Application of Chemical and Biological Indicators for Control of Infectious Waste Steam Autoclave and Correlation Between Them

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Abstract: The management of infectious waste is of great importance due to its potential environmental hazards and hospital infection. In the past decade, the most common method for infectious waste disposal is incineration. But steam sterilization is currently being used as major treatment method of infectious waste. We studied the sterilization efficacy of a steam autoclave in Kashan Shahid Beheshti Hospital (KSBH) for decontamination of infectious waste during 2010. This steam autoclave was operated in eight times- Temperature category (A to H) and three load volume (low, moderate and high loading) at constant pressure. To evaluate the efficacy of waste sterilization a total of 192 biological and chemical indicator test (BI and CI) has been carried out during the study. Results of study were shown that best operation condition for waste sterilization is 121°C for 45 minute holding time at 1 atm pressure (category H). In addition, it is revealed that sterilization process isn`t effected by load volume. A strong correlation were founded between BI and CI test results. Hence, because of lower cost and time CI test can be used in replace to BI test to monitor the sterilization process in steam autoclave.

Key words: Steam autoclave · Infectious waste · Sterilization · Biological Indicator · Chemical indicator

INTRODUCTION

Hospital is a place of almighty, a place to serve the patient. Since beginning, the hospitals are known for the treatment of sick persons but we are unaware about the adverse effects of the garbage and filth generated by them on human body and environment. Now it is a well established fact that there are many adverse and harmful effects to the environment including human beings which are caused by the "Hospital waste" generated during the patient care [1]. Hospital waste is a potential health hazard to the health care workers, public and flora and fauna of the area [2, 3]. Hospital acquired infection, transfusion transmitted diseases, rising incidence of Hepatitis B and HIV, increasing land and water pollution lead to increasing possibility of catching many diseases [4, 5]. Hospital waste divided to infectious and noninfectious, that infectious wastes are more important because of their especial characteristics. According to the type of hospital

and its services the rate of production of hospital wastes are different in Iranian hospitals. According to other studies, amount of medical waste generation in Iranian hospitals is between 1.92 to 4.4 Kg/bed-day which of this 10.5% to 29.5% and in some cases 34.5% are infectious wastes [4, 6-11]. Waste generation per capita in other countries such as England, American United State, France, Spain and India is 2.5, 4.5, 2.5, 3 and 1.5 Kg/bed-day respectively, which 85% of this is nonhazardous and remaining 15% is hazardous. In addition, 33% of hazardous waste is noninfectious and 67% is infectious [12-14]. In Korea and Nigeria the amount of hospital waste is 0.14 to 0.49 and 0.56 to 0.67 Kg/bed-day which of this 26% to 37% are infectious waste [14, 15]. Also in Iran the amount of hospital waste is 3.15 Kg/bed-day which 40% of this is infectious waste [16-21]. Infectious wastes are consist of blood and bloody proceeds, pathologic wastes and infectious tissues along with microbial culture media, syringe and sharp things and nose

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spatters, mucus and excrement of patient and other generated waste of emergency, surgery and hospitalization part [6, 8, 10-13, 22]. In last three decades, the most Iranian hospitals were installed incinerator for disposal of infectious waste. Disadvantages of incinerator are air pollution, high initial cost, operation and maintenance problems and the need of trained staffs for operation. For this reasons, incinerator is discarded [22-25]. 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. Steam autoclave is a set which use for sterilization of medical and surgery devices and also for sterilization of hospitals wastes [26]. In this set wastes sterilized in presence of water vapor with enough pressure, detention time and temperature (1 atm pressure, 15 to 30 minute detention time and 121°C temperature) [27-30]. Autoclaving infectious waste is recommended and widely practiced because it is considered to be the most reliable and easily controlled process for on-location decontamination [31, 32]. After steam sterilization, the final products are often landfills with municipal solid waste. To monitor the effectiveness of the autoclaving cycle, either chemical indicators or biological indicators are typically used. The effectiveness of the autoclave should be verified regularly, based on its frequency of use [33].

Kashan is a city with over 200000 populations which located in central of Iran. Kashan Shahid Beheshti Hospital (KSBH) is a governmental hospital with 400 bed capacity. In this hospital the rate of waste generation is 2.9 Kg/bed-day which of this about 20% is infectious waste[34]. A steam autoclave set with 1000 kg/day capacity is installed at KSBH in 2008. At present, sterilization of infectious waste in KSBH were carried out by this autoclave set. The main aims of this study were to determine the effectiveness of autoclave cycle and optimum operational conditions in KSBH.

MATERIALS AND METHODS

This research was as a cross-sectional analytical-descriptive study which has been carried out on infectious waste steam autoclave operation in Kashan Shahid Beheshti hospital (KSBH) during 2010. Sterilizing efficiency was checked by the commercial biological indicator (Geobacillus Stearothermophilus, American type collection culture 7143) and chemical indicator (Class 6 with three color circle as weekly). In Iran, most

Table 1: Eight alternatives regarding to time, temperature at constant pressure

Time-temp. category	Time (min)	Temp. (°C)	Pressure (atm)
A	10	140	1
B	15	138	1
C	20	136	1
D	25	133	1
E	30	130	1
F	35	127	1
G	40	124	1
H	45	121	1

Table 2: CI test result description

Description	Result
One circle with color change	Failure
Two circle with color change	Optimum
Three circle with color change	Safe

infectious waste steam autoclave is operated in 121°C and 1 atm pressure for 15-20 min. So, we are not able to certify that all waste was completely sterilized at this condition. In this study we examined the effect of time, temperature and load volume in constant pressure (1 atm) on waste sterilization process. For time and temperature 8 category was defined as shown in Table 1.

Load volume ware classified as three categories including:
- Low-load: loading less than 35% container capacity.
- Moderate-load: loading between 35-75% container capacity.
- High-load: loading higher than 75% container capacity.

A total of 192 BI and CI test (8 time-temp. category × three load volume × 8 frequency) were simultaneously designed to check the efficacy of sterilization process on three load volume and 8 time-temperature categories (Table 1). The biological indicator is removed from a load alter it has been autoclaved. Then BI is incubated at 56°C for up to 3 days. If the autoclaved BI is turbid (cloudy, indication growth) the autoclave did not function properly, so, BI test result regarded as positive and if BI is clear without evidence of turbidity, so, BI test regarded as negative. In addition, description of CI test result is shown in Table 2. Finally, results analysis is conducted by Chi-square test and SPSS software.

RESULTS AND DISCUSSION

We examined sterilizing efficacy of medical waste in a steam autoclave at 8 time-temp. category and three load volume by BI and CI test. Results of BI test in various

Table 3: Results of biological indicator in three loading stage and 8 time temp. combination for control of steam autoclave in KSBH (n=192)

Time -temp. combination	Low loading				Moderate loading				High loading			
	Positive		Negative		Positive		Negative		Positive		Negative	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
A	8	100	0	0	8	100	0	0	5	62.5	3	37.5
B	8	100	0	0	6	75	2	25	6	75	2	25
C	8	100	0	0	6	75	2	25	6	75	2	25
D	6	75	2	25	4	50	4	50	4	50	4	50
E	2	25	6	75	3	37.5	5	62.5	2	25	6	75
F	2	25	6	75	2	25	6	75	2	25	6	75
G	3	37.5	5	62.5	4	50	4	50	1	12.5	7	87.5
H	0	0	8	100	1	12.5	7	87.5	1	12.5	7	87.5

Table 4: Results of chemical indicator in three stage and 8 time temp. combination for control of steam autoclave in KSBH (n=192)

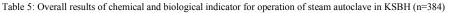| Time temp. comb.	Low loading						Moderate loading						High loading					
	F		O		S		F		O		S		F		O		S	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
A	8	100	0	0	0	0	6	75	2	25	0	0	5	62.5	2	25	1	12.5
B	6	75	1	12.5	1	12.5	5	62.5	2	25	1	12.5	8	100	0	0	0	0
C	4	50	2	25	2	25	4	50	3	37.5	1	12.5	5	62.5	2	25	1	12.5
D	4	50	0	0	4	50	3	37.5	4	50	1	12.5	3	37.5	0	0	5	62.5
E	1	12.5	3	37.5	4	50	0	0	4	50	4	50	1	12.5	3	37.5	4	50
F	0	0	3	37.5	5	62.5	2	25	2	25	4	50	1	12.5	1	12.5	6	75
G	1	12.5	2	25	5	62.5	1	12.5	5	62.5	2	25	2	25	5	62.5	1	12.5
H	1	12.5	1	12.5	6	75	0	0	3	37.5	5	62.5	0	12.5	0	25	6	75

F= Failure O= Optimum S= Safe

operating condition were shown in Table 3. As shown in this table all BI test results for low and moderate load volume in category A (10 min holding time, 121°C temperature and 15 psi pressure) were positive and failed to inactivate the biological indicator. For category H and low load volume all results of BI test were negative which indicate the effectiveness of sterilization of wastes. For category G and H in high load volume configuration the result of 87.5% of BI test were negative. This results suggest that with increase of holding time and decrease of temperature sterilization efficacy has been increased. In Table 4 results of CI test for various operating condition in constant pressure were shown. In category A with low load volume and category B with high load volume all CI test result were in acceptable level. For description of CI test, "Optimum" and "Safe" condition regarded as acceptable sterilization. In this experiment results shows that by increase the holding time from 10 to 45 minute and decreases the temperature from 140 to 121°C, the sterilization efficacy of waste reaches to highest level in 45 minute and 121°C (Table 3 and 4). In addition, regarding to BI and CI test results, the complete sterilization process were obtained in category H time-temperature (45 minute and 121°C temperature) at three load volumes. However, there were a significance relationship between 8 time-temp. category and sterilization efficacy (P<0.05) but weren`t found a relationship between 3 load volume and sterilization efficacy (P>0.05). This findings is compatible with a study in Japan [35]. Overall results of BI and CI test for sterilization of infectious waste in steam autoclave were shown in Table 5. It is apparent from the Table 5 that best sterilization efficacy obtained in category H time-temp. In this time-temp. category 91.7% of BI and 95.8% of CI test results were in acceptable level.

Based on this study we believe that it is necessary to sterilize all the infectious waste for 45 minute holding time at 121°C to ensure sterility for heat resistant materials. In Iran, most manufacturer recommended operation of waste autoclave for 20 to 30 minute. In 121°C to sterilize all infectious waste [22, 36, 37]. By comparison of this operating condition with our study findings we can concluded that 121°C for 20 to 30 minute isn`t enough to sterilize all infectious wastes in a autoclave.

Table 5: Overall results of chemical and biological indicator for operation of steam autoclave in KSBH (n=384)

Time-temp. comb.	Biological indicator				Chemical indicator					
	Positive		Negative		F		O		S	
	No.	%	No.	%	No.	%	No.	%	No.	%
A	21	87.5	3	12.5	19	79.2	4	16.6	1	4.2
B	20	83.3	4	16.7	19	79.2	3	12.5	2	8.3
C	20	83.3	4	16.7	13	54.2	7	29.2	4	16.6
D	14	58.3	10	41.7	10	41.7	4	16.6	10	41.7
E	7	29.2	17	70.8	2	8.3	10	41.7	12	50
F	6	25	18	75	3	12.5	6	25	15	62.5
G	8	33.3	16	66.7	4	16.7	12	50	8	33.3
H	2	8.3	22	91.7	1	4.2	6	25	17	70.8
total	98	51	94	49	71	37	52	27	69	36

F= Failure O= Optimum S= Safe

A strong correlation between BI and CI test results were obtained by linear regression analysis. Correlation coefficient (r^2) was 0.87. This demonstrates that BI test can be replaced by CI test to monitor the efficacy of sterilization process in steam autoclave. BI test is very expensive and required prolonged time against to CI test. So, we suggest CI test for monitoring of infectious waste steam autoclave. Also, operating condition for sterilization of surgery devices is very different with respect. Condition required for infectious was to sterilization in steam autoclave. Time required for waste sterilization is higher than for surgery devices. Most supplier is recommended 14 to 30 minute in 121°C at 1 atm pressure for surgery devices sterilization, while this time isn`t enough for sterilization of infectious wastes. According to this study sufficient time for complete sterilization of infectious wastes is 45 minute.

CONCLUSION

The present study has demonstrated that best sterilization efficacy for infectious waste in a steam autoclave were achieved in 121°C for 45 minute holding time at 1 atm pressure. In addition there were no relationship between load volume and sterilization efficacy. A strong correlation between BI and CI test as found. This means that BI test can be replaced by CI test to monitor the efficacy of sterilization process with lower cost and time.

ACKNOWLEDGMENTS

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