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Professional paper

Efficiency Evaluation of Hospitals Sterilization by Biological and Chemical Methods

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Abstract: Autoclaving is one of the methods which sterilizes medical solidwaste. This study was carried out to evaluate efficiency of autoclaves in two Shahrekord hospitals(Kashani and Hajar) in Iran by biological and chemical indicators. In this study, the performance of autoclave was studied based on biological and chemical through setting 96 tests. Variables were loading type in four groups (light, medium, semi- heavy, and heavy), location, type of hospital , and temperature-135°C, time10min features in fixed pressure equal to 4.2 bar. Biological and chemical indicators were ATCC 7953 which contained *Stearotermophilus Geobacillus* spores ,and chemical indicator Class 6 with three color circle as weekly, respectively.The best autoclave operational condition based on biological indicator in both hospitals were light loading rate in Kashani and Hajar 66%(8), and 75%(9) desirable results, respectively. Each four loading rate level based on biological and chemical indicators the Hajar hospital with 68% desirable results were more efficiency than Kashani hospital with57% desirable results. According to results of this study (biological index) sterilization failure in kashani and Hajar hospitals were 65%, and 50%, respectively.There is an increased need for suitable regulation and control of autoclave devices and for monitoring and suitable handling of these devices in developing countries.

Keywords: Medical solidwaste, Sterilization, Autoclave, Biological indicator, Chemical indicator.

INTRODUCTION

Medical solids waste management is still the most important health and safety challenge in developing countries due to conspicuously inappropriate disposal methods, and insufficient financing and infrastructural challenges (Toktobaev et al. 2015).

Medical solids waste treatment technologies include thermal processes, chemical treatment technologies, autoclaves, integrated steam-based treatment systems, microwave treatment technologies, dry-heat treatment technologies,irradiation treatment, biological processes, mechanical treatment processes, and incinerators. The most benefit of autoclaves is that they cost less than traditional medical solid waste incinerators.Steam sterilization inactivates microorganisms through heat generated by the saturated steam(Rutala and Weber 2015). An autoclave consists of a metal chamber surrounded by a steam jacket. Steam is introduced into the outside jacket and the inside chamber.A common contact temperature–time factor is 121°C andpressure 2 bar for 30 min or above 134°C and 3.1 bar time 5 min(Maamari et al. 2016). A number of tools are available to assess the performance of the autoclave; these include physical, chemical and biological indicators. Physical indicators: Temperature and pressure recording devices such as thermocouples can be put inside the load to specify the temperature obtained in the bag itself. Chemical indicators are used in the autoclave sterilization of biomedical waste. When the sterilization is completed, color change must be detected in the chemical indicator carrier that has been autoclaved together with the waste. Biological indicators are used in the efficacy testing of the autoclave process to effectively sterilize the contents being treated.A common microbial inactivation standard for Health Care Waste treatment based on the State and Territorial Association in Alternative Treatment Technologies (STAATT) criteria is Level III, i.e. inactivation of vegetative bacteria, fungi, lipophilic/hydrophilic viruses, parasites and mycobacteria at a 6 $\log_{10}$ reduction or greater; and inactivation of *Geobacillus stearothermophilus* (Bs) spores and *Bacillus atrophaeus* spores at a 4 $\log_{10}$ reduction or greater(Datta et al. 2018; Lemieux et al. 2006). In the recent years, many researches were conducted to hospital waste management in Iran and other countries around the world (Kulikowska et al. 2019; Rafiee et al. 2016; Winter et al. 2017; Wojnowska-Baryła et al. 2019). Deficiency to sterilize medical equipmens properly presents a risk of healthcare-associated infections(Panta et al. 2019a). The average general waste production rate was 2.12±0.37 kg/bed/day at Shahrekord hospitals(Sadeghi et al. 2020).According to other studies, amount of medical solid waste generation in Iranian hospitals is between 1.92 to 4.4 Kg/bed-day and 10.5% to 34.5% are infectious wastes(Farshad et al. 2014; Hossain et al. 2012). Solid waste production per capita in other countries such as Barzil, Jordon, France, Spain and Portugal is 2.63, 3.41, 2.5, 3 and 1.4 Kg/bed-day respectively, which 85% of this is nonhazardous and remaining 15% is hazardous(Farshad et al. 2014; Miranzadeh et al. 2012). In last thirty years, the most Iranian hospitals were installed incinerator for disposal of infectious waste. Disadvantages of incinerator are high initial cost, air pollution, , operation and maintenance problems and the need of trained personnel for operation. For this reasons, incinerator is discarded)Miranzadeh et al.2012; Sadeghi et al. 2020(. Recently health, cure and medical education administration suggest application of steam autoclaves for immunization of hospital infectious wastes, so several cases of this set was installed in hospitals of Iran. The primary objective of this study was to evaluate efficiency of autoclaves in Shahrekord ho hospitals. The secondary objective of this study was to investigate the time, pressure, and temperature dependence of loading type.

This study was carried out to evaluate study on the operation management of medical solid waste autoclaving disposal facilities,variables were loading type in four groups (light, medium,semi- heavy, and heavy), location,type of hospital , and temperature-time.

METHODOLOGY

Study area

This research was implemented in two hospitals(Kashani and Hajar) in Shahrekord in southwest, Iran with a population of 190,441 people (2016). This study was performed in laboratory School of Health, Shahrekord University of Medical Sciences during 2018. Selection of hospitals was based on their bed and type of treatment technologies used for waste disposal. Table 1 shows the hospital specifications and their waste disposal equipments.Both hospitals had same autoclaves (Table1).

The average health-care waste generation in Shahrekord hospitals is 900 to1000 kg/day.Total medical solid waste were 63% general,36.05% were infectious wastes while 0.18% were sharps, 0.1% were chemical and pharmaceuticals, 0.1% were pathological wastes,0.02% were radioactive.The composition of the generated waste was found to be 16.6±1.44% paper, 18.8±2.35 % plastic, 4.9±0.27% glass, 16.5±1.01 % textile , 0.87±0.03% metals, 24.7±2.35% foodwaste,and 17.63±1.91% other (Sadeghi et al. 2020).

Table 1. Characteristics of hospitals and the devices they used for waste disposal

Hospital	Number of active beds	Total generation rate (kg/bed-day)	Type of device
Kashani	330	1.94	Autoclave without shredder
Hajar	290	1.85	Autoclave without shredder

Sterilization procedure

The performance of subjected autoclave was studied based on biological index and chemical indicator through setting 96 tests.Variables of both autoclaves were temperature-135°C, time duration-10min were and pressure(4.2 bar) fixed.Loading type are grouped in four groups: (light, medium, semi- heavy, and heavy).Light loading rate:equal to 25% or lower than 25% volumetric capacity of autoclave, medium loading rate:45 to50% volumetric capacity of autoclave, semi- heavy loading rate:70 to75% volumetric capacity of autoclave, and heavy loading rate:equal to 95% or higher than 95% volumetric capacity of autoclave. Microbial analysis of waste residue was performed based on the guidelines of the Iranian Ministry of Health and Medical Education(Farshadet al. 2014). ProSpore2 (a self contained biological indicator) containing 10^6 spores of *Geobacillus stearothermophilus* ATCC7953 was used to test the efficacy of devices in disinfecting the waste residue. ProSpore2 consists of a paper disc carrier with *Geobacillus stearothermophilus* (ATCC 7953) spores.The disc is in a plastic tube with a glass vial of growth media for the bacterial spores. Bromocresol purple (a pH detector) was added to detect spore growth. The growth of spores decreases pH and changes the color purple to yellow after a 24-hour incubation period(Farshad et al. 2014; Fraiha et al. 2010). The biological indicator in the test trial was placed in a horizontal as possible, as recommended by the manufacturer.At the end of cycle, the ProsPore2 indicator was cap sealed.The glass ampoule of media was crushed and the *Geobacillus stearothermophilus* disc was contaminated.Figure1 showed that biological indicator.Vials were then incubated at 55°C for 48 hours.If the ProsePore2 biological indicator retained its purple color(Figure 1(a)), it showed an adequate sterilization cycle and if it signed turbidity or a color change toward yellow for that sterilization cycle, it explanated insufficient of sterilization and the chance of microbial pollution Figure 1(b)). In each round, untreated ProsPore2 biological indicators were incubated as controls (Datta et al. 2018). Chemical indicator Class 6 with three color circle as weekly.Figure 2 showed that chemical indicator: (safe, optimum,and failure). For description of chemical indicator test, “Optimum” and “Safe” status regarded as desirable sterilization.

Statistical analysis

Descriptive statistical parameters, such as the mean ,percentage, median, minimum and maximum, were applied to the data. Data was coded and analyzed using SPSS 16 software.

a. Pass/ sterilization

b. Fall/unsterilization

Figure 1. Biological Indicator (a. pass, and b. fall)

Figure 2. Chemical indicator (safe, optimum, and failure)

RESULTS

Table.2. showed that status biological indicator of hospitals, and Figure 3. Shows that status the number of sample based on biological indicator in hospitals.The best autoclave operational condition based on biological indicator in both hospitals were light loading rate in Kashani and Hajar 8 of 12 (66%), and 9 of 12 (75%) desirable results, respectively (Table 2). Each four loading rate level the Hajar hospital with 24 of 48 (50%) desirable results were more efficiency than Kashani hospital with17 of 48(35%) desirable results (Table 2 and Figure 3). Figure 4 shows that status the number of sample based on chemical indicator in hospitals.Table 3 showed that status chemical Indicator of hospitals.The best autoclave operational condition based on chemical indicator in Kashani hospitals was light loading rate 100% desirable results (Table3), and Hajar hospitals was light loading rate and medium loading rate 12 of 12 (100%),and 12 of 12 (100%) desirable results, respectively. Each four loading rate level the Hajar hospital with 41 of 48 (85%) desirable results were more efficiency than Kashani hospital with 38 of 48(79)% desirable results (Table 3 and Figure 4). Figure 5 shows that status the number of sample based on biological and chemical indicators in hospitals.Each four loading rate level based on biological and chemical indicators the Hajar hospital with 65 of 96(68%) desirable results were more efficiency than Kashani hospital with 55 of 96(57%) desirable results (Figure 5).

Table 2. Status biological indicator of hospitals

Type of loading	Kashani				Hajar			
	Desirable		Undesirable		Desirable		Undesirable	
	Number	%	Number	%	Number	%	Number	%
Light(N=12)	8	66	4	46	9	75	3	25
Medium(N=12)	6	50	6	50	8	66	4	46
Semi-heavy(N=12)	3	25	9	75	5	41	7	59
Heavy(N=12)	0	0	12	100	2	16	10	84
Total=48	17	35	31	65	24	50	24	50

Pressure equal to 4.2 bar, temperature-135°C, time10 min,Desirable=no microbial growth, undesirable= microbial growth

Table 3. Status chemical indicator of hospitals

Type of loading	Kashani				Hajar			
	Desirable		Undesirable		Desirable		Undesirable	
	Number	%	Number	%	Number	%	Number	%
Light(N=12)	12	100	0	0	12	100	0	0
Medium(N=12)	11	91	1	9	12	100	0	0
Semi-heavy(N=12)	8	66	4	46	9	75	3	25
Heavy(N=12)	7	58	5	42	8	66	4	46

Pressure equal to 4.2 bar, temperature-135°C, time10 min Desirable=no microbial growth, undesirable= microbial growth

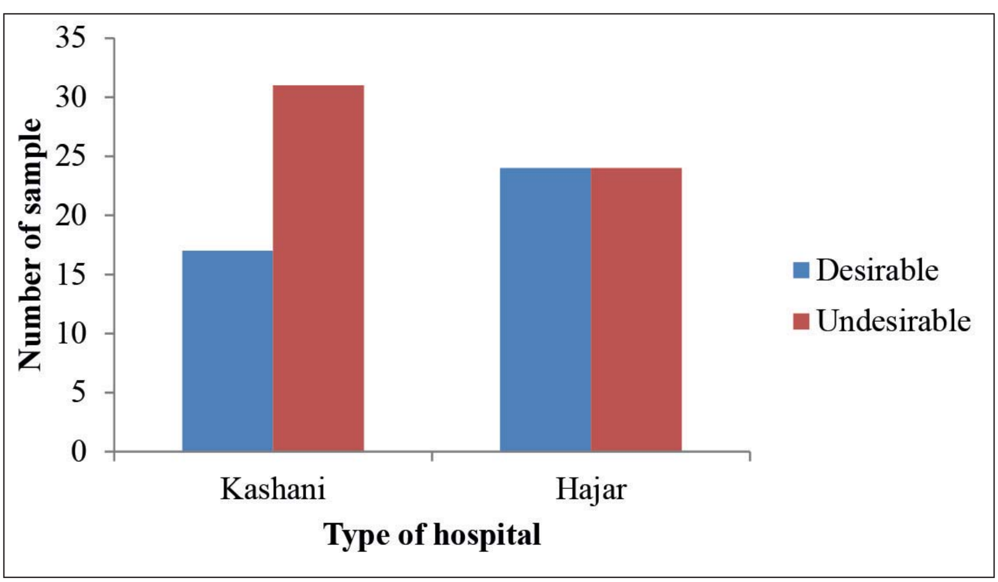

Figure 3. Status the number of sample based on biological indicator in hospitals

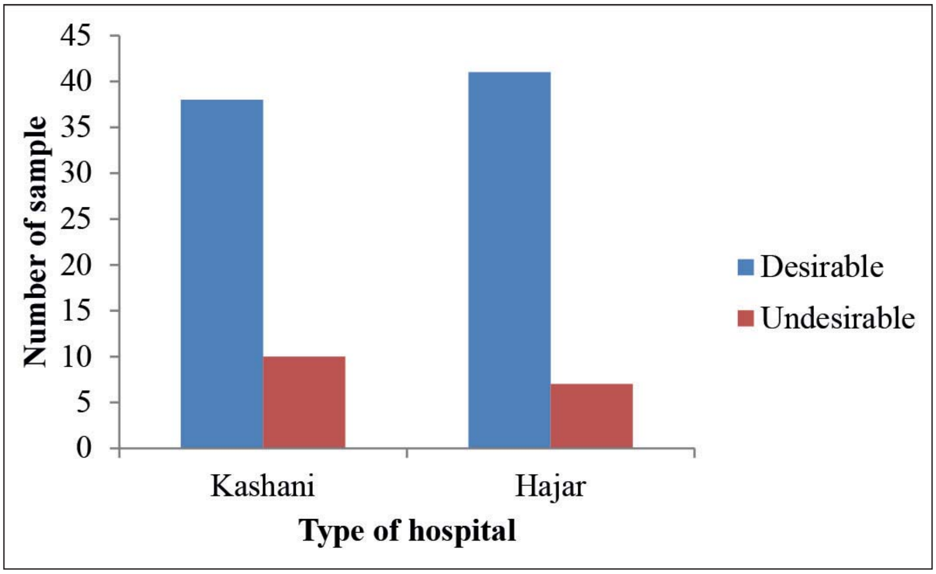

Figure 4. Status the number of sample based on chemical indicator in hospitals

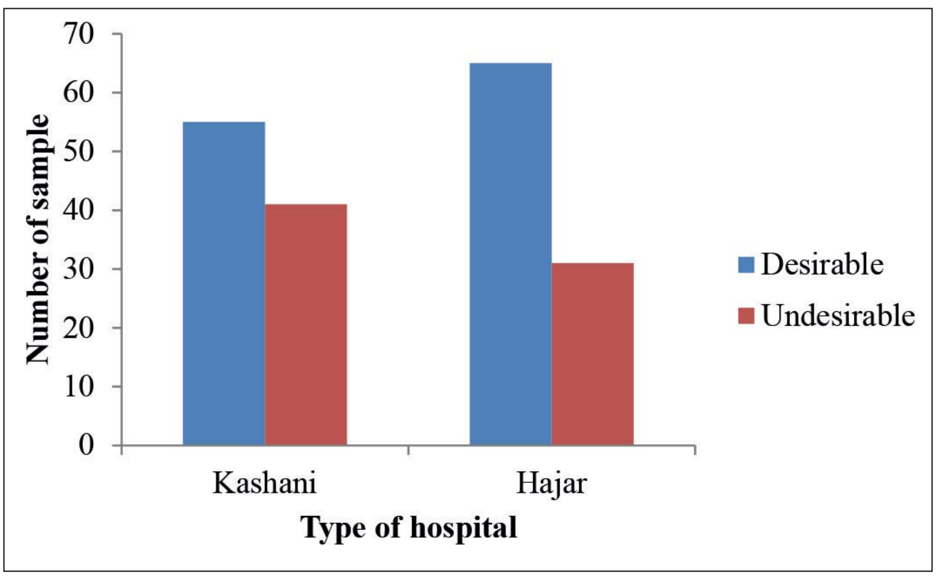

Figure 5. Status the number of sample based on biological and chemical indicators in hospitals

DISCUSSION

This study was carried out to evaluate efficiency of autoclaves in two Shahrekord hospitals by biological and chemical indicators.Based on the results of this research, the best autoclave operational condition for sterilizing medical solid wastes are: Light loading rate lower than 25% and temperature-time equal to 10min-135°C in fixed pressure of 4.2 bar,respectively.Another study conducted to evaluate the best condition for sterilizing medical solid wastes are: temperature-time equal to15 min-134°C and 10min-140°C in fixed pressure of 101 kPa(Miranzadeh et al. 2012)**.** Another study reported that tests on autoclaves in undesirable results, with bacterial growth occurring in 18 of 22 ampules, and chemical indicators failing in 19 of 22 locations (Hossain et al. 2012). Another study reported that STAATT method, acceptable technology for treating medical solid waste must reach inactivation level III, which is a $6Log_{10}$ reduction for the vegetative bacteria (Hossain et al. 2012).

Another study found that 84% autoclave cycles performed using factory default settings failed to sterilize the biological indicators in the center of the load(Garibaldi et al. 2017).This included all runs performed using a liquid or gravity cycle for 30 min or a vacuum cycle for 15 min at 123°C or 134°C, respectively(Garibaldi et al. 2017). According to results of this study(biological index) sterilization failure in Kashani and Hajar hospitals were 65%, and 50%, respectively. The results of this research (chemical index) showed that sterilization failure in Kashani and Hajar hospitals were 21%, and 15%, respectively. A few studies that have evaluated the effectiveness of autoclaving in diffrent countries.Studies in Kenya, India, Canada, UK, and Mexico showed (12%, 31%,2.3%,1.5%, and 21% respectively) of sterilization failure (Panta et al. 2019a).One study reported that autoclave cannot be considered as an alternative technology to disposal in clinical solid waste management (Hossain et al. 2012). Another research found that 71% of biological indicators remained non-sterile after exposure to sterilization processes in hospitals in Nepal (Panta et al. 2019b). Sterilization efficiency is dependent upon many variables that affect the physics of heat transfer and steam infiltration, including the waste load, composition, weight, liquid content, and types of reservoirs.Biological and chemical indicators the Hajar hospital desirable results were more efficiency than Kashani hospital, for this reasons:lack of staffs training,high loading volume,and position of the load within the autoclave chamber in Kashani hospital (Farshad et al. 2014; Hossain et al. 2012). The Standard Operating Procedures (SOP) for the autoclave unit, and training should be provided for any new autoclave operators.

Finally, autoclaves need to be operated and tested on a regular basis to ensure that they achieve the suitable pressure,time,and temperature before being used for patient care. Recommends that the following adjustments to policies and practices be implemented in order to better achieve sterilization and ensure proper maintenance for each autoclave:

a.Reregulation of cycle times:The standard 121°C, 1.05 bar, and 15-minute contact time are sufficient for sterilization.

b. Proper autoclave use:The autoclave bag should never be over-packed or sealed too tightly.

c. Record keeping:The use of an autoclave logbook is recommended for each autoclave.

d. Safety maintenance:General maintenance should be conducted on an annual basis or as recommended by the manufacturer.

e. Training:Each autoclave user should be trained on the proper use of the autoclave(Le et al. 2005).

CONCLUSIONS

It was shown in this study that the biological and chemical indicators were investigated for the effectiveness of steam on bacteria during the sterilization process. It was observed during this study that the steam autoclave performed most effectively at a contact time of 10 min, a temperature of 135°C, and at a pressure of 4.2 bar, to inactivate *Bacillus stearothermophilus*. Each four loading rate level based on biological and chemical indicators the Hajar hospital with65 of 96 (68%) desirable results were more efficiency than Kashani hospital with 55 of 96(57%) desirable results.This study may alarm other developing countries to possible defects in autoclave performances and provide a method. There is an insist need to improve autoclave processes in both hospitals.There is a need for awareness of medical solid waste management amongst the patient and worker in order to prevent nosocomial infection and environment hazards.Policy and regulation gulidelines must be prepared to all of the hospitals through out the Iran as also recommended in Shahrekord.

Management of medical waste in the Shahrekord, and Iran has shown positive signs of improvement in recent years. This improvement has been demonstrated through national medical solid waste legislation, and the establishment of a centralized controlled autoclaving and incineration facility for treating hazardous and infectious medical solid wastes.

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