFU did not exclusively result in increased SSI, then the outer surface of the glove in contact with patients'

wound must have been sufficiently clean. In this scenario, it is based on the assumption that there is no glove perforation.

Looking at the figures from the study, our results suggest that Avagard is more efficacious in reducing colony counts than PVP-I. Other authors demonstrated superior efficacy of hand rub over scrub whilst Hajipour *et al*<sup>12</sup> found aqueous scrub to be more effective. Another study found no significant difference between the two.<sup>13</sup>

### Conclusion

From our pilot study, the alcohol-based hand rub with an additional active compound (chlorhexidine) demonstrated superior efficacy in CFU reduction and maintenance compared to PVP-I. With the results pooled from other authors, we recommend that such alcohol-based hand rubs be included in the operating theatre as a viable alternative to traditional PVP-I surgical scrub for surgical hand antisepsis.

### Acknowledgements

Sister Lee Siew Hong, SSN Yoong Lee Chiang, J&J Ethicon, operating theatre personnel, and volunteers.

### REFERENCES

1. Delgado-Rodríguez M, Gómez-Ortega A, Llorca J, Lecuona M, Dierssen T, Sillero-Arenas M, et al. Nosocomial infection, indices of intrinsic infection risk, and in-hospital mortality in general surgery. *J Hosp Infect* 1999;41:203-11.
2. Fry DE. The economic costs of surgical site infection. *Surg Infect* 2002;3:S37-S43.
3. Kralj N, Beie M, Hofmann F. Surgical gloves – how well do they protect against infections? *Gesundheitswesen* 1999;61:398-403.
4. Marchetti MG, Kampf G, Finzi G, Salvatorelli G. Evaluation of the bactericidal effect of five products for surgical hand disinfection according to prEN 12054 and prEN 12791. *J Hosp Infect* 2003;54:63-7.
5. Parienti JJ, Thibon P, Heller R, Le Roux Y, von Theobald P, Bensadoun H, et al. Hand-rubbing with an aqueous alcoholic solution vs traditional surgical hand-scrubbing and 30-day surgical site infection rates: a randomized equivalence study. *JAMA* 2002;288:722-7.
6. Pietsch H. Hand antiseptics: rubs versus scrubs, alcoholic solutions versus alcoholic gels. *J Hosp Infect* 2001;48A:S33-6.
7. Tavolacci MP, Pitrou I, Merle V, Haghighat S, Thillard D, Czernichow P. Surgical hand rubbing compared with surgical hand scrubbing: comparison of efficacy and costs. *J Hosp Infect* 2006;63:55-59.
8. Hobson DW, Woller W, Anderson L, Guthery E. Development and evaluation of a new alcohol-based surgical hand scrub formulation with persistent antimicrobial characteristics and brushless application. *Am J Infect Control* 1998;26:507-12.
9. Rotter ML. Arguments for alcoholic hand disinfection. *J Hosp Infect* 2001;48 Suppl A:S4-8.
10. Tanner J, Swarbrook S, Stuart J. Surgical hand antisepsis to reduce surgical site infection. *Cochrane Database Syst Rev* 2008;23:CD004288.
11. Herruzo-Cabrera R, Vizcaino-Alcaide MJ, Fdez-Acinero MJ. Usefulness of an alcohol solution of N-duopropenide for the surgical antisepsis of the hands compared with handwashing with iodine-povidone and chlorhexidine: clinical essay. *J Surg Res* 2000;94:6-12.
12. Hajipour L, Longstaff L, Cleeve V, Brewster N, Bint D, Henman P. Hand washing rituals in trauma theatre: clean or dirty? *Ann R Coll Surg Engl* 2006 ;88:13-5.
13. Gupta C, Czubytyj AM, Briski LE, Malani AK. Comparison of two alcohol-based surgical scrub solutions with an iodine-based scrub brush for presurgical antiseptic effectiveness in a community hospital. *J Hosp Infect* 2007;65:65-71.