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Aliu Candé, Tcherno; Ferreira Veiga Tippie, Anaclara; Martins Mendonça, Katiane; Custódia Silva Souza, Adenícia; Valeriana Miranda, Patrícia; Piemnta, Fabiana Cristina
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Influence of cleaning in sterility of silicone tubes: a quasi-experimental study

Tcherno Aliu Candé[1], Anaclara Ferreira Veiga Tippie[2], Katiane Martins Mendonça[3], Adenícia Custódia Silva Souza[4], Patrícia Valeriana Miranda[5], Fabiana Cristina Piemnta[6].

1 Hospital General de Guiné –Bissau, África del Sur

2,3,4 Facultad de Enfermería. Universidad Federal de Goiás

5 Secretaria Municipal de Salud de Goiania (GO)

6 Centros de Prevención y Control de enfermedades, Estados Unidos de América

ABSTRACT

Objective: Evaluate the sterility of silicone tubes after sterilization in autoclave of saturated vapor under pressure before and after intervention in the cleaning stage. **Method:** It is a quasi-experimental study performed in a College hospital, in the municipality of Goiania, Brazil. 120 segments were analyzed: 60 in the extremity (E) and 60 in the middle (M). Group (1): 30 tubes, before the cleaning stage and group (2): 30 tubes after this intervention. Samples were inoculated, peaked in nutrient agar and the colonies were isolated and identified. **Results:** in group (1), 23 (76,67%) were contaminated and in the group (2) eight (26,67%). There was a significant statistical difference between the groups (X2 = 25699, p = 0,0001) and not between the segments. Prevailing microorganisms were: Staphylococcus coagulase-negative. **Discussion:** the significant statistical difference between the groups related to microbial development, reveals interference in the cleaning stage of reprocessing. **Conclusion:** the cleaning stage is fundamental for the success of reprocessing.

Descriptors: Nursing; Sterilization; Microbiology; Hospital Infection.

INTRODUCTION

The reprocessing of dental-medical-hospital items has become a challenge due to complexity of the process and the responsibility it involves. It includes a sequence of steps that starts with the dismantling of the item, followed by a cleaning (the cleaning itself, the rinse and the drying), inspection, packing, labeling, disinfection/sterilization, storage, distribution and quality control, guaranteeing the development and safety of the whole process.[1].

The dental-medical-hospital articles present particularities that require different formats of execution of each one of the steps of the reprocessing to achieve the desired final quality in the end of the process. Tubular items are detached, and because of their particularities based on conformation and the presence of lumen, deserve special attention in all steps of the process.

Among the tubular items, there are silicone and latex tubes that have a vast application in assistive practice, including from basic proceedings to surgical operations, when are used to aspirate of the exudate of the surgical site. These are supposed to be polyvinyl chloride (PVC) or polyurethane (PUR) of individual and disposable use, however, this is not the reality of the majority of healthcare service units, which instigates to rethink the reprocessing of this type of article.

When the alternative is the reprocessing of these items, it is recommended the acquisition of transparent tubes, as the silicone ones, that facilitate the internal visualization and verification of the lumen cleaning step, a fact that when erroneous, compromises the quality of the process and the control of sterilization[1-2].

The cleaning step must be solid and based on the recommendations related to the arrangement of conditions that guarantee the adequate reduction of the biocharge, through appropriate inputs/equipment and the capacity of the professionals, enabling the following steps. The cleaning can occur by manual or automatic methods (ultrasonic or

thermodisinfectant cleaner), preceded by the immersion in solution of enzymatic detergent[1].

A relevant aspect to consider the cleaning of tubular items is the formation of a biofilm inside the lumen, as a consequence of an incorrect execution of this stage, that contributes to the failing of the following steps, even though the rigorous adherence to the previewed protocols of each step, impacting directly the level of sterility security[1,3]. This constitutes as a risk factor to the occurrence of adverse events during the assistance, which sometimes is sublimed.

After the cleaning, the exhausting and rigorous rinse in current water must be executed in sinks with a pressure nozzle or water pistol under pressure to the removal of dirtiness and loosen organic material, as well as detergent residual[1]. And, for the last rinse, use water in a higher level of purity (treated after distillation or reverse osmosis)[4]. Then, drying follows throughout the hole extension of the lumen, helped by compressed air or air pistol[3].

Related to the packing, it should be used a compatible enclosure with the sterilization method. The disposition of the silicone tube is a relevant aspect during this step, because the effective contact of the sterilizing agent depends on the correct positioning of the circular form, without folds or closing of the edges.

As desired, the sequence of a correct flux of reprocessing, for these items they must be inspected in each step according to the dirtiness, integrity and functionality, aspects that are made visibly possible in workbenches with good illumination, amplifying lenses and other resources that aim these goals.

As a final step of the reprocessing, sterilization can be done by saturated vapor under pressure, ethylene oxide, hydrogen peroxide plasma and low temperature vapor with formaldehyde[1]. All formats depend on the quality of the previous steps.

Seen as difficulties to the modus operandi of the reprocessing of tubular items, transparent or not, as well as in finding studies related to the topic until now usual, and establish strategies that better respond to a safe use of these during the attention to the client. The quality control during the reprocessing of these tubes is of extreme relevance to the safety of the user and of the professional, facilitating the health institution to collaborate in a real manner in the reduction of Infections related to Health Care (IrHC).

Thus, the objective is to evaluate the sterility of silicone tubes after sterilization in saturated vapor under pressure autoclave, before and after the cleaning step.

METHODOLOGY

This is a quasi-experimental study, conducted at the Center of Material and Sterilization Center (CMSC) of a large-scale teaching hospital in the municipality of Goiania, Brazil. The collection of material occurred between October and November 2007, after the acquiescence of the hospital, the management of the CMSC and the approval by the Ethics Committee of the Institution (protocol number 067/2005).

The all stages of the reutilization process of silicone tubes in this institution were centrally conducted by the CMSC. Sixty silicone tubes were analyzed, which were divided in two groups of 30, as shown in Figure 1 (Flowchart 1).

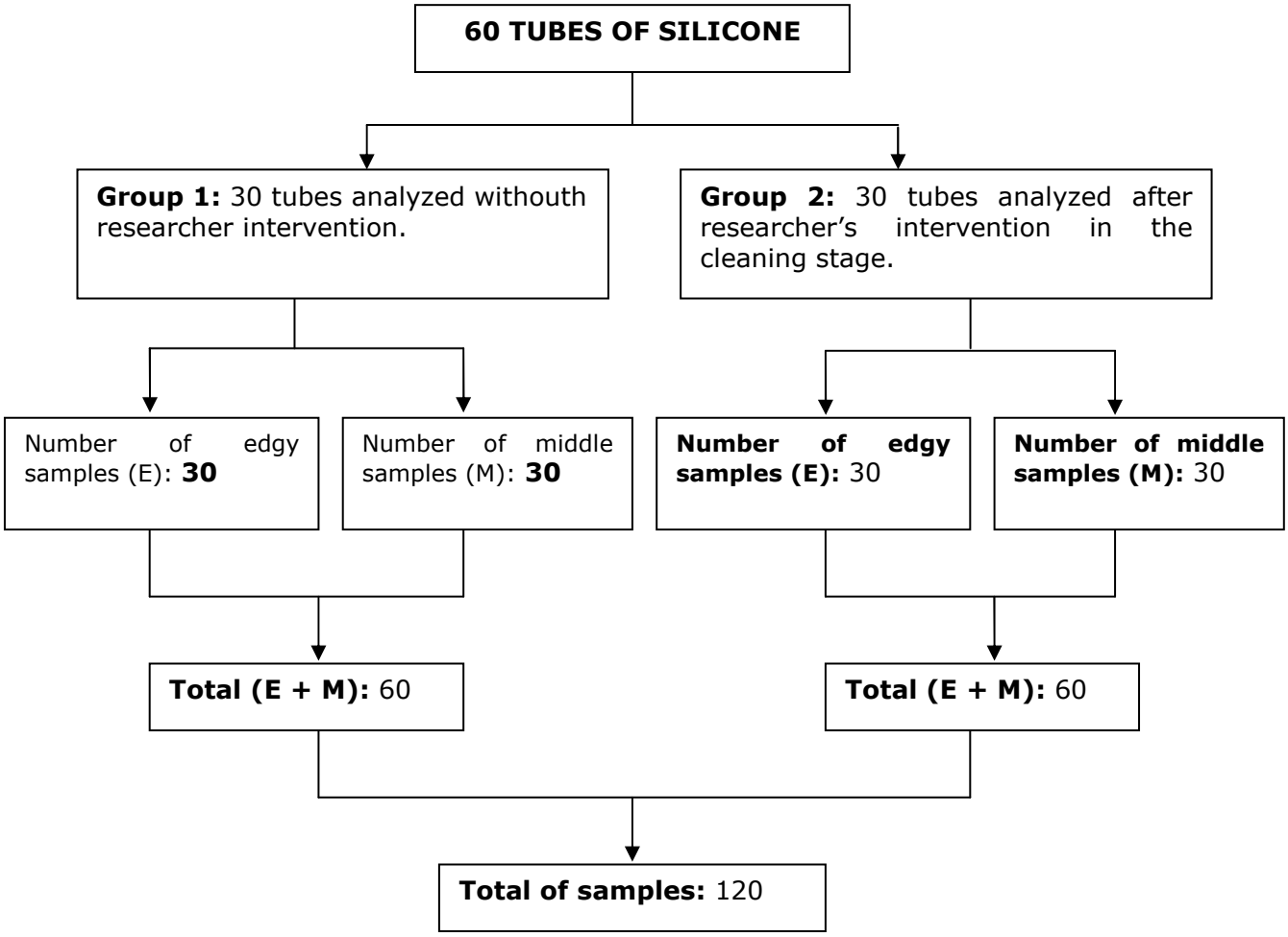

Figure 1: Flowchart of the collection of silicone tubes for microbiological analysis. 2007, Goiania, Brazil

In the first group of 30 tubes of silicone, the steps of reprocessing followed the routine. After collection of this group was established by the intervention of the researchers, who began performing the step of cleaning, all silicone tubes reprocessed in the CMSC, fulfilling the protocol already established in the unit, closely following the recommendations for cleaning and drying. The intervention took place two weeks prior to the collection of the second group (30 silicone tubes) and maintained throughout the studied period.

The cleaning routine of silicone tubes advocated in the institution and fulfilled by one of the researchers was: pre-rinsing the tubes in running water, followed by immersion in an

enzymatic detergent (made by three enzymes) and aspiration of the product until filling the entire lumen using a 20 milliliters syringe.

After five minutes, the immersion time recommended by the manufacturer, the tubes are placed in a washing machine during 15 minutes, in which successive circular movements are performed. Then, the rinse starts under running water with adapted nozzles, drying externally with a clean pad, and internally with compressed air.

In both groups, the practice was standardized while collecting five tubes a day, three times a week, every other day, for a total of two weeks. The tubes were made of one centimeter of extension, in a cross-section, divided into two segments, the edge (E) and the middle (M), corresponding to 120 samples.

The collection of this material was made within the area of custody of the articles of CMSC, being conducted by two researchers, a collector and an assistant, which garmenting with private uniforms, including a cap, surgical mask and shoes, and hand hygiene was performed with soap and water. For the preparation of the collection desks, the assistant researcher carried out a cleaning with soap and water, followed by disinfection with 70% alcohol. After that, the professional overlaid it with tarpaulin and sterile surgical field, while the collector equipped himself with surgical gown and sterile gloves. With the objective to assist in the collection separating the E and M segments, anatomical clamps and scalpel blades, all sterilized, were used. All these steps ensured the maintenance of the aseptic during the sample collection.

The segments were cut from silicone extensions and inoculated into test tubes containing Brain Heart Infusion broth (BHI). After the collection, it was transported to the Laboratory of Bacteriology of the Medical Institute of Tropical Pathology and Public Health, of the Goias Federal University (IPTSP/UFG) and incubated at 37 degrees Celsius for up to 20 days.

Samples with visible turbidity were plated on agar nutrient isolation. The colonies developed were characterized macroscopically and microscopically by Gram stain standard. Those identified as Gram-positive cocci (GPC), were subcultered on mannitol

agar and subjected to biochemical identification (catalase and coagulase). The other isolated samples characterized as Gram-negative rods (GNR), were transferred to MacConkey agar and identified by biochemical tests(5).

Then, colonies were stored in vials containing simple inclined agar at 4 degrees Celsius. The chi-square test was used for statistical analysis, between the first and the second groups and sites of contamination (M and E). P values <0.05 were considered statistically significant.

RESULTS

Table 1 presents the results of the microbiological analysis of two groups: 30 silicone tubes that did not receive any sort of intervention during the cleaning step and 30 others that suffered the intervention. The chi-square test showed that the difference between groups was statistically significant ($X^2 = 25699$, $p = 0,0001$).

Table 1: Microbiological detection in tubes of silicone, sterilized in under pressure vapor autoclaves. 2007. Goiania, Brazil

Steps of the analysis		**Results of the analysis**			
		Positive		*Negative*	
	N	n	%	n	%
Before the intervention	30	23	76,67	07	23,33
After the intervention	30	08	26,67	22	73,33

There was not a significant statistical difference in the E and M segments between the two groups.

Table 2 presents the isolated microorganisms.

Table 2. Isolated microorganisms in tubes of silicone, sterilized in under pressure saturated vapor autoclaves. 2007. Goiania, Brazil

Isolated microorganisms	N
ECN – *Stafilococcus Coagulase – Negative*	27
BGP – *Bacillus Gram Positive*	11
Stafilococcus aureus	09
BGNNF – Gram Rods – Non-Fermenters Negative	01
Micrococcus sp	01
Total	**49**

A single researcher performed the step of cleaning all silicone tubes used in the institution, in strict compliance with the protocol provided for this step, for a period of approximately 40 days, starting two weeks before the collection of the second group.

DISCUSSION

Silicone tubes are not related among the articles of single use determined by the Brazilian Ministry of Health, thus, can be reused after an adequate reprocess.

These are transparent articles, a facilitating aspect for visualization if lumen persists or any other organic material residual, which consequently would facilitate the formation of biofilm and block the sterility[1-2].

Within this context, the necessity of more scientific publications are needed, especially those with emphasis for the formation of the biofilm in dental-medical-hospital items, featuring the ones in tubular format and of difficult cleaning and handling. Besides the importance of biofilms within the IrHC context, the scientific evidences through these experimental studies in hospital environment are still recent and scarce[6], and deserve more discussions.

There are multiple reprocessing standards to compare, on which the silicone tubes are submitted and resulting as unfavorable, as in the final quality of sterilization the

mentioned tubes wear out, collapse, dry out and/or crack, making it possible the retention of microorganisms.

The contamination levels found in this study (first and second groups) were higher that the reported in a study that analyzed sterile latex tubes after reprocessing in under pressure saturated steam autoclaves[2], a fact that seems unusual, since silicone tubes are considered to the resistant, easy cleaning and display of dirt[1].

There was a significant reduction between the groups 1 and 2 ($X^2 = 25699$, $p = 0,0001$) related to contamination. However, it was expected to detect no microorganisms at all, since the silicone tubes were submitted to reprocessing with quality control at all stages, starting with cleaning as detailed in the methodology.

For the packaging, the unit's routine is to have the silicone tubes in a circle, fixed by a tying gauze and surgical grade wrapping paper.

The sterilization was performed in an autoclave-type pre-vacuum cycle and pressurized sanitary barrier. It is emphasized that the quality control during the operation of the autoclaves during the study, carried out by the monitoring of physic/mechanic (every cycle), chemic (Bowie-Dick and integrator Class V: daily) and biologic (3^{rd} generation: daily) aspects, showed satisfactory performance of the two autoclaves used in the institution. The guard system was exclusive and had restricted flow of people.

It is known that the human factor can interfere, positively or not, to the expected results directly influencing the quality of this process (1-4). The qualification of human resources can be considered as one of the best investments for the final quality of any process. Human failures at any stage of reprocessing may interfere negatively. In this context, it is stressed the role of the nurse as the manager of the centers of material and as major researcher in the field of reprocessing articles.

In this study, a single researcher carried out the cleaning stage of all silicone tubes of the second group in use by the institution and, even though there was contamination in this group. It is possible to confirm that the procedures were followed with highest expected

quality by the institution's protocol, however it is to be considered there may have failed to clean some of these item properly, as the protocol does not foresee the manual rubbing of the lumen and the institution did not made appropriate brushes available. Those are factors, which act directly in the cleaning quality[1,4,7].

Manual cleaning is limited based of the variations of the techniques that can vary from professional to professional, influencing its effectiveness. This method includes the manual friction using fabric and brushing and the immersion and/or fluxes with cleaning solutions[4]. It is supposed to be followed by the visual inspection, with the support of a magnifying glass[1,4]. Despite the fact the tubes were submitted to a mechanic process of circular movements in a machine for 15 minutes, this was not appropriated to the cleaning of tubular items and adaptors were not present.

It is important to call attention to the fact that the 15 minutes which the tubes were exposed to the enzymatic detergent in the washer was above the recommended time according to the manufacturer, of five minutes.

The enzymatic detergent does not eliminate microorganisms and not even inhibit them; by the contrary, when the time of contact is not observed, this product is an ideal environment for the growth of pathogens, besides creating a proper fixation of organic material on the instruments[1,4]. It is indispensable the mechanic action on the surfaces of the items as to avoid the formation of biofilm and the deposition of organic material[1,3,4,6].

A study that meant to know the efficiency of cleaning[8] affirms that one of the greatest challenges of reprocessing items is the handling of those which present a narrow lumen and indicate the use of automated washers with connection devices for this type of item as an option.

Besides that, it is necessary to consider that the manual aspiration process of the enzymatic detergent allows the formation of bubbles, places where the product would not act.

It is possible to think that the configuration of the tubes would make it difficult the penetration of vapor, and in this case, a even higher difficulty would be the segment in the middle (M), but between the segments (E) and (M) of both groups, no considerable difference related to contamination was found. Other elements related to the steps of packing and handling of the camera can have contributed to the result found. Because of that, it is suggested the continuation of studies with a larger number of samples and with a higher control of variables that allow interferences in this important topic.

In relation to the isolated microorganisms of the silicone tubes, the greater number was from the group *Stafilococcus coagulase*-negative, especially *Staphylococcus epidermidis,* constituting one of the principal etiological agents of bacteremias and directly involved in the production of biofilms[9].

The second group of microorganism found in the samples were the *Staphylococcus coagulase-positive*, in special *Staphylococcus aureus* by the frequent relationship with the etiology of the IrHC and to present many mechanisms of resistance to antimicrobial agents[10].

In Brazil, it is observed a rise in the prevalence and resistance in cases of infection by *Staphylococcus aureus*, varying from 17% to 26% and from those, 70% to 100% are classified as multiresistant[10]. This is one of the main agents of infection in the surgical site, and despite that in this study there are not enough evidences for this affirmative, it is possible to infer an increase of these taxes in those surgical proceedings in which the tubes are used to aspire the exudate and that after aspiration become the main medium and that sometimes, stay in a prolonged contact with the operatory field. Considering that during the aspiration, this exudate drains out to the collection bottle through negative pressure generated by the vacuum. This risk should be better investigated and evaluated.

The isolation of the Gram-negative non-fermentative rod calls attention by the increase of this type of microorganism in the case of infection and its relation with the rise of morbimortality rates in hospitalized patients and of the resistance index.

The IrHCA generate the increase of the time of hospitalization, the risk of obit, a higher economic cost of the health institution, besides the extreme physical and emotional stress for the patient, relatives and professionals of the field of health, or in other words, added costs – direct, indirect and intangible ones.

This study instigates the development of others of the same topic, in favor of the safety of the users. It is worth remembering the reality of the services of health in the majority of the Brazilian hospitals that vastly use silicone tubes in different situations of diverse levels of invasiveness. It is possible to imagine, for example, that one of these tubes used in a certain surgical proceeding for aspiration, can in a subsequent use be used in a tracheal aspiration in an immunosuppressed patient in an intensive care unit.

CONCLUSION

The analysis of sterility of silicone tubes reprocessed in under pressure saturated vapor, before and after the intervention of the cleaning process has shown an increase in a microbiological growth in both groups, being the difference between the groups statistically significant.

The results allow us to affirm that the accomplishment of the cleaning step according to the protocol of the health unit interfered improving the quality of reprocessing, reducing the index of microbiological contamination and reiterating the importance of the cleaning for the success of reprocessing of dental-medical-hospital items. On the other hand, it also allows us to infer that there is a necessity of some adjustments related to the cleaning of the lumen.

In the present study, microorganisms associated with IrHC were isolated, mostly the estafilococos coagulase-negative.

It is highlighted the necessity of qualification of human resources and of supervision, once the operation of protocols depend directly from the workers, that have the responsibility to offer safe items for the use. The results also point out to the material resources – quantity and quality – as facilitators or complicators in the implementation of professional conducts.

Nurses are important in this process of supervision and qualification of human resources in the context of reuse of articles. It can be affirmed that they are greatly responsible by the elaboration and implementation of protocols about the handling of dental-medical-hospital items in many health institutions, acting in the centers of materials and sterilization, able to visualize adequate reprocessing of items and consuming units, to guarantee safety in the use of these items.

While reporting the concept of sterilization that aims to eliminate all forms of microorganisms in a way these beings are not detected in a standard environment, it is possible to conclude the contamination in silicone tubes represent risk of IrHC and other direct and indirect losses for the patients and for the institution.

Until recently, the role of the items in the development of IhHC was placed in a secondary plan. However, this is a premise that evidences in great evolution in the information about reprocessing of items have denied, demanding from the managers of the area of the care to the human health a critical-reflexive analysis of the quality indexes (structure, process and result).

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