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Original Article

Autoclaving: Current Practices, Problems and Solutions

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ABSTRACT

Aims: To evaluate different sterilization & monitoring practices among the ophthalmologists of Haryana and identify potential factors leading to failure of sterilization and possible remedies thereof.
Methods and Material: A questionnaire was sent to all eye hospitals of Haryana, responses were compiled and analyzed.
Results: Response was received from 100 such hospitals. Out of 100, majorly are using Two drum vertical autoclaves, followed by single drum autoclave. Horizontal autoclaves are being used by the least number of hospitals. Failure rate is maximum in single drum autoclaves, followed by vertical autoclaves. Common causes of failure of sterilization cycles are improper purging, faulty drum, faulty autoclave, improper settings.
Conclusions: We conclude that whatever autoclave we are using, with proper knowledge and technique regarding the autoclave use and indicators, we can safeguard ourselves and our patients by preventing the healthcare associated infections.

Key Words: *Autoclaving, Infection control, Purging, Healthcare Associated Infection*

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INTRODUCTION

Medical devices are sterilized before being used for invasive clinical procedures and surgeries to prevent infections. Failure to sterilize medical devices properly increases the risk of healthcare-associated infections. Previously done studies and reports have already proved that improper sterilization techniques and inadequately sterilized medical devices are the causes of higher hospital associated infections in developing countries. Steam sterilization (autoclaving) is the most widely used method for sterilization and is considered the most robust and cost-effective method for sterilization of medical devices [1]. To check the effectiveness of steam sterilization, various indicators/ methods are available these days (Class I to Class VI).

SUBJECTS AND METHODS

A questionnaire containing one demographic question and 8 questions regarding sterilization practices was sent to all Eye Hospitals of Haryana. Responses were compiled and analyzed. Mails were again sent to the persons reporting problems to know details of their problems, possible reasons and solutions. Only one response from one eye care establishment was accepted. A literature search was undertaken to understand the effectiveness of autoclaving in sterilizing reusable medical devices in healthcare facilities across the globe. Failures of steam sterilization practices were identified and discussed as a means of identifying factors that might be associated with the ineffectiveness of steam sterilization practices between different hospitals in Haryana

RESULTS

We have received responses from 100 eye hospitals/ eye care centres of Haryana. Out of 100, 29 are using single drum autoclaves (so called pressure cooker type autoclaves). 47 are using vertical two drum autoclaves, 12 are using horizontal autoclaves and 12 are using plasma/ flash autoclaves. Horizontal autoclaves are being used only by bigger institutes or centres.

Out of 100 responses, 55 are using only class one chemical tape as sterilization indicator, 75 are using class five or six indicators, 15 are using biological indicators periodically just to cross check their sterilization process, none is using biological indicators as routine in all loads, nine are using Bowie dick tests periodically to check sterilization/ vacuum cycle. 30 Hospitals are using more than one type of indicators; 21 hospitals using both class I and class V indicators. nine hospitals are using all types of indicators as per their accepted protocols.

Out of 100, 81 hospitals are doing autoclaving at temperature 121 degree centigrade/pressure 15 lbs or above, seven hospitals are doing at a temperature less than 121 degree centigrade / pressure 15 lbs, 12 hospitals are using flash autoclaves at 134 degree centigrade.

Out of 88 hospitals using autoclaves at or up to a temperature of 121 degree centigrade, 21 (24%) hospitals are doing the autoclaving for 35 minutes, 51 (58%) hospitals for 45 minutes, 16(18%) hospitals for 60 minutes.

Amongst the 29 single drum autoclave users, five has reported failed sterilization cycles, one due to wetting of contents due to leaking drum, two due to large quantity of water and two due to burning of element during the cycle.

Amongst the 47 users of vertical autoclaves, six have reported failed cycle; one due to faulty autoclave and five due to improper purging cycle/ insufficient time.

Amongst the 12 users of horizontal autoclaves, only one hospital has reported that one cycle has failed due to faulty vacuum pump.

DISCUSSION

Though horizontal autoclave is the best and recommended mode for sterilization for eye surgery as per the guidelines by Government of India, still majority of small hospitals and eye centres are using single or two drum vertical autoclaves as these are sufficient and convenient as per their work load. But failure rate in these autoclaves is more. Failure rate is highest in single drum users, followed by vertical two drum autoclaves. Failure rate is minimum in horizontal autoclaves.

The number of studies measuring the effectiveness of steam sterilization is small, and few evaluate the effectiveness of steam sterilization specifically in developing countries [2]. Study done by Garibaldi BT et al proved that default factory settings may be insufficient to adequately sterilize pathogens in the center of medical waste autoclave loads. Autoclave parameters may need to be adjusted [3].

Single Drum autoclave

As per our data, failure rates are highest with single drum autoclaves. Commonest cause of failure is wet linen as water enters the drum through the leaking joint of the drum at the base or excess water is used in the autoclave and it enters through holes. If seamless drums are used along with proper water level, the chance of this failure is reduced. (Table 1)

Second common cause of failure is due to damage to heating element due to less water content in the autoclave. Usually the water is filled upto the height of the bottom stand. Water level gets reduced due to long exposure, repeat autoclave cycle without adding water. Secondly, there can be less water level at the beginning, which increases the chances of damage to the element. To solve these two problems, we have increased the height of the bottom stand by 1 inch, thus increasing the space to add more water. At the same time, bottom of drum is at a higher level, thus reducing the chances of water entering the drum and making the linen wet and saving the heating element also.

Third is the setting of safety valve. The safety valve should be adjusted in such a way that the pressure inside drum is maintained at 15 pound per square inch (psi). It can be adjusted by loosening the check nut and change the tightness of the safety valve so that steam releases at about 16-17 psi through the whistle and the safety valve works only in case of failure of whistle. Though there might be some meter/ gadget available to check this but we have done it manually by hit and trial. Human error in setting sterilization cycle parameters is the predominant cause of failure [4]. These findings should initiate prompt actions toward increasing knowledge of the sterilization processes and their monitoring.

Vertical Autoclaves

We talk about purging in vertical autoclaves which means when the steam starts getting generated and starts filling the vertical autoclaves by gravity, the cold stale air is pushed out of autoclave. Normally what happens is when we buy the vertical autoclave, most of the manufacturers recommend to use their autoclaves at default settings of 121 degree centigrade for 45 minutes but does it really works all the times and with all the autoclaves. Or is this a thumb rule. (Table 2)

What we have observed / analyzed from the data that whenever there is failure of sterilization, mostly it is in the lower drum. The cause is improper purging and insufficient time so that all stale air is not pushed out during the pre set exposure time. In gravity displacement autoclaves, purging takes longer time as compared to vacuum displacement autoclaves. Solution is to increase the time to 60 minutes atleast. The study done by Palenik, Charles John et al. recommends that processing of sharps containers within a gravity-displacement autoclave appears to require extended exposure intervals to achieve sterilization [5]. As per The Bio-Medical Waste Management Rules, 2016, When operating

a gravity flow autoclave, medical waste shall be subjected to: (i) a temperature of not less than 121 degrees centigrade and pressure of 15 pounds per square inch (psi) for an autoclave residence time of not less than 60 minutes. For Vacuum autoclave, this time is not less than 45 minutes for same temperature & pressure [6].

Secondly the failure of sterilization in lower drum is more common because air being heavier then steam, gets locked in and around lower drum and obstructs the circulation of steam. Further, there is usually no gap between the drums and between the lower drum and autoclaves. If we keep wired mesh in between the drums and at the bottom, failure rate in lower drum decreases.

Thirdly, if it is due to faulty autoclave, it has to be repaired by the manufacturer.

Horizontal Autoclave

Vacuum pump is used for purging in horizontal B class autoclaves. Chances of failure are only when the vacuum is not properly achieved due to leakage/ improper sealing which is detected by the Bowie Dick test and leak test. Second chance is human failure because there are 5-6 steps in semi automatic/ manual horizontal autoclaves and each step is in sequence with proper time exposure. Fully automatic PCR controlled autoclaves are being used mainly by large multispecialty hospitals/ teaching institutions because of their size and cost.

Indicators

Class I Chemical tape changes the colour when temperature reaches 121 degrees centigrade; time of exposure doesn't matter. It only indicates that the particular pack has been exposed to sterilization [7]. It doesn't indicate if the cycle was complete and successful or not.

Chemical integrators (class 5/6) change the colour when exposed at 121 degrees centigrade for more than 20 minutes. Chemical integrators with moving front ink display reaches pass area when exposed at 121 degrees centigrade for 20 minutes or 132 degrees centigrade for 4 minutes [8]. Thus these indicators are better as these show the success of sterilization cycles.

Spores in Biological indicators get deactivated when exposed at 121 degrees centigrade for 20 minutes [9]. These are the best and most reliable indicators but less practical but these have to be incubated at particular temperature for 48 hours before reading. Though now, some modified biological indicators are available which can be read after 3 hours or 24 minutes or so.

As the indicators show success of sterilization when the temperature of 121 degrees centigrade is maintained for 20 minutes of more, additional time required for successful autoclaving is mainly for purging and achieving proper steam temperature.

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Tables:

Table 1: Problems & Solutions for Single Drum Autoclave

S. No.	Problem	Probable Cause	Possible Solution
1	Wet Contents	Leaking Drum Water level higher than bottom of drum	Use seamless drum Increase the height of bottom stand
2	Damage to heating element	Water content less	Increase the height of bottom stand
3	Setting of Safety valve	Setting is at a pressure lower than that of whistle	Readjust the safety valve so that whistle works regularly

Table 2: Problems & Solutions for Vertical two Drum Autoclave

S. No.	Problem	Probable Cause	Possible Solution
1	Improper purging	Time setting is less	Increase the time of sterilization cycle to 60 minutes in case of gravity displacement
2		Obstructed air/ steam circulation	Put wired mesh in between and below drums
3	Faulty autoclave		Repair by the manufacturer