The Effect of Different Surgical Hand Scrubbing Methods and Duration of Scrubbing Time on the Bacterial Flora

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Study Protocol And Statistical Analysis Plan

Aim

The aim of this study is to compare evidence-based surgical hand scrubbing methods in order to prevent surgical site infections.

Study Setting

This study was conducted at the Department of Operating Room of the Gülhane Training and Research Hospital in Ankara, Turkey between November 2019 and April 2020.

Hypothesis

1. Method

H0: There is no difference between the effectiveness of different surgical hand scrubbing methods on the bacterial flora in the hand

H1: There is a difference between the effectiveness of different surgical hand scrubbing methods on the bacterial flora in the hand.

2. Time

H0: There is no difference between the effectiveness of different the duration of scrubbing time on the bacterial flora in the hand.

H1: There is a difference between the effectiveness of different the duration of scrubbing time on the bacterial flora in the hand.

Method and Participants

The research is a randomized controlled prospective study. The universe of the research will be surgeon and operating room nurses in Gülhane Training and Research Hospital.

Sample Size

The sample size is at least 180 people for one-way analysis of variance with G * Power version 3.1.19 software to determine a medium level (0.25) effect size between 4 groups at 0.80 power and 0.05 type I error level calculated (Tsai, 2016). Participants will be divided into 4 groups by randomization method.

Randomization

- ✓ Group I: The participants in the first group performed the surgical hand scrubbing for 1 minute and with using nail brush (n=45).
- ✓ Group II: The participants in the second group performed the surgical hand scrubbing for 1 minute and without using a nail brush (n=45).
- ✓ Group III: The participants in the third group performed the surgical hand scrubbing for 2 minute and with using nail brush (n=45).
- ✓ Group IV: The participants in the fourth group performed the surgical hand scrubbing for 2 minute and without using a nail brush (n=45).

Inclusion Criteria:

-Being a surgeon or operating room nurse
-Having six months and more surgical experience
-Agree to participate in the research

Exclusion Criteria:

-Not wanting to participate in the research
-Being allergic to the skin due to surgical antiseptic use
-Being latex allergy
- Wounds and abrasions on the hand and nail edges
-To have used a systematic antibiotic at the data collection stage and within two weeks

Volunteers' Exclusion Criteria (Different from Exclusion Criteria):

• Participants want to leave the research
• Expected surgery time is less than 1,5 hours.
• A tear / puncture in the glove during the operation.
• During the operation, data collection will be terminated in cases where the sterility of the glove is impaired.

The interventions

Standard Protocol in All Groups

• The application will take place during the first surgeries entered in the morning.

• All groups will be used hand antiseptic (4% Chlorhexidine gluconate) which is used in the operating room.

• It will be examined whether the nails are smaller than 2 mm. If the nails are long, individuals will be asked to cut their nails with the help of disposable nail scissors before surgical hand scrubbing.

• There will be no nail polish on the nails and there will be no jewelry on the hand and the ring.

• 3 ml of antiseptic solution will be used at each washing stage.

Scrubbing Stage

Group I: Surgical hand scrubbing group using a brush (only nails) (Total scrubbing time 1 min)

1. The bottom of the nails is cleaned under running water with a disposable nail brush (30 seconds).

2. Hands and forearms are washed by scrubbing them towards the elbow for 30 seconds with the help of 3ml antiseptic solution.

3. Hands and forearms are thoroughly rinsed under running water.

4. Hands and forearms are washed by scrubbing them towards the elbow for 30 seconds again with the help of 3 ml antiseptic solution.

5. Hands and forearms are rinsed thoroughly under running water.

Group II: Surgical hand scrubbing group (Control group) without brush (Total scrubbing time 2 min)

1. Hands and forearms are washed by scrubbing towards the elbow for 30 seconds with the help of 3 ml antiseptic solution.

2. Hands and forearms are thoroughly rinsed under running water.

3. Hands and forearms are washed by scrubbing them towards the elbow for 30 seconds again with the help of 3 ml antiseptic solution.

4. Hands and forearms are rinsed thoroughly under running water.

Group III: Surgical hand scrubbing group using a brush (only nails) (Total scrubbing time total 2 minutes)

Applications made in Group I are applied in the same way as scrubbing for 2 minute.

Group IV: Surgical hand scrubbing group (Control group) without brush (Total scrubbing time 2 minutes)

Applications made in Group IV are applied in the same way as scrubbing for 2 minute.

Data Collection

This research will take place in three stages. At all stages (before surgical hand scrubbing, immediately after and at the end of the surgery), culture will be taken from the active hands of the participants with the Glove Juice Method. At all stages, culture will be taken from the participants via Glove Juice Method.

Glove Juice Method

It is a method used to determine the number of bacteria on hand. In this method, individuals will be provided to wear gloves on their dominant hand. Powder-free sterile gloves were used for all sampling. Then, 50 ml of 'Tryptic Soy Broth' medium was placed inside the glove and all surfaces of the gloved hand were massaged for 60 seconds by the researcher. A sample was taken from the liquid in the glove using aseptic techniques and analyzed.

Applications in Medical Microbiology Laboratory

Before surgical hand scrubbing, samples taken with glove liquid technique were diluted 1:10 in Müeller Hinton Broth broth in the laboratory (500 µl sample, 4.5 ml. Müeller Hinton Broth). And 300 µl of it was placed on 5% sheep blood agar plates with sterile micropipettes. 1 ml each of the other samples (after surgical hand scrubbing and at the end of the surgery) was spread diluted into three 5 % sheep blood agar plates with sterile micropipettes. All samples were incubated at 35° C for 48 hours under atmospheric conditions. Total bacterial load was determined by counting the total colony forming units (CFU) on the plates.

Ethical Approval

For the implementation of the research, Ministry of Health, Provincial Health Directorate, Health Sciences University, Abdurrahman Yurtaslan received approval from Ankara Oncology Training and Research Hospital, Health Practice and Research Center Clinical Research Ethics Committee (decision no: 2019-02 / 218)

Ethical Consideration

Written permission and approval was obtained from the Oncology Training and Research Hospital, Health Practice and Research Center Clinical Research Ethics Committee before the study started (decision no: 2019-02 / 218). Surgeon and operating room nurses within Gülhane Training and Research Hospital were informed of the study and verbal approval was obtained.

Statistical Analysis

The data obtained from this study were evaluated by using the Statistical Package for the Social Sciences (SPSS,Inc.,Chicago,IL,USA) 22.0 software program. After the data were transferred to the SPSS database, error controls were performed. Their compliance with a normal distribution was evaluated with Kolmogorov Smirnov test. The data determined were mean ± standard deviation (X ± SS), median and minimum-maximum (min-max) for the variables determined by the measurement and number (n) and percent (%) for the variables determined by counting. Since the variables determined by counting did not comply with a normal distribution, the difference between the four groups was evaluated by the Chi square test. The one-way ANOVA test was used to investigate the difference between the four groups regarding the measured values for values complying with normal distribution and the Kruskal-Wallis test was used for the values that did not comply with a normal distribution. The Bonferroni correction was implemented to determine the source of the difference in group comparisons. In the comparison of four measurements within the group, the "Friedman Test" was used for data that did not conform to normal distribution. In order to understand from which measurement the difference arises, "Wilcoxon Test with Bonferroni Correction" was used as Post Hoc Test.The Mann-Whitney U test was used to investigate the difference between two groups of variables. A p value <0.05 was accepted as statistically significant.