

Hand-Rubbing With an Aqueous Alcoholic Solution vs Traditional Surgical Hand-Scrubbing and 30-Day Surgical Site Infection Rates

A Randomized Equivalence Study

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SURGICAL SITE INFECTIONS (SSI) prolong hospital stays¹; they are also among the leading nosocomial causes of morbidity² and a source of excess medical costs.³ Sterile gloves contribute to preventing surgical wound contamination,⁴ but some are permeable to bacteria and all can be damaged during use. Effective hand antisepsis thus remains crucial. Guidelines on hand and forearm antisepsis for operating department staff⁵ aim at removing transient microorganisms and reducing the resident flora (by at least 2-log).

In France, 2 protocols are recommended for surgical hand preparation: 5 minutes of hand-scrubbing with antiseptic soap; and an optional 1-minute hand wash with nonantiseptic soap and tap water, followed by 5 minutes of hand-rubbing with a liquid aqueous alcoholic solution (AAS) alone. In other European countries, only 3 minutes of hand-rubbing with AAS are

Context Surgical site infections prolong hospital stays, are among the leading nosocomial causes of morbidity, and a source of excess medical costs. Clinical studies comparing the risk of nosocomial infection after different hand antisepsis protocols are scarce.

Objective To compare the effectiveness of hand-cleansing protocols in preventing surgical site infections during routine surgical practice.

Design Randomized equivalence trial.

Setting Six surgical services from teaching and nonteaching hospitals in France.

Patients A total of 4387 consecutive patients who underwent clean and clean-contaminated surgery between January 1, 2000, and May 1, 2001.

Interventions Surgical services used 2 hand-cleansing methods alternately every other month: a hand-rubbing protocol with 75% aqueous alcoholic solution containing propanol-1, propanol-2, and mecetronium etilsulfate; and a hand-scrubbing protocol with antiseptic preparation containing 4% povidone iodine or 4% chlorhexidine gluconate.

Main Outcome Measures Thirty-day surgical site infection rates were the primary end point; operating department teams' tolerance of and compliance with hand antisepsis were secondary end points.

Results The 2 protocols were comparable in regard to surgical site infection risk factors. Surgical site infection rates were 55 of 2252 (2.44%) in the hand-rubbing protocol and 53 of 2135 (2.48%) in the hand-scrubbing protocol, for a difference of 0.04% (95% confidence interval, -0.88% to 0.96%). Based on subsets of personnel, compliance with the recommended duration of hand antisepsis was better in the hand-rubbing protocol of the study compared with the hand-scrubbing protocol (44% vs 28%, respectively; $P = .008$), as was tolerance, with less skin dryness and less skin irritation after aqueous solution use.

Conclusions Hand-rubbing with aqueous alcoholic solution, preceded by a 1-minute nonantiseptic hand wash before each surgeon's first procedure of the day and before any other procedure if the hands were soiled, was as effective as traditional hand-scrubbing with antiseptic soap in preventing surgical site infections. The hand-rubbing protocol was better tolerated by the surgical teams and improved compliance with hygiene guidelines. Hand-rubbing with liquid aqueous alcoholic solution can thus be safely used as an alternative to traditional surgical hand-scrubbing.

JAMA. 2002;288:722-727

www.jama.com

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recommended. Many reports suggest that AAS has better and more sustained antimicrobial activity than traditional scrubs.⁶⁻¹¹ For example, Hobson et al¹¹ compared hand antimicrobial count after either 3 minutes of hand-scrubbing with solutions containing 7.5% povidone iodine and 4% chlorhexidine gluconate or 3 minutes of hand-rubbing with an AAS. Mean logarithmic reduction of colony forming units (CFU) from baseline was significantly higher in the AAS protocol when compared with povidone iodine or chlorhexidine gluconate after 1 minute (2.90 log₁₀ vs 1.20 log₁₀ and 1.68 log₁₀ of CFU reduction from baseline), 3 hours (1.58 log₁₀ vs 0.71 log₁₀ and 1.08 log₁₀ of CFU reduction from baseline) and 6 hours (1.94 log₁₀ vs -0.21 log₁₀ and 0.86 log₁₀ of CFU reduction from baseline) at day 1 and day 2. However, these investigations involved healthy volunteers or short study periods, with hand microorganism counts as the primary end point. Poor compliance and the risk of dermatitis were not taken into account. Because of the need for a very large population sample, together with the existence of numerous confounding factors and prohibitive costs, clinical studies comparing the risk of nosocomial infection after different hand antisepsis protocols are scarce.^{5,9}

To confirm the validity of current recommendations for hand antisepsis before surgery, we conducted a randomized equivalence study comparing hand-scrubbing and hand-rubbing protocols with a multiple service crossover experimental design. The aim was to demonstrate the equivalence of the 2 protocols in terms of SSI rates.

METHODS

Setting and Study Design

Six surgical services in France were invited to participate in this study and all accepted. They consisted of 3 surgical services of a teaching hospital (Côte de Nacre University Hospital Centre, Caen) and the surgical services of 3 nonteaching hospitals (François Baclesse Cen-

tre, Caen; General Hospital, Colmar; General Hospital, Pont-Audemer). A 2-month feasibility study was first conducted in a single surgical service, during which training requirements were determined; the surgical team switched readily from traditional hand-scrubbing to hand-rubbing with AAS. Surgeons from the 6 candidate centers were then invited to discuss the project. The clinical trial started January 1, 2000, and lasted 16 months (May 1, 2001). The following end points were used: nosocomial SSI rates (main end point), compliance by the surgical teams, and tolerance of the 2 hand antisepsis protocols by the surgical teams in real world conditions. The first protocol to be used in each surgical service was chosen randomly. Each participating surgical service was assigned a 2-digit random number by using a random number table. Surgical services corresponding to the 3 higher numbers were assigned to hand-rubbing with AAS and the remaining 3 services were assigned to traditional hand-scrubbing. The alternative antiseptic product was systematically removed from the services during each period. At the end of each month, the antiseptic products were switched in a multiple service crossover design.

Definition, Surveillance, and Validation of Nosocomial SSIs

Diagnosis for SSI was standardized in accordance with the Centers for Disease Control and Prevention (CDC) definitions for nosocomial infection.¹² For the purpose of this study, however, SSI surveillance lasted 30 days regardless of prosthesis implantation. It should be noted that our hygiene department has been involved in SSI surveillance for many years.¹³

In-hospital SSIs were prospectively diagnosed by a surgeon, infectious disease specialist, or hygiene specialist on a standard data-collection form. Post-discharge surveillance was based on chart review of visits and telephone contacts with the surgeons. If data at 30 days were unavailable, the patient was contacted by telephone and asked to answer a brief questionnaire on fever and

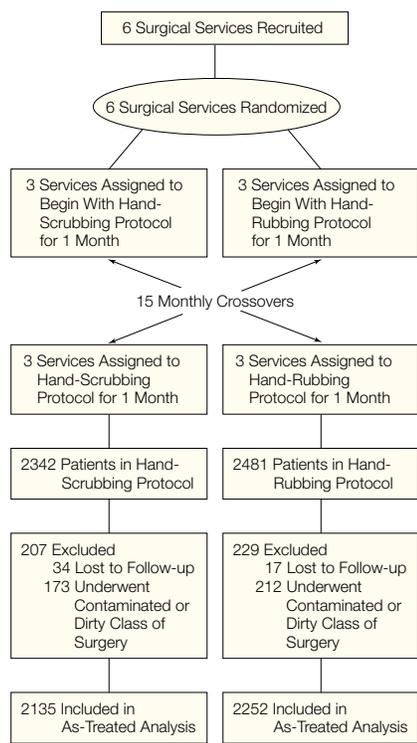
other potential symptoms of SSI, together with antibiotic use and visits to an emergency department or to another physician, who was then contacted to confirm the SSI.

According to CDC guidelines, all SSIs had to be confirmed by the surgeon or the physician in charge of the patient. Thus, observers of the clinical outcome could not be blinded to the hand antisepsis protocol. For possible post-discharge SSIs reported by the patient only, a data validation for SSIs according to CDC guidelines was performed by investigators who were blinded to the protocol used by surgeons prior to surgical procedure.

Patients and Data Collection

All consecutive patients treated in the 6 participating surgical services were screened for SSI. Because bacteria on operating department personnel hands are more likely to affect the outcome in clean and clean-contaminated surgical wounds (classified according to Altmeier et al¹⁴), our study group decided to exclude from analysis patients in contaminated or dirty procedure groups, when designing this study. Patients undergoing a second operation less than 15 days after the first were also excluded, because this is an independent risk factor for SSI.

The first 2 months after randomization of the services, investigators checked if the protocols were correctly performed. Therefore, because introduction of a new protocol and feedback can influence short-term surgical personnel behavior, compliance observations for the hand antisepsis protocol started at month 3 and continued until month 16. Twice as many observations were performed in the new hand-rubbing protocol compared with the traditional hand-scrubbing protocol. Compliance observers did not belong to the operating department team but were usually present in the surgical suite. To avoid a Hawthorne effect, the surgical teams were not informed of the timing of the evaluations. Only the first hand antisepsis of the day was observed in the 2 study protocols.

Figure. Overview of 2 Surgical Hand-Cleansing Protocols

Each surgical service included (alternately) patients in both hand-cleansing protocols.

In the 3 participating surgical services of our teaching hospital (Côte de Nacre University Hospital Centre), the surgical personnel (77 subjects) were asked to estimate the effect of the 2 protocols on their skin. We used 2 10-cm visual analog scales, at month 0 and after 3 crossovers; 0 cm representing absence of any tolerance problem and 10 cm representing maximal dryness with chapped hands and desquamation or maximal irritation with erythema, burning sensation, and abrasion.

Hand Antisepsis Protocols

The standard surgical scrubbing antisepsis technique was as defined in CDC guidelines. In particular, at least 5 minutes of systematic hand-scrubbing was required with a sterile sponge and brush. Hand-scrubbing with antiseptic solutions containing 4% povidone iodine (Betadine, Asta Medica, Merignac, France) or 4% chlorhexidine glu-

conate (Hibiscrub, AstraZeneca, Rueil-Malmaison, France) had been used for many years by the surgical teams and was thus chosen as the control protocol for this study.

Hand-rubbing involved a 75% AAS containing propanol-1, propanol-2, and mectronium etilsulfate (Stérillium, Rivadis Laboratories, Thouard, France). We chose this product because it was the only AAS licensed for surgical antisepsis in France. Prior to the first procedure of the day, or if the hands were visibly soiled, the surgical team was instructed to use a nonantiseptic soap (Savon Codex, Rivadis Laboratories, Thouard, France) for a 1-minute hand wash, including subungual space cleaning with a brush. The hands and forearms were then rinsed with nonsterile tap water and wiped carefully with nonsterile paper. The user was instructed to take enough AAS to fully cover the hands and forearms (at least 5 mL, which represents at least 4 pump strokes), and to apply it twice for 2 minutes 30 seconds (for a total of 5 minutes) without drying. As recommended by the manufacturer, users were also instructed to rub their hands with AAS for 30 seconds when changing gloves. The hand-rubbing technique was based on the European Norm 1500 from the Association Française de Normalisation.

Statistical Power and Analysis

The study was designed to demonstrate the equivalence of hand-scrubbing and hand-rubbing in preventing SSI (primary end point). We chose an SSI rate of 4% in the control group, a maximal difference between the protocols of 2% (considered as clinically relevant), a real difference between the 2 protocols of 0%, a type I error α risk of .05, and 90% power when calculating the number of patients required. On this basis, at least 4158 patients had to be enrolled.¹⁵ We performed an as-treated analysis as well as a conservative intent-to-treat analysis computing missing value equals SSI in the new protocol and missing value equals no SSI in the control group. The

2 protocols were considered equivalent if the 95% confidence interval (CI) of the SSI rate difference, calculated according to the Wallenstein method,¹⁶ was within the limits of -2% to $+2\%$ and contained the bound zero in both analyses, the as-treated as well as in the conservative intent-to-treat. The level of significance for equivalence was given by the highest P value related to the lowest χ^2 value of the continuity-corrected 1-sided test described by Dunnett and Gent.¹⁷ Compliance and tolerance (secondary end points) were compared using the Fischer exact test for qualitative data and Mann-Whitney test or a matched t test for quantitative data as appropriate (2-sided P values). After checking for the absence of interaction, observations regarding compliance with and tolerance of hand hygiene protocols from different surgical services and from different quarters of the study were merged. $P < .05$ was considered statistically significant. We used EPI-INFO version 6.04dfr (EPI-INFO, CDC, Atlanta, Ga) for data collection and EPI-INFO and SAS version 6.12 (SAS Institute Inc, Cary, NC) for data analysis.

RESULTS

During the study period (FIGURE), 4823 consecutive patients underwent surgery. Among these, 385 patients underwent contaminated or dirty-contaminated surgery, and 51 were lost to follow-up at 30 days (17 in the hand-rubbing group). The remaining 4387 patients (68.5% of whom underwent clean surgery) were considered for analysis. The characteristics of these patients are shown in TABLE 1, according to the type of protocol. There were 446 gynecological operations (33%), 383 cesarean deliveries (28%), and 356 breast operations (26%) ($n = 1359$). Thyroidectomy was the most frequent otolaryngology procedure ($n = 346$). Urological indications ($n = 540$) comprised 384 (71%) bladder or urethral operations and 85 (16%) kidney operations. Orthopedic procedures ($n = 746$) comprised 290 (39%) osteosyntheses and 147 (20%) prosthesis insertions.

SSI Rates

The surveillance system identified 99 in-hospital and 9 postdischarge SSIs. The global SSI rate 30 days after surgery was 2.46% (95% CI, 1.81%-3.11%). The SSI rates for clean and clean-contaminated surgery were 2.03% (95% CI, 1.33%-2.73%) and 3.40% (95% CI, 2.07%-4.73%), respectively. In the hand-scrubbing protocol, 21 SSIs were superficial, 19 deep, and 8 organ-space (5 unknown). In the hand-rubbing protocol, 24 SSIs were superficial, 15 deep, and 7 organ-space (9 unknown). The distribution of these categories of SSI did not differ between the 2 protocols.

There were 53 of 2135 SSIs (2.48%) in the hand-scrubbing protocol and 55 of 2252 (2.44%) in the hand-rubbing protocol (TABLE 2). The difference between the SSI rate with hand-scrubbing and the SSI rate with hand-rubbing with AAS was 0.04% (as treated 95% CI, -0.88% to 0.96%). In an intention-to-treat analysis, considering that all the 17 patients lost to follow-up in the hand-rubbing group had an SSI and none of the 34 patients lost to follow-up in the hand-scrubbing group had an SSI (maximal bias), the rate difference would have been -0.69% (95% CI, -1.67% to 0.29%). The equivalence of the 2 protocols in preventing SSI was thus accepted.

Compliance With the Antisepsis Protocols

During the study period, 278 individual compliance assessments were made of the operating teams (174 in the hand-rubbing group), corresponding with 160 surgical procedures (102 in the hand-rubbing group). On average, the first hand-cleansing protocol of the day (TABLE 3), excluding the simple nonantiseptic hand wash prior to hand-rubbing, lasted significantly longer in the hand-rubbing group than in the hand-scrubbing group (mean [SD], 313 [80] seconds vs 287 [75] seconds; $P = .01$). Scrub nurses complied better with the recommended duration of hand antisepsis than did surgeons and assistants (56% vs 33%; $P < .001$). Compliance with the recommended dura-

tion of hand hygiene was poor in both protocols but was significantly better in the hand-rubbing group than in the hand-scrubbing group (44% vs 28%, respectively; $P = .008$).

In the hand-rubbing group, 6 of 102 (6%) of first procedures did not in-

clude a simple nonantiseptic hand wash before hand-rubbing (4 in abdominal surgery, 2 in gynecology). During the days nonantiseptic hand washing prior to the first handrub with AAS was not performed by the surgical personnel in the hand-rubbing protocol, 2 SSIs oc-

Table 1. Characteristics of the Patients According to the Hand-Hygiene Protocol*

Characteristic	Protocol, No. (%)	
	Hand-Scrubbing (n = 2135)	Hand-Rubbing (n = 2252)
Age, mean (SD), y	51.1 (17.6)	49.5 (17.4)
ASA physical status class		
1	948 (44.4)	1057 (46.9)
2	795 (37.2)	840 (37.3)
3	351 (16.4)	306 (13.6)
4 and 5	15 (0.7)	16 (0.7)
Unknown	26 (1.2)	33 (1.5)
Atmeier clean class	1485 (69.6)	1520 (67.5)
Duration of surgery, mean (SD), min	79.1 (73.6)	76.3 (71.6)
Emergency surgery	189 (8.9)	213 (9.5)
Type of surgery		
Gynecology	629 (29.5)	730 (32.4)
Urology	268 (12.6)	272 (12.1)
Abdominal	374 (17.5)	390 (17.3)
Orthopedic	378 (17.7)	368 (16.3)
Otolaryngology	167 (7.8)	179 (7.9)
Other	319 (14.9)	313 (13.9)

*ASA indicates American Society of Anesthesiologists. The ASA physical status classification indicates class 1, a healthy patient; class 2, a patient with mild systemic disease; class 3, a patient with severe systemic disease; class 4, a patient with severe systemic disease that is a constant threat; and class 5, a moribund patient who is not expected to survive without an operation.

Table 2. Surgical Site Infection (SSI) Rates and Differences Between Hand-Scrubbing and Hand-Rubbing*

Atmeier Class of Contamination	No. SSI/No. Operations (%)		SSI Rate Difference (Hand-Scrubbing-Hand-Rubbing), % (95% Confidence Interval)	χ^2 Test of Equivalence (P Value)
	Hand-Scrubbing Protocol	Hand-Rubbing Protocol		
Clean	29/1485 (1.95)	32/1520 (2.11)	-0.15 (-1.16 to 0.85)	16.0 (<.001)
Clean-contaminated	24/650 (3.69)	23/732 (3.14)	0.55 (-1.36 to 2.46)	1.9 (.09)
All	53/2135 (2.48)	55/2252 (2.44)	0.04 (-0.88 to 0.96)	19.5 (<.001)

*The 95% confidence interval of the SSI rate difference was calculated according to Wallenstein¹⁶ and the χ^2 test was the lowest χ^2 value of the Dunnett and Gent¹⁷ continuity-corrected double 1-sided test for equivalence at -2% and +2%.

Table 3. Compliance With the Recommended Duration of Hand Antisepsis During the First Procedure of the Day*

Operating Room Personnel	Hand-Scrubbing Protocol	Hand-Rubbing Protocol	P Value†
Duration of hand antisepsis, mean (range), s	287 (100-480)	313 (60-510)	.01‡
No. of hand antisepsis \geq 5 min/total no. of hand antisepsis (%)			
Surgeon/assistant	20/83 (24)	51/133 (38)	.04
Scrub nurse	9/21 (42)	26/41 (63)	.18
All	29/104 (28)	77/174 (44)	.008

*Time required for the nonantiseptic hand wash prior to hand-rubbing with aqueous alcoholic solution has been excluded.

†Analyzed using Fisher exact test.

‡Analyzed using Mann-Whitney test.

curred for a total of 34 procedures (5.9%) compared with 2 SSIs for 56 procedures (3.6%) when the nonantiseptic hand washing was performed in the same services. Glove changes occurred during 32 of the 102 observed procedures in the hand-rubbing protocol; the recommended 30-second AAS rub before a glove change was complied with in 16 of these 32 cases, not complied with in 10 cases, and 6 were unknown.

Subjective Tolerance of the Antisepsis Protocols

A total of 77 operating department staff members were assessed for skin tolerance at entry to the study and after the first 3 crossovers. Based on the visual analog scales scores, skin dryness decreased by 0.9 cm (95% CI, 0.5-1.2) after the hand-rubbing periods and increased by 0.4 cm (95% CI, -0.1 to 1.2) after the hand-scrubbing periods ($P = .046$). Similarly, skin irritation decreased by 1.5 cm (95% CI, 1.1-1.9) after the hand-rubbing periods and increased by 0.4 cm (95% CI, 0.2-0.6) after the hand-scrubbing periods ($P = .03$). One scrub nurse reported hand and eye irritation (swelling) when using AAS for hand-rubbing.

COMMENT

To our knowledge, this study is the first randomized trial to compare hand-rubbing with alcohol-based solution and traditional hand-scrubbing in the routine surgical setting, with the 30-day SSI rate as the primary end point. The hand-rubbing with AAS was equivalent to traditional hand-scrubbing in preventing SSI after clean and clean-contaminated surgery. In addition, hand-rubbing with AAS improved the tolerance of and compliance with hand antisepsis protocols, as evaluated for 4 and 14 months, respectively.

This study involved an unselected population of patients undergoing routine surgery in teaching and non-teaching hospitals. The baseline SSI rates for abdominal surgery procedures only, with routine 3-month per year surveillance methods were 45 of

912 (4.9%) on average during 1997-2000.¹³ The SSI rates we observed in this study are consistent with those reported elsewhere.^{18,19} In a cohort of 59352 patients, Haley et al¹⁸ found an SSI rate of 2.9% and 3.9% in clean and clean-contaminated class of procedures, respectively. Olson and Lee¹⁹ reported an infection rate of 1.4% in clean and 2.8% in clean-contaminated procedures in 40915 patients. However, we observed a very low proportion of postdischarge SSIs (8.3%) compared with recent studies. The percentages of SSIs occurring after hospital discharge vary from 13.6% to 84.0% according to studies²⁰⁻²²; thus, we cannot exclude that possible SSIs were not validated in the absence of evidence, although they were real.

Any direct comparison between reported studies would be hazardous, as they differ in several respects, such as the SSI rate surveillance methods, the study period, and the characteristics of the study population. In our study, differences in the characteristics of the patients and surgical personnel in the 2 protocols were minimized by the randomized service crossover experimental design.

Infection control epidemiology has clearly demonstrated that bacteria responsible for SSI can be shed from the surgical team's hands, despite standard antisepsis.²³⁻²⁵ Alcohol-based hand disinfection has previously been shown to reduce nosocomial infection rates and to improve compliance with hand hygiene rules when implemented throughout a hospital, particularly at the bedside in medical wards,²⁶ although other studies are less favorable.^{27,28} An 8-month prospective study conducted in 3 intensive care units showed that the rate of nosocomial infections was significantly higher after alcohol-based vs scrub-based hand hygiene, possibly due to poor compliance with hand-rubbing instructions.²⁸ This underscores the need to evaluate new protocols in the routine context.

As previously reported in intensive care unit patients,²⁸ the rate of SSIs was higher when nonantiseptic hand wash

was not performed prior to use of AAS. Although the number of observations is too low to perform any test, it underscores the importance of the optional simple nonantiseptic hand wash in the hand-rubbing protocol. However, we cannot exclude that surgical personnel did not perform previous nonantiseptic hand wash before hand-rubbing in the case of an emergency procedure with a higher risk for SSI (confounding by indication).

We chose each surgical service for initial randomization of the antisepsis protocol. This allowed us to evaluate the compliance and tolerance of each protocol during 1-month periods. In addition, the alternative antiseptic was removed from the surgical service at each crossover, as contamination between protocols of a study increases the chances of declaring equivalence in the equivalence trials.²⁹

As reported in previous studies, AAS was, on average, better tolerated than traditional hand-scrubbings by the surgery team.^{9,30,31} Less reported are issues regarding compliance of the operating department personnel to hand antisepsis protocols. For presurgery hand antisepsis, the critical end point for compliance is not the occurrence of the protocol but how well and how long it is performed. We observed significantly better compliance with the duration of hand hygiene in the AAS hand-rubbing group, and this effect persisted throughout the 14-month evaluation. One possible explanation is that the necessary duration of hand-rubbing in the AAS-based protocol depends on the amount of AAS applied, whereas the hand-scrubbing protocol can be shortened by drying the hands with absorbent material. Contrary to studies performed in nonsurgical settings,^{26,30} compliance was also improved by the use of AAS in the surgeon or assistant subgroup; this subgroup had already been identified³² as complying poorly with hand-hygiene regimens. The fact that the rate of SSI is equivalent in both groups, despite a better compliance in the hand-rubbing group is not surprising given the low SSI occurrence rate.

A previous French study³³ has compared the costs of the 2 techniques for hand and forearm antisepsis before scheduled orthopedic surgery. They reported a relative cost of 203 euros per week when using povidone iodine or chlorhexidine gluconate and 25 euros per week when using AAS (1 euro-US \$1.03). Nonetheless, AAS may not be accepted or tolerated by all surgical personnel. Thus, we do not believe that AAS should systematically replace surgical hand antisepsis with traditional hand-scrubbings for economic reasons. The choice of the technique for hand and forearm antisepsis before surgery should remain a matter of personal preference among users. In conclusion, given its equivalence to standard hand-scrubbing in preventing SSI, we consider that preoperative hand-rubbing with AAS preceded by

a nonantiseptic hand wash is a safe alternative.

Author Contributions: Dr Parienti, as principal investigator, had full access to all the data and takes full responsibility for the integrity of the data and accuracy of the data analyses. *Study concept and design:* Parienti, Thibon, Le Roux, von Theobald, Le Coutour. *Acquisition of data:* Parienti, Heller, Le Roux, von Theobald, Bensadoun, Bouvet, Lemarchand, Le Coutour. *Analysis and interpretation of data:* Parienti, Heller, Le Coutour. *Drafting of the manuscript:* Parienti. *Critical revision of the manuscript for important intellectual content:* Parienti, Thibon, Heller, Le Roux, von Theobald, Bensadoun, Bouvet, Lemarchand, Le Coutour. *Statistical expertise:* Parienti, Thibon, Heller, Le Coutour. *Obtained funding:* Parienti, Le Coutour. *Administrative, technical, or material support:* Heller, Le Roux, Bensadoun, Le Coutour. *Study supervision:* Parienti, Thibon, Heller, Le Coutour. **Members of the Antiseptique Chirurgicale des Mains Study Group:** Caen, France: C. Alin, RN, P. Barjot, MD, DCh, H. Bensadoun, MD, DCh, P. Bottet, MD, DCh, A. Bouvet, MD, J. L. Brefort, MD, DCh, L. Chiche, MD, DCh, H. Crouet, MD, DCh, J. De Ranieri, MD, DCh, M. Dreyfus, MD, DCh, K. Droulon, P. Herlicoviez, MD, DCh, X. Le Coutour, MD, Y. Le Roux, MD, DCh, G. Lebreton, MD, DCh, J. Leroux, RN, J. Maurel, MD,

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