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Sterilization monitoring of gravity autoclaves in dental services in a municipality in the interior of the state of São Paulo

Monitoramento da esterilização de autoclaves gravitacionais em serviços odontológicos de um município do interior do estado de São Paulo

Rodney Francisco Donha[I]

Claudia Benedita dos Santos[II,*]

Wanessa Teixeira Bellissimo-Rodrigues[III]

Liliana Junqueira de Paiva Donatelli[IV]

Edson Zangiacomi Martinez[V]

Maria José Bistafa Pereira[I]

[I] Universidade de Ribeirão Preto, Ribeirão Preto, SP, Brasil

[II] Escola de Enfermagem de Ribeirão Preto, Ribeirão Preto, SP, Brasil

[III] Hospital das Clínicas, Faculdade de Medicina de Ribeirão Preto, Universidade de São Paulo, Ribeirão Preto, SP, Brasil

[IV] ProBio Biossegurança em Saúde, Bauru, SP, Brasil

[V] Faculdade de Medicina de Ribeirão Preto, Universidade de São Paulo, Ribeirão Preto, SP, Brasil

***** **E-mail:** cbsantos@eerp.usp.br

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ABSTRACT

Introduction: Biosafety recommendations for dentistry aim to protect patients and professionals from health risks. Studies have demonstrated a causal link between dental care and infection occurrence among patients and dental professionals. **Objectives:** To determine the prevalence and compare frequencies of adequate sterilization monitoring in gravity autoclaves, through mechanical, physical, chemical, and biological controls, performed by professionals responsible for private dental services in Ribeirão Preto - SP, as well as to identify the professional category responsible for carrying it out. **Method:** This descriptive population-based study was quantitative with a cross-sectional design. The population consisted of dental surgeons linked to the services who applied for a license for initial operation and renewal in the second half of 2018. Data were collected between January and March 2019. A validated questionnaire was used. The study was approved by the Research Ethics Committee of the University of Ribeirão Preto. **Results:** Among the 142 participants, 95.8% reported monitoring of the sterilization process. A total of 38.2% of the professionals who performed chemical and biological control were found to have periodically performed the chemical control at least once a day and the biological control weekly, 43.1% in the renewal category, and 10.0% in the initial request category. In the renewal category, 77.6% of dentists delegate responsibility to assistants and other professionals. This percentage is 40.0% for the initial request category. **Conclusions:** It is very worrying that six professionals did not perform any type of sterilization control. It is necessary to accelerate the revision of the regulations of the sterilization monitoring process and their standardization, and also invest in the educational process.

KEYWORDS: Infection Control; Sterilization; Dentistry

RESUMO

Introdução: As recomendações de biossegurança em odontologia visam proteger pacientes e profissionais dos riscos à saúde. Estudos demonstram o nexo causal entre o atendimento odontológico e a ocorrência da infecção, em pacientes e profissionais de odontologia. **Objetivos:** Obter prevalência e comparar frequências de realização do monitoramento adequado de esterilização em autoclaves gravitacionais, utilizando os controles mecânico, físico, químico e biológico, pelos profissionais responsáveis nos serviços privados de odontologia de Ribeirão Preto, SP, bem como identificar a categoria profissional responsável pela realização. **Método:** Estudo descritivo populacional, natureza quantitativa com delineamento transversal. A população constituiu-se por dentistas vinculados aos serviços que pleitearam licença para funcionamento inicial e renovação, no segundo semestre de 2018. A coleta de dados ocorreu entre janeiro e março de 2019. Foi utilizado um questionário validado. O projeto foi aprovado pelo Comitê de Ética em Pesquisa da Universidade de Ribeirão Preto. **Resultados:** Dentre os 142 participantes,

95,8% relataram realização de monitoramento do processo de esterilização. Foram encontrados 38,2% dos profissionais executando controle químico e biológico com periodicidade de realização do controle químico pelo menos uma vez ao dia e do controle biológico semanalmente, sendo 43,1% da categoria renovação e 10,0% da categoria de solicitação inicial. Na categoria de renovação, 77,6% dos dentistas delegam a responsabilidade para auxiliares e outros profissionais. Na categoria de solicitação inicial esta porcentagem é de 40,0%. **Conclusões:** É muito preocupante o fato de seis profissionais não realizarem qualquer tipo de controle da esterilização. Faz-se necessário acelerar a revisão dos regulamentos do processo de monitoramento de esterilização, e sua padronização, e ainda investir no processo educativo.

PALAVRAS-CHAVE: Controle de Infecções; Esterilização; Odontologia

INTRODUCTION

Biosafety recommendations in dentistry were established decades ago with the aim of protecting the health of patients and professionals from the risks inherent in dental care, especially after the discovery of the acquired immunodeficiency virus (HIV)[1,2,3,4]. More recently, with the emergence of the COVID-19 pandemic, such measures have been widely reiterated in the literature, especially those related to biological risks[5,6,7].

During healthcare, cross-infections can result from the transmission of microorganisms between patients, from patients to the team of professionals involved in their care and vice versa. In dental practices, the transmission of infectious diseases can occur through direct contact with biological fluids or indirect contact through contaminated instruments, clinical contact surfaces or equipment[8,9].

It is worth mentioning that the oral cavity is home to a great diversity of microorganisms, and fungi (*Candida albicans)*, viruses, including the hepatitis B (HBV) and C (HCV) viruses, acquired immunodeficiency virus (HIV), herpes simplex virus type 1 and 2 (HSV-1, HSV-2), cytomegalovirus (CMV), SARS-CoV-2, and pathogenic bacteria such as *Pseudomonas aeruginosa* and *Mycobacterium tuberculosis*[7,8,9,10,11] can be found in this body topography. What's more, during dental procedures, dental professionals often come into contact with patients' saliva, blood, and respiratory secretions.

Cases of cross-transmission of infections have been described in the international literature, demonstrating a causal link between dental care and the occurrence of infection in patients and dental professionals. Most of these cases occurred in the United States of America (USA). In the period prior to vaccination against hepatitis B, 175 cases of patients infected by dental surgeons with hepatitis were identified[9]; another 20 patients acquired HSV-1 from a hygienist (a higher-level professional category qualified to perform certain dental procedures)[9,12]; and two patients were infected by *Pseudomonas aeruginosa* from the water in the dental office equipment and one patient was infected with hepatitis B after oral surgery[9,13,14]. In 2009, new cases of cross-transmission were reported at a dental care center in West Virginia, where three patients and two volunteers were infected with hepatitis B[9,13,15].

In 2011, an elderly woman died in Italy from *Legionella pneumophila pneumonia* acquired through contaminated water from dental equipment[9,16].

In 2013, the first case of cross-transmission of hepatitis C between patients treated at a dental clinic was described in Oklahoma (USA)[9,13,17,18]. At the time, many non-compliances were found, including the absence of a record of biological monitoring of the autoclaves used to sterilize instruments[17,18].

More recently, serious cases of infection by *Mycobacterium abscessus* were reported after pulpotomy procedures were carried out on dozens of children in Georgia and California[9,19,20]. Sequelae include loss of part of the mandible, loss of permanent and deciduous teeth, bone loss and partial hearing loss. The water lines of the dental equipment were considered the source of contamination in both clinics[9,19,20].

Studies investigating compliance with biosafety recommendations in dental services[21] and the monitoring of sterilization in dental services in terms of the frequency with which it is carried out and the type of indicators used have shown inconsistencies and a lack of standardization in its execution[22]. This increases the risk of cross-infection among patients treated in dental establishments[11].

It is worth mentioning that cases of cross-transmission of infections resulting from dental care are possibly under-reported, especially in developing countries such as Brazil, due to the difficulty in proving the causal relationship.

In view of the above, it is essential to implement biosafety measures routinely and in a standardized manner, in accordance with scientific evidence and relevant legislation[3,4,23,24,25]. Among these measures, it is essential to be rigorous in the processing of articles, which includes cleaning, visual inspection, packaging, sterilization, sterilization monitoring, and storage of instruments.

Critical and semi-critical heat-resistant items used during dental care should be sterilized using an autoclave[4,6,23,24]. To ensure the quality of the sterilization process, it is necessary to use indirect indicators, since the sterility of the instruments cannot be proven directly[6,9,26,27]. As a result, monitoring is the established method for evaluating sterilization, consisting of physical, chemical and biological monitoring[23]. In addition, the autoclave must be checked for routine and preventive maintenance in accordance with the manufacturer's instructions[6,23,28]. Calicchio and Laranjeira[29] use the term mechanical control for this type of maintenance.

Unfortunately, in Brazil there is still no specific legislation for dentistry regarding sterilization monitoring requirements. Collegiate Board Resolution (RDC) No. 15[23], of March 15, 2012, which regulates health services in general, removes dental practices from its scope, but does not define them, thus leaving a gap in the recommendation for processing health products in the dental area. The existing legislation for dentistry in the state of São Paulo, SS Resolution No. 15, of December 18, 1999, of the São Paulo State Health Department[30], as well as that which regulates the processing of health articles in the state of São Paulo, SS Resolution No. 374, of December 15, 1995[27], is quite outdated in terms of the stages of sterilization, including the monitoring of the process.

Similarly, the Brazilian National Health Surveillance Agency (Anvisa) manual for dentistry does not sufficiently detail sterilization monitoring. The document mentions the need for it, proposing the use of chemical indicators without, however, indicating the category and frequency, as well as the use of biological tests at least weekly[4].

Since there is no specific legislation on the issue of sterilization monitoring and no clear recommendations from Anvisa[4], as discussed above, the Health Surveillance Agency of Ribeirão Preto, SP, recommends the following, based on SS Resolution No. 374[27], as appropriate monitoring of sterilization in autoclaves: biological control at least once a week and chemical control at least once a day, without, however, defining the type of indicator (type 1, 2, 4, 5, or 6) to be used. It was also considered appropriate to carry out the four controls (mechanical, physical, chemical, and biological), as recommended by Calicchio and Laranjeira[29]. These criteria were adopted in this study.

In this scenario, the objectives of this study are: (i) to obtain the prevalence of adequate monitoring of the sterilization process in gravity autoclaves, by means of mechanical, physical, chemical, and biological controls, by the professionals responsible in private dental services in the municipality of Ribeirão Preto; (ii) to compare the frequencies of monitoring of gravity autoclaves in private dental services, according to the types of controls that make them up, between the categories of initial license application or renewal; and (iii) to identify the professional responsible for monitoring gravity autoclaves in private dental services, according to the categories of initial license application or renewal.

METHOD

This is a population-based descriptive study of a quantitative nature with a cross-sectional design[31].

The eligible population for the study was made up of dental surgeons, technical managers, linked to private dental services in the municipality of Ribeirão Preto, in the interior of the state of São Paulo, for which a license to operate (initial operation and renewal categories) was requested from the Health Surveillance of the Municipal Health Department of Ribeirão Preto (Visa-SMS-RP), in the second half of 2018.

The inclusion criteria for dental surgeons were: having a regular registration with the Regional Council of Dentistry of the State of São Paulo (CRO-SP), holding the position of technical manager, effective or alternate, for the health service, and working in health establishments in the form of a dental office, clinic or polyclinic, in accordance with Article 9, items I, II, III, IV, V, and VIII of SS Resolution 15/1999[30].

Dental surgeons linked to Dental Radiology Institutes, Dental Documentation Institutes, Orofacial Harmonization Clinics, and Dental Teaching Polyclinics were excluded according to Article 9, items VI, VII, and XIX of SS Resolution 15/1999[30]. In addition, those who already had an initial operating license as an individual and were applying for a new Initial Operating License as a legal entity, and vice versa, were excluded.

The list of private services applying for both license categories was obtained from the Sanitary Surveillance Information System (Sivisa) - Web-Reports - software of the Sanitary Surveillance Center (CVS) of the São Paulo State Health Department. In the period between July 1 and December 31, 2018, 226 applications were registered. In the initial Operating License category, there were actually 66, however, due to the exclusion criteria, this number was reduced to 29 applications. In the Operating License renewal category, there were effectively 160 applications, all of which met the inclusion criteria. All the people in charge, 189 permanent staff, and their alternates at each of the eligible institutions were invited to take part.

The data was collected from January to March 2019 using a questionnaire based on scientific literature and validated in terms of content by fifteen judges with a minimum doctorate and professional experience in the clinical area of dentistry[32]. The questionnaire was made up of 28 multiple-choice questions on the subject. After first contact to invite participation, the date of the interview was scheduled with those who agreed, according to their availability, and it was carried out at the professional's place of work. Two professionals, duly trained by the first author, administered the questionnaire.

The project was approved by the Research Ethics Committee of the University of Ribeirão Preto (Unaerp), as stated in CAAE Report No 985928 18.1.0000.5498. The results were presented according to frequency distributions, absolute frequencies and percentages.

RESULTS AND DISCUSSION

As described above, data collection took place between January and March 2019 and was carried out according to the professional's time availability at the respective dental establishment. The average duration of the interviews was approximately 20 minutes. During the period, 69.0% (20/29) of the

eligible establishments that applied for an initial license obtained the consent to participate from their respective technical managers.

Of the eligible establishments that applied to renew their license, 61.9% (99/160) also obtained consent to participate from their respective managers.

The refusals were unanimously justified by the lack of time to answer the questionnaire.

A total of 24 technical managers (20 permanent and four alternates), linked to establishments that applied for an initial license, and 118 (99 permanent and 19 alternates), linked to establishments that applied for a license renewal, answered the questionnaire, making up 63.0% (119/189) of the population of permanent managers and 12.2% (23/189) of the population of alternates.

Among the technical managers who answered the questionnaire, 95.8% (136/142) reported monitoring the autoclave sterilization process using some combination of controls. Six professionals did not carry out any type of sterilization control, as shown in Table 1, putting patient safety at risk. This finding is very worrying given that, when it comes to biosafety, this type of practice is unacceptable, regardless of the universe surveyed.

Regarding the type of license applied for, there was a higher frequency of sterilization monitoring among professionals from establishments that applied for a renewal license (98.3% - 116/118) than among professionals with an initial application (83.3% - 20/24). Although the causes of this difference have not been investigated, it is likely that the technical managers of establishments applying for a renewal license had more professional experience than those applying for an initial license, which could be explained by greater accumulated knowledge and therefore justify greater adherence to monitoring. On the other hand, it could be expected that the majority of professionals applying for initial licenses would be recent graduates and supposedly better oriented on the new biosafety recommendations, which was not reflected in the results.

These findings point to the need for investment in education, both in undergraduate and postgraduate training, as well as in-service education, so that these procedures are carried out correctly and by all professionals. There is also a need for continuing and ongoing education so that shortcomings arising from professional training can be remedied and better practices adopted.

One of the fundamental elements of monitoring is the types of control used. Thus, regardless of whether or not the professional carries out monitoring control, answers were also computed in relation to knowledge about the types of controls that make up monitoring.

However, only 18.6% (22/118) of the respondents from establishments that applied for License Renewal and 4.2% (1/24) of those from establishments that applied for an Initial License stated that they knew that the autoclave sterilization monitoring process is made up of the four control categories (physical, chemical, biological, and mechanical), as recommended in the literature and guided by RDC No. 15, which, although it does not fully include dentistry, should be considered a reference for these processes[23,29].

These findings possibly point to the weakness of biosafety teaching in our country's undergraduate dental courses, which is a chronic and persistent problem that is reflected in the non-compliance observed for decades in the national scientific literature[21,33,34,35]. Fortunately, there is the prospect of this scenario changing with the inclusion of biosafety as a compulsory subject in undergraduate dental courses, in accordance with the new Curriculum Guidelines issued by the Ministry of Education and Culture (MEC). In addition, the "Guidelines for Teaching Biosafety in Dentistry in Brazil", drawn up by professors and other experts during the 57th Meeting of the Brazilian Dental Education Association - Abeno[36,37], are available.

All these elements are fundamental for training professionals who are committed to important aspects related to patient safety, such as monitoring sterilization during the practice of dentistry.

When it comes to monitoring the autoclave sterilization process, one of the fundamental elements refers to the types of controls adopted. The adoption of chemical and biological controls as monitoring standards is supported by legislation such as RDC

Table 1. Distribution of study participants according to the types of control used to monitor the autoclave sterilization process and the category of operating license applied for. Ribeirão Preto, SP, Brazil, 2019.

	License category		
Types of Controls	**Renewal n (%)**	**Initial n (%)**	**Total n (%)**
Four controls[a]	22 (18.6)	1 (4.2)	23 (16.2)
Chemical and biological	74 (62.8)	12 (50)	86 (60.6)
Other combinations of controls[b]	20 (16.9)	7 (29.1)	27 (19.0)
No control	2 (1.7)	4 (16.7)	6 (4.2)
Total	118 (100)	24 (100)	142 (100)

Source: Prepared by the authors, 2023.
[a] Four controls: chemical, biological, physical, and mechanical; [b] Any other combination of controls.

No. 15/2012, SS Resolution No. 15/1999 (Art. 50), and SS Resolution No. 374/1995. The use of the four types of control as a monitoring standard is supported by authors such as Calicchio and Laranjeira[29], according to whom an efficient sterilization monitoring program must include all four types of control in its process.

Table 1 shows the distribution of study participants according to the types of control used to monitor the autoclave sterilization process and the category of operating license applied for.

The results presented in Table 1 show that, among the participants working in establishments that applied to renew their license, only 18.6% monitored using all four types of control (mechanical, physical, chemical, and biological). Among the professionals who applied for the initial license, only one professional (4.2%) monitored using all four. Considering the participants in the two license application categories, 60.6% carried out at least chemical and biological controls, with 62.8% among the professionals who applied for license renewal and 50.0% among those who applied for the initial license.

It was also found that, considering the two categories of operating license, 19.0% carried out other combinations of controls in the monitoring process.

It is worth noting that two (1.7%) of the professionals applying for renewal licenses and four (16.7%) of those applying for initial licenses did not monitor the autoclave sterilization process at all, which compromises the safety of the dental care provided by these professionals.

In addition to the use of the different types of control, the recommended frequency of use for each type, as well as the systematic recording (date of the control, result observed, identification of the person responsible for the recording, among others) of its results are fundamental elements in ensuring the quality of sterilization.

Taking VISA-RP-SP as a reference, Table 2 shows the prevalence of adequate monitoring of the sterilization process according to license categories.

As can be seen in Table 2, 38.2% of the participating professionals carried out chemical and biological controls at least once a day and weekly, respectively, and also recorded the results. Among those belonging to the license renewal category, the percentage was 43.1% and among respondents belonging to license renewal, 10.0%.

It can also be seen that none of the professionals who applied for an initial license used all four controls when monitoring sterilization and, among those who applied for a renewed license, only 16.4% carried out the chemical control at least once a day and the biological control weekly, recording the results. Considering the two types of license applied for, only 14.0% carried out the four checks at the intervals mentioned above, recording the results.

Among the participants, 59.5% of the respondents in the license renewal category and 10.0% of the respondents in the initial application category monitored the sterilization process, using chemical and biological controls or all four controls, properly (Table 2).

This data points to the need to update legislation specific to dentistry in line with recent recommendations available in the literature and based on scientific evidence. It is also necessary to speed up the process of reviewing the standards that deal with the controls that make up the monitoring of the sterilization process, especially in relation to the frequency of performance, as well as the standardization of such standards, in the face of advances and discoveries in biosafety practices and the evolution of materials, products and equipment.

In this way, the municipality's Visa will be able to demand better biosafety practices from professionals, thus minimizing the risks of cross-infection resulting from dental care. Another worrying aspect was that, when asked about their knowledge of the controls required by Visa-SMS-RP and by legislation such as SS Resolution No. 15/1999[30] and SS Resolution No. 374/1995[27] for monitoring the sterilization process, 62.7% (74/118) of the technical managers of establishments applying for license renewal and 50.0% (12/24) of those applying for an initial license said they were aware of this information. However, knowing the requirement was not enough for these professionals to implement it in practice.

Regarding the professional responsible for carrying out the check, of the 136 who reported carrying out the check, in the license renewal category (n = 116), 26 (22.4%) said that it was the dentist who carried it out. In the initial operating license

Table 2. Prevalence of adequate monitoring of the sterilization process, with periodicity of chemical control at least once a day and biological control weekly, and who record the results, according to types of control and License categories. Ribeirão Preto, SP, 2019.

Types of control	License categories		
	Renewal (n = 116)	Initial (n = 20)	Total (n = 136)
	n (%)	n (%)	n (%)
Chemical and biological	50 (43.1)	2 (10.0)	52 (38.2)
Four controls[a]	19 (16.4)	0 (0.0)	19 (14.0)
Chemical and biological or four controls	69 (59.5)	2 (10.0)	71 (52.2)

Source: Prepared by the authors, 2023.
[a] Four controls: chemical, biological, physical, and mechanical.

Table 3. Distribution of study participants responsible for monitoring the autoclave sterilization process and license categories. Ribeirão Preto, SP, Brazil, 2019.

	License categories		
Responsible for control	**Renewal n (%)**	**Initial n (%)**	**Total**
Dentist	26 (22.4)	12 (60.0)	38 (27.9)
OHT/OAT	68 (58.6)	6 (30.0)	74 (54.5)
Others	22 (19.0)	2 (10.0)	24 (17.6)
Total	116 (100)	20 (100)	136 (100)

Source: Prepared by the authors, 2023.
OHT: Oral health technicians; OHA: Oral health assistants.

application category (n = 20), 12 (60.0%) said that it was the dentist who carried it out (Table 3).

In the license renewal category, dentists delegate this responsibility more to oral health technicians (OHT) and oral health assistants (ORA), with a percentage of 58.6%, and 22 (19.0%) to other professionals. In the initial operating license application category, the role of monitoring the autoclave sterilization process was assigned to a lower percentage (30%), and other professionals were also delegated this role less, with two (10%). The "other" category included professionals such as nurses, biomedical specialists, and receptionists.

Carrying out the checks, reading the results and recording them can be delegated to any member of the team, such as the ORA or OHT. However, if the professional delegates these responsibilities, they must train those who will be in charge of carrying them out and supervising their completion, since the final responsibility lies with the dentist/technical manager of the service. The fact that other untrained professionals have no specific competence in this monitoring process is worrying and merits further study. Still on the subject of records, it is essential that they are standardized and the model can be created to meet the specific needs of each establishment, according to their needs, remembering that the records serve as legal support for the professional[38].

A limitation of this study is the fact that the data was obtained from a single municipality and it is not possible to extrapolate these results to other locations.

CONCLUSIONS

The results show that there is a gap between the practice and understanding of the autoclave sterilization monitoring process by the study participants and what is recommended in the literature, thus compromising the safety of dental care in the municipality studied.

These findings highlight the need to implement strategies to correct the practice observed. As an immediate measure, a technical report drawn up by the research group was sent to the Secretary of Health and head of Visa in the municipality where the study was carried out.

From this perspective, it would be desirable to harmonize federal, state and municipal legislation regarding the processing of articles and monitoring of sterilization in dental services.

In this way, inspection agents would have the backing of legislation to enforce the recommendations that already exist in the literature, based on scientific evidence. In addition, dental professionals would be clear about the processing requirements that must be implemented during professional practice.

Another important point would be to bring academic research and industry closer together to develop dental products that facilitate the implementation of biosafety in daily clinical practice.

It is also worth emphasizing the importance of promoting biosafety in undergraduate and postgraduate dental courses as one of the pillars for promoting patient and professional safety.

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Authors' contribution

Donha RF, Prereira MJF - Conception, planning (study design), data acquisition, analysis, interpretation, and writing of the paper. Santos CB - Planning (study design), data analysis, interpretation, and writing of the paper. Bellissimo-Rodrigues WT – Data analysis, interpretation, and writing of the paper. Donatelli LJP, Martinez EZ – Data analysis, interpretation, and writing of the paper. All the authors approved the final version of the paper.

Conflict of Interest

The authors inform that there is no potential conflict of interest with peers and institutions, political or financial, in this study.