Evaluation of the steam sterilization quality and assessment of knowledge, attitude, and practice of clinical directors regarding infection control in dental clinics: A cross-sectional study in Mashhad, Iran

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Abstract

Background: The sterilization cycle is one of the most important parts of infection control. Accordingly, the present study was conducted to assess the quality of steam sterilization and compare the knowledge, attitude, and practice of clinical directors in dental clinics, based on the experimental work in one of the most important and famous dental departments and clinics in the Northeast of Iran.

Methods: This cross-sectional study was conducted from June to September 2017 in 84 dental outpatient clinics of Mashhad, Iran. The status of sterilization quality was evaluated using biological (BI) and chemical indicators (CI) and the results of a questionnaire. The participants include the technical manager and operator of the Autoclave, who were included in this study according to the inclusion criteria by stratified cluster sampling. Information on their knowledge, practices, and attitudes were evaluated. Also, BI and CI were used to evaluate the autoclave accuracy. The data were analyzed by Mann-Whitney U, Wilcoxon signed-rank, and Fisher's exact tests using SPSS (Version 19, SPSS Inc., Chicago, IL, USA).

Results: In this study, the results of 69 (82.1%) biological test were negative. Based on the questionnaire results, 64 (76%) clinics used CI, and only 4 (5%) clinics used CI and BI to evaluate the sterilization quality. The mean scores of attitude (P<0.001), knowledge (P<0.001), and practice (P<0.001) of the technical manager in dental clinics were significantly higher than those in outpatient clinics. Also, there was a significant association between the knowledge and practice of the clinics' technical managers (P<0.001).

Conclusion: According to the results, 93.3% of the clinics that had a positive biological test were outpatient clinics. Also, it was revealed that insufficient knowledge, attitude, and practice lead to imperfect sterilization. Also, the mean score of dentists was higher than that of general practitioners, therefore, in addition to suggesting training programs for managers, it is recommended that employ a dental practitioner as the technical manager of outpatient clinics. In order to control infection in clinics, it is recommended to monitor the sterilization process in clinics according to the instructions of the monitoring units.

Keywords: Health knowledge, Attitudes, Practice, Infection control, Dental, Steam sterilization, Autoclave

Introduction

Nowadays, with increasing the World's population and medical center clients, infection control has become a major health system challenge (1,2). The dental environment is one of the most infected sites of the medical system in any country due to the prevalence of 750 million microorganisms in the oral cavity (3-5). However, the application of infection control policies is an important way to minimize the transmission of bacteria, mostly via saliva, blood, air, or water (2,6-8). Instruments that
are used in dental procedures are categorized as critical and semi-critical procedures because they often separate mucosa or gingiva in patients. Consequently, they should be sterile for use (4,9).

There are various ways for sterilizing dental instruments, however, based on the most recent studies, autoclave is the most common method of sterilization followed by dry heat and cold sterilization, respectively (4,10). It is a cost-effective and reliable method, which protects the integrity of instruments (11,12). There are three types of autoclave: B, S, and N, among which type B is the most common one (3,13).

Previous studies have investigated steam sterilization quality and expressed different factors playing a role in the sterilization quality, such as autoclave type and its pressure, guidelines and rules, and a regular program of sterilization monitoring (14-16). Studies over the past two decades have provided valuable information on the sterilization efficacy, but they are outdated, and new studies should be conducted to update the data (15-17). Several attempts have been made to evaluate the effectiveness of steam sterilization on dental instruments, but all of them were limited to one or two individual devices (4,18-21).

Recent evidence has suggested that one of the major sterilization failures is operator error (5,22,23). With respect to literature, some factors, such as the number of patients, operator age, and gender, may affect the proper sterilization method (4,6,21). Knowledge and education of dental office staff may affect their agreement with effective infection control. Some studies have revealed the lack of knowledge on the transmission of diseases and exposures (5,16). Therefore, it is important that dental staff manage good practical and theoretical concepts that improve the quality of medical treatment and the prevalence of cross-infections in dental practice (16,24,25).

To the best of our knowledge, many studies have been done on medical and hospital instruments, but there is few studies on dental instruments. This indicates the need to understand various perceptions of sterilization assessment in dental clinics, not only the special instruments. Moreover to the extent of our knowledge, no studies has been conducted on this issue in Iran, recently.

Mashhad is the second-largest city in Iran, which is located in the north-eastern region of the country. There are three types of dental service centers in this city, including private dental offices, dental clinics, and dentistry wards in the outpatient clinics. According to the Iranian law, the technical manager of clinics is either a physician or a dentist who supervise all services provided in the clinic, including sterilization processes. An autoclave operator is a person who is responsible for cleaning equipment and working with the autoclave. Despite the emergent need for such studies, there are few documents on the quality of the sterilization procedure in dental offices in the Northeast of Iran. For this reason, the first aim of this study was to assess the quality of steam sterilization in dental clinics.

The second aim was to compare the knowledge, attitude, and practice of clinical managers towards infection control at dental and outpatient clinics. And the third aim was to evaluate the sterilization facilities of each clinic in Mashhad, Iran, in 2017, to evaluate the efficacy of this sterilization method.

Materials and Methods

Study design

This cross-sectional study was conducted from July to October 2017 in Mashhad, Iran. Based on the Helsinki declaration principles, written informed consent was obtained from all participants before enrollment. The study population was selected from all dental clinics and dentistry ward at the outpatient clinics in Mashhad city, which were listed in the Mashhad Dental Directory. Out of which, 84 clinics were selected by stratified cluster sampling. It should be noted that all specialized dental clinics (n=33) were included, due to their great importance. But for outpatient clinics, where dental services are also provided, 51 clinics were selected by sampling according to the study of Patiño-Marin et al. (21). To compute the sample size, the response rate of 0.5, the error level of the first type of 5%, and the acceptable error rate of 0.1, were considered.

Technical managers of clinics and autoclave operators of any gender or education level were included in this study. Exclusion criteria were those who did not submit written consent for enrolment, those who did not complete the sterilization process, as well as those who did not submit questionnaires.

Study variables and data collection

The sterilization quality assessment was performed using biological (BI) and chemical indicators (CI) and a questionnaire. The variables of this study include the questionnaire as well as demographic information for managers and clinics. The device operators and technical managers completed a questionnaire designed to evaluate knowledge, attitudes, and practice. Two double-page, A4-sized, self-reporting questionnaires were sent to each clinic.

In the first series of questions, sterilization tools like autoclave, type of autoclave, presence or absence of coating equipment, the type of coating used, and operator’s knowledge toward device performance, and evaluation of sterilization quality using BI were examined. The questions were also about time intervals for evaluating the performance of the device, the existence of archive office for recording, frequency of the device being turned on during the day, time intervals for checking, and device maintenance. The second series of questions were related to the knowledge of the technical managers and operators of autoclave on working with the device and also changing the color of chemical and biological tests (Table 1).

A questionnaire was sent to 10 dental specialists o
Table 1. Responses of the participants to the questions

| Questions                                                                 | Options                                                                 |
|---------------------------------------------------------------------------|-------------------------------------------------------------------------|
| What is the type of clinic?                                               | 1. Dental clinic                                                        |
|                                                                           | 2. Outpatient clinic                                                    |
| What is the gender of the clinic’s technical manager?                    | 1. Male                                                                 |
|                                                                           | 2. Female                                                               |
| What is the expertise of the technical manager of the clinic?            | 1. General practitioner                                                 |
|                                                                           | 2. Dentist                                                              |
| What tools are used for sterilization?                                   | 1. Autoclave                                                            |
|                                                                           | 2. Autoclave & dry heat oven                                             |
|                                                                           | 3. I do not know                                                        |
| What types of autoclaves are used for sterilization?                     | 1. B type                                                               |
|                                                                           | 2. N-type                                                               |
|                                                                           | 3. Both                                                                 |
|                                                                           | 4. I do not know                                                        |
| Have you ever participated in the infection control retraining?          | 1. Yes                                                                  |
|                                                                           | 2. No                                                                   |
| What steps do you take to decontaminate the turbine and angel between each patient? | 1. Rinse with water to remove debris, lubricate, pack, and sterilize in the autoclave |
|                                                                           | 2. We use disinfectants                                                  |
|                                                                           | 3. Others                                                               |
| What steps do you take to disinfect the dental chair to treat the next patient? | 1. Disinfectant spray and dental chair cover                            |
|                                                                           | 2. Disinfectant spray                                                   |
|                                                                           | 3. Just replace the cover                                                |
|                                                                           | 4. Others                                                               |
| What is your criterion for choosing disinfectants for your clinic?       | 1. Based on the type of disinfectant                                     |
|                                                                           | 2. Brand                                                                |
|                                                                           | 3. Company approval                                                     |
|                                                                           | 4. Recommendation and approval of the Ministry of Health                |
|                                                                           | 5. Based on the advice and consultation with other dentists             |
| How do you check the accuracy of autoclave performance?                  | 1. By CI                                                                |
|                                                                           | 2. By BI and CI                                                         |
|                                                                           | 3. None                                                                 |
| What do you do if the chemical test does not change color properly?      | 1. Repeat the test                                                      |
|                                                                           | 2. Repair the device                                                    |
|                                                                           | 3. Use another chemical test                                             |
|                                                                           | 4. Use the biological test                                               |
| How long can sterilized devices be used for treatment after the sterilization process? | 1. One week                                                             |
|                                                                           | 2. One month                                                            |
|                                                                           | 3. Three months                                                         |
|                                                                           | 4. Six months                                                           |
| How often is the device checked and serviced?                            | 1. Every month                                                          |
|                                                                           | 2. 2 to 12 months                                                       |
|                                                                           | 3. No idea                                                              |
| How do you prepare the equipment before sterilization?                   | 1. Ultrasonic                                                           |
|                                                                           | 2. Hand wash                                                            |
|                                                                           | 3. Disinfection                                                         |
|                                                                           | 4. Ultrasonic and disinfection                                          |
|                                                                           | 5. Disinfection and hand wash                                           |
| After sterilization, how do you store the equipment?                    | 1. It is kept in a pack                                                 |
|                                                                           | 2. It is kept inside a closed container                                  |
|                                                                           | 3. Take it out of the package and keep it in the drawer                  |
| Are the sterilization date and the name of the operator written on the packs? | 1. Yes                                                                  |
|                                                                           | 2. No                                                                   |
| What types of chemical indicator are you using?                          | 1. Class 4                                                              |
|                                                                           | 2. Class 5                                                              |
|                                                                           | 3. Class 6                                                              |
|                                                                           | 4. None                                                                 |
| When do you use a chemical indicator?                                   | 1. Every time an autoclave is used                                       |
|                                                                           | 2. Every day                                                            |
|                                                                           | 3. Every week                                                           |
|                                                                           | 4. Service time                                                         |
|                                                                           | 5. None                                                                 |
check the validity using five-point rating scale (highly appropriate, appropriate, neutral, inappropriate, and extremely inappropriate). Depending on this, some of the questions were changed to increase comprehension consistency. To assess the reliability of the questionnaire, it was piloted with 15 respondents within 14 days, and Cronbach’s alpha was used. Cronbach’s reliability coefficient was obtained to be 0.91, which is appropriate for acceptable analyses. Little changes were needed after the pilot test. Ultimately, the study questionnaire was established for its validity and reliability.

The value of 0 was assigned to an incorrect response and the value of 1 was assigned to a correct answer for each item. The maximum score was 10 for knowledge questions, 5 for attitude questions, and 10 for practice questions. Each section was scored as follows: 1-3 = poor, 4-6 = average, and 7-10 = excellent. It is worth mentioning that this methodology was repeated, according to the study of Singh et al (5).

Also, the biological indicator of Geobacillus stearothermophilus spore (BT20, Bionova, Argentina) and a chemical indicator (Class XI, Netherland) were used to check the accuracy of the autoclaves in the clinics. After delivering the indicators, the operator put the indicators in the appropriate pack (v-pack). Then, according to the manufacturer’s instructions, the operator put the pack containing the indicators on the middle floor of the autoclave and near the door, where it has less chance of sterilization. Autoclave completed its cycle as usual with a full load, then, the pack was removed from it by the operator.

In the chemical indicator samples, either the lack or incomplete color change demonstrated the autoclave performance error, but if the color changed completely, the autoclave output would be verified.

Biological samples were examined in the microbiology laboratory of Ghaem hospital, Mashhad, Iran. Three milliliters of each vial was processed in a tube, and the tubes were incubated at 58°C for 48 hours. The samples were carefully screened after 48 hours. The change in the color of the vials from purple to yellow indicated that the sterilization device had not worked effectively (positive). The lack of color change meant that the test result was negative and the sterilization process was applied completely. A positive control (bacterial growth) and a negative control (the absence of bacterial growth) were used for each sample.

Data analysis
According to the studies, the best tool for evaluating autoclaves is BI, therefore, all statistical analyses are based on the biological tests (19,21). The statistical analysis was performed using SPSS (version 19, SPSS Inc., Chicago, IL, USA). Qualitative variables were described as percentage (%), and quantitative variables were expressed as mean ± standard deviation (SD). Data were analyzed using Mann-Whitney U, Wilcoxon signed-rank, and Fisher’s exact tests. Statistical significant level was considered at $P < 0.05$.

Results
In this study, 84 clinics in Mashhad city were evaluated, of which 33 (39%) were dental clinics, and 51 (61%) were...
dentistry wards in the outpatient clinics. The technical managers include 53 men (63.1%) and 31 women (36.9%). Regarding the expertise of the technical managers, 47 (56%) participants were general practitioners, and 37 (44%) were dentists.

In the present study, it was found that the majority of clinics (n = 63, 75%) used only autoclave, while 11 clinics (13.1%) used both autoclaves and hot-air ovens. Interestingly, 10 technical managers (11.9%) had no information on the sterilization device. Forty-seven (63.5%) clinics used type B autoclave, 14 (18.9%) used type N autoclave, 10 (13.5%) used both N and B autoclaves, and 3 (4%) did not know the type of autoclave device. In response to the question „How do you evaluate the practice of the autoclave?”, 64 (76%) clinics used CI, 16 (19%) clinics claimed that they do not evaluate the practice of devices, and only 4 (5%) clinics used CI and BI.

In current study, 10 (11.9%) positive results were identified by the CI and 15 (17.9%) positive results by the BI. Outpatient clinics were among 93.3% of the clinics that had a positive biological test. There was a statistically significant relationship between biological and chemical test results (P < 0.001).

Also, Fisher’s exact test revealed no relationship between the results of biological test and gender of the technical managers (P = 0.134). Additionally, it was revealed that the clinics that used type B autoclaves significantly had less positive results compared to the clinics that used type N autoclaves (P < 0.001).

Based on the findings, there was a significant difference between the knowledge and practice of the clinics’ technical managers in Fisher’s exact test (P < 0.001). The mean scores of attitude, knowledge, and practice of the technical managers in dental clinics were 1.58 ± 0.61, 6 ± 0.79, and 7.58 ± 0.79, respectively. These differences were significant in the Mann-Whitney U test (P = 0.001, P < 0.001, P < 0.001, respectively).

The comparison of the attitude scores of technical managers in outpatient clinics revealed no significant difference based on the results of the biological tests (P = 0.128). However, the knowledge and practice scores of outpatient clinics managers were significantly higher in those with negative biological tests (P = 0.025, P = 0.030, respectively) (Table 2).

In the present study, the mean attitude score of technical managers of dental clinics was higher than those of the operator, but the difference was not significant (P = 0.078). However, the knowledge and practice scores of technical managers of dental clinics were significantly higher than those of the operator (P = 0.03, P = 0.04, respectively). It is worth mentioning that the mean scores of all variables for the operators of outpatient clinics were significantly higher than those for the technical managers who were general practitioners (P = 0.002, P < 0.001, and P < 0.001) (Table 2).

Discussion

Today, with the global COVID-19 pandemic, dentists have to protect their patients and themselves. Hence, it is necessary to stay cautious and take the necessary measures to prevent cross-transmission of any infection (8). Hence, the sterilization process in dental clinics environment must be done with special care (18, 24, 25). One of the most important factors for a good sterilization process is the knowledge of human resources (5, 16, 23). Therefore, this study aimed to find out whether technical managers of the clinics have enough knowledge and attitude to use autoclave properly and whether they can perform all the necessary measures to control infection, especially in

| Clinics                  | Attitude (Mean ± SD) | Knowledge (Mean ± SD) | Performance (Mean ± SD) |
|-------------------------|----------------------|-----------------------|-------------------------|
| Dental clinics          | Positive             | 1.00 ± 0.00           | 6.00 ± 0.00             | 7.00 ± 0.00             |
|                         | Negative             | 1.59 ± 0.61           | 6.00 ± 0.80             | 7.59 ± 0.80             |
|                         | P value*             | 0.238                 | >0.99                   | 0.396                   |
|                         | Biological test      |                       |                         |                         |
|                         | Technical manager    | 1.58 ± 0.61           | 6.00 ± 0.79             | 7.58 ± 0.79             |
|                         | Operator             | 1.33 ± 0.69           | 5.61 ± 1.09             | 7.18 ± 1.24             |
|                         | P value*             | 0.078                 | 0.03                    | 0.04                    |
| Outpatient clinics      | Positive             | 0.71 ± 0.83           | 2.86 ± 1.88             | 3.36 ± 2.79             |
|                         | Negative             | 1.11 ± 0.81           | 4.24 ± 1.82             | 5.24 ± 2.71             |
|                         | P value*             | 0.128                 | 0.025                   | 0.030                   |
|                         | Biological test      |                       |                         |                         |
|                         | Technical manager    | 1.00 ± 0.82           | 3.86 ± 1.92             | 4.73 ± 2.84             |
|                         | Operator             | 1.33 ± 0.62           | 5.49 ± 0.99             | 6.73 ± 1.37             |
|                         | P value*             | 0.002                 | <0.001                  | <0.001                  |

*Results obtained from Mann-Whitney U test.
†Results obtained from Wilcoxon signed-rank test.
dental departments.

It was found that 75% of the clinics used only autoclaves, and 13.1% used hot-air ovens in addition to autoclaves. In a study by Ahmed, 61.8% of the clinics in Karachi, Pakistan used autoclaves, and 25.9% used more than one sterilization method (9). Also, Davis and BeGole (26), Cash (27), and Silva et al (16) reported lower usage rates in the USA, Georgia, and Peru, respectively. The better situation of Mashhad city in the use of autoclaves can be due to strict rules and accurate monitoring in clinics.

In the present study, 56% of the participants used type B autoclaves, 16.7% used type N autoclaves, and 11.9% used both types. Besides, the clinics that used type B autoclaves significantly had less positive test results than those that used type N autoclaves, indicating that type B autoclaves had a better performance compared to type N ones. Consistent with this finding, Winter et al concluded that type N autoclave is unreliable for sterilization of dental handpieces and has more failure than the other types (28). Therefore, at least one type B autoclave is required in all dental centers.

The results of this study demonstrated that 76% of the clinics used CI, and 5% used both BI and CI to evaluate the efficiency of autoclaves. However, the use of BI in dental clinics in Brazil is about 50% (10). Also, the use of BI in Mashhad is higher than that reported in other studies (9,19). The possible reasons can be the lack of knowledge and legal awareness of the use of BI in our study population.

The results of biological test showed that the autoclave failure rate was about 18%, while the results of chemical test showed the failure rate of 12%. This result indicates the accuracy of biological tests, which is confirmed by the evidence.

Based on the BI tests, some studies have reported failure rates ranged from 17% to 21% worldwide (12,16,21). Röhm-Rodowald et al, found that only 33% of dental instruments were properly sterilized (29), which is not consistent with the results of the present study. The possible explanation of autoclaves failure might be both instrument handling and sterilizer problems, such as improper device cleaning, improper packaging, operator and technical manager errors, device malfunction, high frequency of daily sterilization cycles, and lack of sterilization process monitoring (5,10,16,21,22,24,25,28).

Based on the results of this study, there is a significant relationship between knowledge and practice. In other words, with increasing the knowledge of technical managers, the quality of infection control increased \(P<0.001\), which is not consistent with the results of the study of Singh et al (5). However, this study was performed on dental students, and the possible reason for this difference may be forgetfulness through the years of training.

It was found that the quality of steam sterilization in outpatient clinics was lower than that in dental clinics. It was also revealed that outpatient clinics were among 93.3% of the clinics that had a positive biological test, which is consistent with the results of studies of Röhm-Rodowald et al (29) and Matsuda et al (10), which were performed in Poland and Brazil, respectively. Typically, a physician is the technical manager of an outpatient clinic, and a dentist is the technical manager of a dental clinic. Physicians lack of familiarity with the type of dental equipment and the importance of proper sterilization can be a possible reason for this difference (29, 10).

Comparison of the scores of knowledge, attitude, and performance of the technical manager in outpatient clinics showed that the scores of knowledge and performance of technical managers in clinics in which the test results were positive, were lower than those in clinics with negative test results, and the difference was significant. This result indicates the effect of knowledge, attitude, and performance of employees on better quality of the sterilization process in clinics.

Another remarkable finding is that the mean attitude scores of the technical managers of dental clinics were average, and the mean score of the knowledge, attitude, and practice of the technical managers of outpatient clinics were poor. A study conducted in Italy showed that 27% of the participants had low level of knowledge on the sterilization methods (30). Askarian et al revealed that the score of dentist knowledge was poor, but it was higher among the more practiced dentists (23). However, Deogade et al showed that the knowledge and awareness scores of most participants were good and average, which is not consistent with the results of the present study (18). This result shows that the current methods and strategies to increase the practice, knowledge, and attitude of the technical managers of dental clinics in Mashhad about infection control are not sufficient, and more courses will be needed in the future.

By ranking the scores of participants’ questionnaires from the highest to the lowest, it is concluded that general practitioners have less knowledge, attitude, and practice compared to operators and dentists. It is due to the fact that the operators in outpatient clinics work and train with dentists. Hastreiter et al who monitored 406 sterilizers in 381 dental offices, reported that sterilization failures were mainly due to the operator errors (31). So, outpatient clinics are recommended to employ a dentist as the technical manager. Additionally, the operators of autoclaves must undergo the necessary training for cleaning, preparing, maintenance, and storing sterile items and having complete control over all instructions for the use and maintenance of the device.

**Strength and limitations**

This study had also some limitations. The first limitation is that due to the design of the study, randomization and follow-up were not possible. The second limitation is that since only one biological test was received from
each center, if there were several autoclaves in that center, only that device was evaluated. Therefore, future studies are recommended to provide a biological test for each autoclave in the center.

Conclusion
The sterilization and monitoring of the procedures in dentistry, as well as being sure that the instrument was properly disinfected is necessary. The present study emphasized the importance of sterilization and showed that not all the clinics achieve effective sterilization, and it depends on different agents such as the trained operator. The findings of this study showed that insufficient knowledge, attitude, and practice lead to imperfect sterilization. Also, the mean score of questionnaires of dentists was higher than that of general practitioners, therefore, outpatient clinics are recommended to replace general practitioners with dental practitioners. To control infection, it is recommended to monitor the sterilization process in clinics according to the instructions of the monitoring units.

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Ethical issues
All procedures performed in this study involving human participants were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki declaration. This study was approved by the Ethics and Research Committee of Mashhad University of Medical Sciences (Ethical code: IR.MUMS.sd.1394.2751). The authors certify that all data collected during the study are as stated in the manuscript, and no data from the study has been or will be published elsewhere separately.

Competing interests
The authors declare that they have no conflict of interests.

Authors’ contribution
All authors were equally involved in the collection, analysis, and interpretation of the data. All authors critically reviewed, refined, and approved the manuscript.

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