Original Article

Journal of Iranian Medical Council, Volume 5, Issue no. 3
http://dx.doi.org/10.18502/jimc.v5i3.10945

A Comparative Study of the Manual, Automated, and Ultrasonic Surgical-Instrument Cleaning Methods

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Received: Oct 23 2021
Accepted: Jan 19 2022

Citation to this article:
Hashemi Beni H, Shafiei Z, Ghadami A. A Comparative Study of the Manual, Automated, and Ultrasonic Surgical-Instrument Cleaning Methods. J Iran Med Counc. 2022;5(3):486-93.

Abstract

Background: Cleaning is one of the most important steps in preparing surgical instruments for reuse. Thorough cleaning can ensure more effective sterilization, protect treatment teams and patients from transmissible infections, and extend the life of surgical instruments. This study was conducted to compare the manual, automated, and ultrasonic methods of cleaning surgical instruments.

Methods: In this quasi-experimental study, three types of surgical instruments, namely curved hemostats, suction tips, and Metzenbaum scissors, (n=90) from among 20 surgical sets were randomly selected and assigned to three cleaning groups *viz* manual, automated, and ultrasonic. After the instruments were cleaned, surface protein and blood residue swab tests were conducted and the results were recorded on a data-registration form. Data were analyzed using SPSS version 16 and descriptive and inferential statistical methods.

Results: According to the research results, in manually cleaned instruments group, 8 (26.7%) tested positive for blood and 10 (33.3%) tested positive for protein. Of the 30 automatically cleaned instruments, 6 (20%) tested positive for blood and 7 (23.3%) tested positive for protein and of the 30 ultrasonically cleaned instruments, 1 (3.3%) tested positive for blood and protein. The chi-square test showed a statistically significant difference between the three methods of cleaning residual blood and protein from the surgical instruments ($p<0.05$).

Conclusion: The results revealed that according to the research results, of the three cleaning methods, ultrasonic cleaning was by far the most effective in removing blood and protein residues from the surgical instruments. Hence, we suggest that ultrasonic cleaning can be routinely utilized as an efficient cleaning method in medical centers.

Keywords: Chi-square distribution, Humans, Membrane proteins, Sterilization, Suction, Surgical instruments, Ultrasonics

Introduction

Cleaning is the initial step of preparing surgical instruments for reuse. The Association for the Advancement of Medical Instrumentation (AAMI) defines it as the surface decontamination of instruments for greater effectiveness. Cleaning medical devices involves using water and detergents for the mechanical and manual removal of impurities such as blood (or hemoglobin), protein substances, and other residual debris from surfaces, crevices, serrations, hinges, and lumens of devices, instruments, and equipment, thereby preparing them for disinfection (1).

Healthcare workers hold the common misconception that sterilization alone is sufficient to prepare surgical equipment for reuse; however, Food and Drug Adiministration (FDA) guidelines necessitate effective pre-sterilization cleaning, stating that surgical instruments can cause a Surgical Site Infection (SSI) when cleaning procedures are not carried out effectively (2). The SSI rate in developing countries such as Iran is reported to be more than 25%. CDC guidelines emphasize thorough cleaning prior to any High-Level Disinfection (HLD) and sterilization (3).

If the protein residue test proves positive after manual cleaning, it is very likely that tissue debris such as protein will also be detected on surgical instruments after HLD. Therefore, the effective cleaning of surgical instruments in preparation for reuse is of great significance (4). Contamination from surgical instruments which have not gone through the complete cycle of cleaning, disinfection, and sterilization for any reason is one of the primary causes of wound infections, NIs, and SSIs (5,6). Therefore, the effective use of disinfection and cleaning techniques plays an important role in preventing Nosocomial Infections (NIs) (7).

According to the World Health Organization (WHO) guidelines, contaminated surgical instruments can provide an opportunity for microorganisms to enter the surgical site during a procedure (5). An effective cleaning process reduces bioburden and therefore prepares instruments for disinfection and sterilization and enhances the longevity of surgical instruments, keeps them in an optimum condition, and increases the sterility assurance level (8,9).

In general, there are three ways to clean surgical instruments: manual, automated, and ultrasonic. Manual cleaning is done by a Central Sterile Supply (CSS) technician in three phases, namely immersion, rinsing, and drying. Automated washing machines with adjustable time and temperature settings, acid-base compounds, and detergents are used for automated cleaning. In the ultrasonic method, instruments are placed in an ultrasonic cleaner which removes foreign materials from instrument surfaces using ultrasonic waves, vibration, and cavitation (10,11).

Hamed *et al* showed that manual cleaning reduced microorganisms on endoscopes from 1.4×10^7 to 4.9×10^2 CFU per device and sped up the HLD process (12). Azizi *et al* demonstrated that ultrasonic cleaning was more effective than automated cleaning in reducing the amount of tissue debris on instrument surfaces (10). Popovic *et al* evaluated biological debris on dental instruments after manual, automated, and ultrasonic cleaning. The results showed that 34, 25, and 5% debris persisted in the manual, automated, and ultrasonic cleaning groups, respectively (13). Perakaki *et al* compared the automated and ultrasonic methods of cleaning dental instruments in 2007 and revealed that the two test groups had significantly less debris than the control group; moreover, there was significantly less debris in the ultrasonic cleaning group than the automated cleaning group (14).

In Iranian hospitals, surgical instruments are usually cleaned manually or using an automated machine and then re-sterilized. The researchers frequently observed tissue debris on instrument surfaces. Thus, we decided to conduct the present study since the results of existing studies contradict each other and no relevant research has been carried out in Iran. This study aims to compare the manual, automated, and ultrasonic surgical-instrument cleaning methods to recommend the most appropriate method for implementation in medical centers.

Materials and Methods

This quasi-experimental study drew a comparison between three cleaning procedures, namely manual, automated, and ultrasonic. It was conducted in the OR and the Central Sterile Supply Department (CSSD) of Seyed-al-Shohada Hospital in Isfahan in 2020 with the ethics code of IR.MUI.RESEARCH.REC.1398.378. The mentioned medical center had

automated and ultrasonic washing machines and the three procedures could be carried out there.

The sample size calculation formula is shown in figure 1. The research population comprised all instruments in surgical sets (also known as surgical kits) of the OR. After surgery, 90 of them, which met inclusion criteria, were selected from among 20 sets. They included three types of widely used surgical instruments, namely curved hemostats, Metzenbaum scissors, and suction tips. The selection process was as follows: one curved hemostat, one pair of Metzenbaum scissors, and one suction tip were selected from each set and then 10 instruments from each type were evaluated in each cleaning group. In other words, 30 instruments (10 curved hemostats, 10 pairs of Metzenbaum scissors, and 10 suction tips) were assigned to each group. There were three cleaning groups in this research: manual, automated, and ultrasonic.

The inclusion criteria consisted of selecting any surgical instrument, except for those used for HIV and hepatitis patients, without any surface damage, fractures, or scratches but with obvious postsurgical contamination such as blood and organic matter; complying with the machine manufacturer's safety instructions, including maintaining the optimum water temperature and volume required for washing in the automated and ultrasonic cleaning methods; making the instrument selection three hours after surgery at most, counting the washing and testing time; and choosing instruments utilized for surgery between 8 am and 2 *pm*. The exclusion criteria were instrument contamination during the research process, the observation of instrument damage such as surface scratches during the study, and failure to go through the washing process properly.

Data were collected using a four-part form. The first part was intended for recording data on the type of surgery, the presence or absence of infectious diseases, and the set code. The second part was designed for recording data regarding the type of instrument, the surgery start time, the surgery end time, and the cleaning start time after surgery. The third part reported the cleaning methods, namely manual, automated, and ultrasonic. The fourth part demonstrated results of the blood residue test (also known as hemotest or hemocheck) and the protein

$$\frac{(z_{(1-\frac{\alpha}{2})})^2 * pq}{d^2}$$

$$: z_{(1-\frac{\alpha}{2})} = 1.96$$
$$P=q=0.5$$
$$d=0.103$$

Figure 1. Sample size formula.

residue test. Procheck and hemocheck chemical indicators and sterile swabs were utilized for sample collection. In order to evaluate the validity and reliability of the assessment tools, *i.e.*, the blood and protein residue test kits, some of the surgical instruments were deliberately contaminated and the tests were carried out. In case the blood and protein indicators showed color changes, the test performance proved accurate. Furthermore, the researchers examined the approval of Roshan Rai Sepahan (RRS) received from the FDA and the Bureau of Infection Prevention and Control of the Ministry of Health in Iran for manufacturing the hemocheck and procheck kits.

Using the simple random sampling method, surgical instruments were selected from the sets that met the inclusion criteria and the first part of the data-registration form was completed. Medical records of the patients were examined for infectious diseases and the time and type of surgery, and then a code was assigned to each patient. It was written down on both the form and the set used for the patient. The interval between the surgery end time and the cleaning start time was also recorded on the form. The surgical sets were taken to the CSSD and went through the cleaning cycles after special labels were stuck on the instruments. Necessary arrangements for using the automated and ultrasonic washing machines were made and the researchers were provided with them on the sampling days. By drawing lots, the surgical instruments were assigned to each of the three groups on a daily basis. This process continued until the sample size was reached. After the transfer of the sets to the CSSD, three types of instruments were selected from the labeled sets that had met the inclusion criteria.

In the manual cleaning method, the CSS technician washed the instruments under the direct supervision of the researcher. They were immersed for 15 minutes in the first sink containing an enzymatic solution with a standard pH. To prepare the desired solution, 20 *ml* of the Sayasept-HI 2% disinfectant manufactured by Behbahan Shimi Company was added to one liter of water. The enzymatic solution had didecyldimethylammonium chloride (DDAC), which is active against mycobacteria, enveloped viruses, adenoviruses, bacteria, and fungi. It should be stored at 5-35 °*C*. Moreover, the solution does not corrode surgical instruments and maintains its effectiveness in the presence of hard water. The two-minute instrument decontamination was conducted using a medium-soft brush. The instruments were washed and rinsed in the second sink with regular water (*i.e.*, tap water) at 25-30 °*C*. After being rinsed, they were placed on a special instrument drying table. Before the instruments dried out, the protein and blood residue tests were performed by swabbing the instrument surfaces with medium pressure according to the manufacturer's instructions. First, the hemostat jaws, hinges of the Metzenbaum scissors, and lumens of the suction tips were swabbed. Next, the reagent bottle cap was unscrewed, the swab was rotated in the brown reagent for 30 seconds, it was removed from the bottle, the cap was screwed back onto the bottle, and the reagent was examined for a visible color change. The protein residue test would prove positive and there would be protein residues on the sample if the reagent turned blue. However, if the reagent remained brown, the test would prove negative and there would be no residual protein on the sample. In the present research, the surface protein and blood residue swab test kits had been manufactured by RSS. The blood residue test would prove positive and there would be blood on the sample if the reagent turned blue or green within one minute. Nevertheless, if there was no color change in the reagent, the test would prove negative and there would be no blood on the sample.

For ultrasonic cleaning, first, the form was filled out. Next, the instruments were transferred to the CSSD and placed in the ultrasonic washing machine by the researcher according to the instructions. The instruments were washed within 5-10 *min* at 40-50 °*C* in accordance with instructions of the manufacturer, Pars Sonic Company. Then, liquid detergent such as liquid soap was added to regular water to wash the instruments in the machine. Finally, after the washing process, the blood and protein residue tests were conducted in compliance with the instructions and the results were recorded on the form.

In the automated cleaning method, the instruments were washed using a washing machine, the LW 200 model manufactured by Tosan Tajhiz Company, according to the manufacturer's instructions. First, the instruments were prewashed in cold water. Next, they were rinsed with regular water at 90°*C*. Then, 5-10 *ml* of a detergent was added to the machine. After the instruments were polished, they were finally washed with soft water. Each washing cycle of the machine took 55-60 *min* and the temperature was maintained at 90°*C*. After the washing process, the blood and protein residue tests were conducted once more and the results were recorded on the form. Descriptive and inferential statistical methods and SPSS version 16 were used to examine the data, which were analyzed employing descriptive indices, *i.e.*, frequency and percentage, the chi-square test, and one-way analysis of variance. An analysis with $p<0.05$ was considered statistically significant and the Confidence Interval (CI) was 0.95.

Results

In this quasi-experimental study, which was performed at Seyed-al-Shohada Hospital affiliated to Isfahan University of Medical Sciences, 90 surgical instruments were randomly divided into three groups, namely manual, automated, and ultrasonic cleaning.

According to the research results, of the 30 manually cleaned instruments, 8 (26.7%) tested positive for blood but 22 (73.3%) tested negative and had been thoroughly cleaned. Moreover, of the 30 instruments, 10 (33.3%) tested positive for protein but 20 (66.7%) tested negative and had been thoroughly cleaned. Of the 30 automatically cleaned instruments, 6 (20%) tested positive for blood but 24 (80%) tested negative and no blood was detected on the instrument surfaces. Furthermore, of the 30 instruments, 7 (23.3%) tested positive for protein and there was protein on the surfaces but 23 (76.7%) tested negative and had been thoroughly cleaned. Of the 30 ultrasonically cleaned instruments, 1 (3.3%) tested positive for

blood and protein and their residues were detected on the instrument surfaces. However, 29 (96.7%) of the instruments had been thoroughly clean and no blood or protein was found on the surfaces.

Table 1 compares the frequency distributions of cleaning blood from the surgical instruments manually, automatically, and ultrasonically. According to table 1, there was a statistically significant difference between the three cleaning methods ($p<0.05$). Table 2 compares the frequency distributions of cleaning protein off the instruments using the three methods. It shows that a statistically significant difference existed between the three methods ($p<0.05$). Moreover, Spearman's rank correlation coefficient demonstrated a significant association between the mean duration (from the surgery end time to the cleaning start time) and the removal of blood and protein from the instruments so that the number of the instruments testing positive for blood and protein after cleaning increased as the mean duration increased ($p<0.05$).

Discussion

The present research compared the manual, automated, and ultrasonic methods of cleaning blood and protein residues from surgical instrument surfaces. It revealed that, of a total of 30 manually cleaned instruments, three curved hemostats (40%), three suction tips (30%), and one pair of Metzenbaum scissors (10%) had blood on their surfaces. Moreover, of a total of 30 automatically cleaned instruments, three curved hemostats (30%), two suction tips (20%), and one pair of Metzenbaum scissors (10%) had blood on their surfaces. In addition, blood was detected on the surface of only one suction tip (10%) out of a total of 30 ultrasonically clean surgical instruments. These findings show that ultrasonic cleaning was the most effective of the three methods for cleaning blood from the surgical instruments ($p=0.044$).

In 2012, Azizi *et al* showed that the ultrasonic cleaning method was more successful than the automated cleaning method in reducing tissue debris on the surfaces of suction tips (10). Moreover, in a 2013 study about endodontic instruments, Khullar *et al* compared the manual and ultrasonic clearing methods. Their results revealed that the mean value

Table 1. The frequency distributions of cleaning blood from the surgical instruments manually, automatically, and ultrasonically

Instruments	Cleaning method	Positive		Negative		Total		p-value
		Frequency	%	Frequency	%	Frequency	%	
Curved hemostat	Manual	40		60		100		0.089
	Automated	30		70		100		
	Ultrasonic	0		100		100		
	Total	23.3		76.7		100		
Suction tip	Manual	30		70		100		0.535
	Automated	20		80		100		
	Ultrasonic	10		90		100		
	Total	20		80		100		
Metzenbaum scissors	Manual	10		90		100		0.585
	Automated	10		90		100		
	Ultrasonic	0		100		100		
	Total	6.7		93.3		100		
Total	Manual	26.7		73/3		100		0.044
	Automated	20		80		100		
	Ultrasonic	3.3		96.7		100		
	Total	16.7		83.3		100		

Table 2. The frequency distributions of cleaning protein from the surgical instruments manually, automatically, and ultrasonically

Instruments	Cleaning method	Positive		Negative		Total		p-value
		Frequency	%	Frequency	%	Frequency	%	
Curved hemostat	Manual	60		40		100		0.015
	Automated	40		60		100		
	Ultrasonic	0		100		100		
	Total	33.3		66.7		100		
Suction tip	Manual	30		70		100		0.535
	Automated	20		80		100		
	Ultrasonic	10		90		100		
	Total	20		80		100		
Metzenbaum scissors	Manual	10		90		100		0.585
	Automated	10		90		100		
	Ultrasonic	0		100		100		
	Total	6.7		93.3		100		
Total	Manual	33.3		66.7		100		0.013
	Automated	20		80		100		
	Ultrasonic	3.3		96.7		100		
	Total	20		80		100		

of contamination by blood and tissue debris was significantly lower in the ultrasonic method than the manual method (15). However, Vassey *et al* evaluated residual protein levels on endodontic instruments reprocessed by manual, ultrasonic and automated cleaning methods in 2011 and declared that residual protein levels were lower in manual washing combined with automated cleaning than manual washing combined with ultrasonic cleaning (16). This inconsistency must have emerged from differences between the interventions, machines, detergents in automated cleaning and enzymatic solutions in initial manual cleaning.

A broad comparison between the manual, automated, and ultrasonic methods of cleaning blood from the surgical instruments showed a statistically significant difference between them. Ultrasonic cleaning resulted in significantly the lowest residual blood levels on the instruments ($p<0.05$). In line with these results, a 2010 study by Popovic *et al* considering effects of the three cleaning methods on endodontic instruments demonstrated that the mean values of contamination by blood and tissue debris were 34, 25, and 5% in the manual, automated, and ultrasonic cleaning groups, respectively (12). Likewise, comparing effects of the ultrasonic and automated cleaning methods on 90 different surgical instruments in 2007, Perakaki *et al* showed that the treatment groups were cleaned more effectively than the control group and tissue debris persisted less on the ultrasonically cleaned instruments than the automatically cleaned instruments (14).

Nevertheless, in 2006, a study examined the efficacy of manual, ultrasonic, and automated plus retroflush cleaning in decontaminating biopsy forceps and showed that the manual and ultrasonic cleaning methods were totally ineffective in removing debris (11). Furthermore, in 2018, de Camargo *et al* compared the group receiving manual-only cleaning with the group receiving manual cleaning followed by ultrasonic cleaning and demonstrated that there was no statically significant difference between the two groups (17). This inconsistency must have arisen from differences in the methodology and sampling.

A broad comparison between the three methods

of cleaning protein from the surgical instruments demonstrated a statistically significant difference between them. Ultrasonic cleaning led to significantly the lowest residual protein levels on the instruments ($p<0.05$). In India in 2013, Khullar *et al* assessed the persistence of tissue debris on endodontic instruments cleaned manually, ultrasonically, and using HLD. Their results showed a statistically significant difference between the three methods, of which the ultrasonic method had by far the lowest mean value of contamination with blood and tissue debris ($p<0.001$) (15). However, the results of the studies by Vassey *et al* in 2011 and de Camargo *et al* in 2018 were not consistent with the present study (16,17). This inconsistency must have emerged from the application of different intervention and sampling methods.

A separate examination of the surgical instruments revealed that, of the three types of instruments, the curved hemostats were the least cleaned type in all the groups. In other words, the curved hemostats had the highest residual blood and protein levels in all the groups following the cleaning process. This must have been due to the presence of numerous serrations on the inner edges of curved hemostats, requiring extra attention during the cleaning process. Likewise, in 2011, Vassey *et al* found it necessary to clean instruments having serrations on their surfaces with particular attention while implementing all cleaning methods (16). Nevertheless, a 2006 study by Baxter *et al* showed no significant correlation between instrument complexity and residual protein contamination (18). The inconsistency must have arisen from the difference in the type of instrumentation because this study had utilized needle holders and suture scissors.

Moreover, as the research results demonstrated, the number of the surgical instruments testing positive for blood and protein after cleaning increased as the mean duration from the surgery end time to the cleaning start time increased ($p<0.05$). Likewise, in 2018, Wanke *et al* showed that residual blood, protein, and bioburden levels on surgical instruments increased since cleaning requirements were not fulfilled in the routine hospital cleaning of reusable instruments; that is to say, the interval between the surgery end time and the cleaning start time was long and the instruments were not cleaned thoroughly (19).

Conclusion

According to the research results, of the three cleaning methods, ultrasonic cleaning was by far the most effective in removing blood and protein residues from the surgical instruments. In other words, the results showed the lowest levels of residual contamination on the instrument surfaces after this cleaning process. Therefore, the ultrasonic method can be routinely used as an efficient cleaning method in medical centers to improve infection control practices and patient safety indicators by reducing postsurgical tissue residues and to minimize NIs by reducing SSIs. It is recommended that further studies be carried out with larger sample sizes and using a combination of cleaning methods.

Acknowledgements

The researchers wish to express their gratitude to the Vice Chancellor for Research and the Research Center of the School of Nursing and Midwifery at Isfahan University of Medical Sciences and officials of the operating room and the CSSD of Seyed al-Shohada Hospital in Isfahan for their cooperation with the researchers. This research was approved by the Ethics Committee of Isfahan University of Medical Sciences (REC.1398.378) and the research code is 398432.

Conflict of Interest

There are no conflicts of interest.

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