Comparison of steam sterilization conditions efficiency in the treatment of Infectious Health Care Waste

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A B S T R A C T

Many studies show that the treatment of Infectious Health Care Waste (IHCW) in steam sterilization devices at usual operating standards does not allow for proper treatment of Infectious Health Care Waste (IHCW). Including a grinding component before sterilization allows better waste sterilization, but any hard metal object in the waste can damage the shredder. The first objective of the study is to verify that efficient IHCW treatment can occur at standard operating parameters defined by the contact time–temperature couple in steam treatment systems without a pre-mixing/fragmenting or pre-shredding step. The second objective is to establish scientifically whether the standard operation conditions for a steam treatment system including a step of pre-mixing/fragmenting were sufficient to destroy the bacterial spores in IHCW known to be the most difficult to treat. Results show that for efficient sterilization of dialysis cartridges in a pilot 60L steam treatment system, the process would require more than 20 min at 144 °C without a pre-mixing/fragmenting step.

In a 720L steam treatment system including pre-mixing/fragmenting paddles, only 10 min at 144 °C are required to sterilize IHCW proved to be sterilization challenges such as dialysis cartridges and diapers in normal conditions of rolling.

1. Introduction

Health Care Waste (HCW) includes materials generated during patient diagnosis, treatment, or immunization. Infectious Health Care Waste (IHCW) constitutes a fraction of HCW (approximately 15–25%) that could transmit infectious diseases (Shinee et al., 2008; Voudrias and Graikos, 2015). HCW management is still a serious public health challenge in developing countries due to conspicuously inappropriate disposal methods, and insufficient financing and infrastructural challenges (Toktobaev et al., 2015). Therefore, the development of sustainable systems with low investment and operating costs is essential (Toktobaev et al., 2015). IHCW should be promptly sorted into appropriate bags and containers (Graikos et al., 2010; WHO, 2013). IHCW treatment technologies include autoclaves; integrated steam-based treatment systems; microwave treatment technologies; dry-heat treatment technologies; chemical treatment technologies; and incinerators (WHO, 2013). The two first technologies are generally less costly than the others (Rashidian et al., 2015). These technologies could be supplemented by post-treatment shredders, grinders and compactors (WHO, 2013). One of the advantages of steam sterilization compared to incineration is that sterilized waste is considered nonhazardous and can be placed in a sanitary landfills designed for municipal solid waste, whereas ash produced by incineration is generally considered hazardous and should be treated before disposal (Voudrias and Graikos, 2015). On the other hand, the incineration ensures a greater volume reduction than the steam sterilization. For example, steam sterilization technologies that rely on shredders or grinders decrease waste volume by about 60–70 percent, compared to 90 or 95 percent with incineration (HCWH, 2001). In many countries, there are difficulties to find disposal sites. Therefore, it is important studying the advantages and disadvantages of each technology. Steam sterilization is widely

Abbreviations: Bs, Bacillus stearothermophilus; HCW, Health Care Waste; HCWH, Health Care Without Harm; IHCW, Infectious Health Care Waste; NIIR, National Institute of Industrial Research; STAATT, State and Territorial Association in Alternative Treatment Technologies); WHO, World Health Organization.

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used for IHCW treatment (Toktobaev et al., 2015; Voudrias and Graikos, 2015). Steam sterilization inactivates microorganisms through heat generated by the saturated steam.

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 exposure temperature–time parameter is 121 °C and 2 bar for 30 min (WHO, 1999; HCWH, 2001; Karagiannidis et al., 2009) or above 134 °C and 3.1 bar during 5 min (WHO, 1999). The Hydroclave is a type of integrated steam-based treatment system that combines the idea of an autoclave (except that steam is applied to an outside jacket only) and mixing/fragmenting paddles that fragment the waste. The Hydroclave is a double walled tank where steam is injected in the outer jacket to heat the interior of the machine containing the IHCW. This heating induces the evaporation of the moisture contained in the waste, which increases the pressure. Paddles positioned inside the steam treatment vessel and rotated by a rod tumbles waste against the inside walls of the machine, allowing for the mixing and fragmenting of the waste. In the absence of sufficient moisture, additional steam is injected (NIIR, 2005). In fact, if the control panel of the machine detects a rise in temperature, but not a corresponding rise in pressure, the control panel will command the addition of steam to the vessel interior. Fragmentation of the load during the heat up phase ensures even heat distribution. Tests conducted for the supplier show inactivation of microbial load greater than 10^6 equivalent of Bacillus stearothermophilus (Bs) within 30 min at 121 °C or 15 min at 132 °C (HCWH, 2001).

D-value, or decimal reduction time, is the time necessary to destroy 90% of the organisms being tested. Sterility is monitored by allowing for a sterility assurance level usually at 10^{-3} or 10^{-6}; this means that there is a one in a thousand and one in a million chance respectively that a material would not be microorganism free. Ultimately this means that at least a 3 or 6 log reduction should be achieved (Revox sterilization, 2014).

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 (WHO, 2013).

Bs spores have traditionally been used to evaluate sterilization processes (Periago et al., 1998a; Toktobaev et al., 2015). In fact, Bs spores are considered to be the most physically and chemically resistant life forms known. Therefore situations that result in Bs death indicate the destruction of other microorganisms (Sheldrake et al., 1995.). In addition, Bs indicators are relatively easy to work with, because they grow under aerobic conditions at 60 °C and results can be obtained rapidly (Periago et al., 1998b; Lemieux et al., 2006).

Sterilization efficiency is dependent upon many variables that affect the physics of heat transfer and steam penetration, including the composition, density, liquid content, weight, and types of containers (Lemieux et al., 2006). Insufficient air evacuation, excessive loading weight, low thermal conductivities of waste, air pockets and sealed heat-resistant containers may reduce exposure to steam or heat transfer, and thus decrease the effectiveness of steam sterilization (HCWH, 2001).

Steam sterilization equipment used for IHCW treatment are usually operated at the minimum standards (121 °C for 30 min (WHO, 1999; HCWH, 2001; Karagiannidis et al., 2009) or 134 °C for 5 min (WHO, 1999), based on the past application of steam sterilization in the treatment of medical devices. Nevertheless, many studies show that these operating parameters are not adapted for the proper sterilization of all IHCW (Tiller et al., 2004; Lemieux et al., 2006; AFEC Solutions LLC New Jersey, 2007). In fact, even if some waste such as syringes, intravenous sets, cotton swabs, bandages and gloves can be successfully decontaminated in standard conditions (Toktobaev et al., 2015), other types of IHCW are more difficult to treat.

Notably, contaminated dialysis cartridges present serious sterilization challenges, mainly because of their physical makeup (Sheldrake et al., 1995).

An evaluation conducted in 2005 by the California Department of Health Services showed that in certain circumstances, suction canister waste may not be adequately treated by steam sterilization. An autoclave test report released by the autoclave supplier OnSite Sterilization, LLC, showed that load residence times at 121 °C would need to be 6–9 h if the waste loads included sharps containers and suction canisters (AFEC Solutions LLC New Jersey, 2007).

Another study conducted to evaluate the effectiveness of a commercial autoclave for treating simulated building decontamination residue showed that the makeup of the waste and its packing density has an impact on the efficiency of the sterilization process. Operating the autoclave at 135 °C within 40 min duration cycle at 2.17 bars did not kill Bs spores contained within the simulated building decontamination residue. More than 120 min of exposure at 135 °C was requested to inactivate the biological indicator (Lemieux et al., 2006).

Another study conducted by the Louisiana State University Health Sciences Center in Shreveport on the treatment of adult diapers in a medical waste autoclave showed sterilization failure for 132.22 °C, at 60 min (Tiller et al., 2004).

A study conducted to evaluate the effectiveness of steam autoclaving on the contents of sharp containers showed that the contents of containers required between 30 and 60 min of autoclaving before being sterilized. The size and shape of the containers influenced ease of sterilization (Palenik et al., 1990).

Including a grinding component before sterilization allows better waste sterilization since it exposes a greater waste surface area to the heat or steam (AFEC Solutions LLC New Jersey, 2007). Internal shredding renders the waste unrecognizable and results in final volume reduction up to 80% (Voudrias and Graikos, 2015). Nevertheless, any large, hard metal object in the waste can damage the shredder or grinder (HCWH, 2001). Knowing that sorting errors are frequent in developing countries (Tsakona et al. 2007; Ferreira et al., 2010; Graikos et al., 2010), utilization of autoclaves with an integrated shredder and/or grinder can lead to repeated failures and high maintenance costs.

In this context, treatment systems including mixing/fragmenting paddles inside the steam treatment vessel could be an optimal option since the mixing/fragmenting step increases the exposure of IHCW surfaces to steam and thus allows for proper sterilization of IHCW. Since mixing paddles are less susceptible to damage caused by metallic pieces, they are therefore more resistant than shredders. In fact, the blades of the shredder will try to shred non crushable solids, whereas the mixing/fragmentation paddles will only strike them (Fig. 1).

In Lebanon, two main types of steam sterilization systems are used by the same operator: the autoclaves with an integrated shredder, and the Hydroclave which uses mixing/fragmenting paddles. The cost analysis for 5 years of activity shows that the treatment cost with an autoclave including a shredder is 59.15% higher than the treatment cost of a Hydroclave. In terms of maintenance and reparation, the autoclave with shredder is 147.09% more costly than a Hydroclave.

This study has 2 main objectives. The first objective is to verify if efficient IHCW treatment can occur at standard operating parameters in steam treatment systems without a pre-mixing/

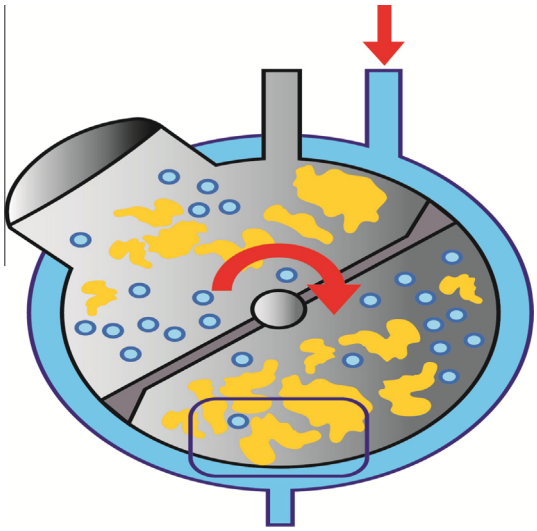

Fig. 1. Mixing/fragmenting paddles of the Hydroclave (in grey).

fragmenting or pre-shredding step. The second objective is to establish scientifically whether the standard operation conditions for a medical steam treatment system including a step of pre-mixing/fragmenting were sufficient to destroy the bacterial spores in IHCW known to be the most difficult to treat, mainly diapers, dialysis cartridges, as dialysis tubes and dialysis syringes placed within sharp containers.

2. Material and methods

2.1. Sample preparation

A biological indicator (Bs bacterial spores suspensions (prospore2, mesa lab, population: $2.4 \cdot 10^5$ CFU, provided by the supplier Kettaneh S.A) was introduced into different materials simulating 4 types of IHCW. These materials included (i) syringes (with needles) (ii) dialysis tubes placed within sharp containers of 10L three-quarters-filled with a representative mix of syringes, needles, and tubes, (iii) dialysis cartridges and (iv) artificially contaminated rolled diapers. In the case of diapers, different configurations were prepared: (1) diapers tightly rolled in a pad, in thick plastic bags integrated in jute bags; (2) Diapers tightly rolled in jute bags only; (3) Diapers tightly rolled in pad and integrated in jute bags; (4) Diapers loosely rolled and integrated in jute bags; and (5) Diapers rolled 2 times (intermediate scenario) (Figs. 2 and 3). The dialysis tubes were cut to introduce the biological indicator and then sewn back together. The dialysis cartridges were perforated with a milling machine to introduce the biological indicator and then resealed with flexible plastic pieces (Fig. 4).

These samples were introduced in plastic bags.

2.2. Sterilization procedure

A first phase on tests was conducted on a steam treatment system without paddles, in order to establish if efficient IHCW treatment can occur at standard operating parameters in steam treatment systems without a pre-mixing/fragmenting or pre-shredding step. As follows, the first phase of the tests was performed on a 60L prototype reproducing the Hydroclave model, fabricated for the experience, including a double jacket, but without the mixing and fragmenting paddles usually integrated in Hydroclaves.

Dialysis cartridges, dialysis tubes, syringes in sharp containers, and tightly rolled diapers samples were processed after the addition of 127 ml of water per cycle to generate steam, at 144 °C during respectively 10 min; 20 min; 30 min, 50 min and 60 min. Each trial was repeated 2 times.

Fig. 2. Example of a dialysis cartridge.

The volume of water added was calculated using the Ideal Gas Equation:

$$PV = nRT$$

P = pressure (atm)
V = volume of the enclosure (L)
n = number of moles (mol)
R = gas constant (0.082 atm $*$ L/mole $*$ K^1)
T = Temperature (K)

A second phase on tests was conducted on a Hydroclave H25 including paddles, in order to establish objectively whether the standard operation conditions for a medical waste treatment sys-

Fig. 3. Diapers samples preparation (tightly rolled in pads).

Perforation with the milling machine

Introduction of the biological indicator

Fig. 4. Introduction of the biological indicator in the dialysis cartridge.

tem including a step of pre-mixing/fragmenting were sufficient to destroy the bacterial spores in IHCW known to be the most difficult to treat. Therefore, second phase of the tests were performed on a Hydroclave H25 within a Health Care Waste treatment facility for IHCW located in North Lebanon. The hydroclave H25 has a maximum batch weight of 116 kg and a maximum loading volume of 720L. The two steam sterilization equipment used in the experiment didn't have the same capacity for the following reasons: First, it was too costly to produce a prototype without paddles with a loading volume of 720 L. Secondly, the system of fragmentation and the paddles of the Hydroclave was too complex to be reproduced at a small scale. The following samples were introduced in the H25: (1) dialysis cartridges in sharp containers and bags, (2) dialysis tubes in sharp containers and bags, (3) syringes in sharp containers and bags, (4) diapers tightly rolled in a pad, in thick plastic bags integrated in jute bags, (5) diapers tightly rolled in jute bags only; (6) diapers tightly rolled in pad and integrated in jute bags, (7) diapers loosely rolled and integrated in thick plastic bags integrated in jute bags, (8) diapers rolled twice and integrated in thick plastic bags integrated in jute bags. Samples were processed along with 110 kg of real IHCW collected from health care centres in an industrial IHCW treatment facility, at usual operating conditions, by the usual operator of the facility, and under the supervision of the team conducting the experiment. The operating conditions were the usual parameters adopted by the operator: 144 °C for 10 min. These parameters are based on WHO recommendations (134 °C during 5 min, (WHO, 1999)), with the addition of a margin of safety. Each trial was repeated 3 times.

2.3. Biological testing

After completion of the sterilization cycle, biological indicators were removed (the diapers were unrolled, and the dialysis cartridges opened with a clamp (Fig. 5)). Then, the biological indicators were incubated aerobically at 55–60 °C for 24 h and spores survival/no survival read after 24 h of incubation. For every cycle, one biological indicator ampoule was directly incubated without treatment as an untreated control. Data were collected on a qualitative basis ("spores survival" or "no spores survival"). In fact, the biological indicator consists of a spores strip (spores that are coated on a paper strip) enclosed in a plastic vial along with a growth medium (comprised of a Tryptic Soy broth with a pH indicating dye (bromocresol purple)) contained inside of a crushable glass ampoule. The cap is designed to allow heat to penetrate into the plastic vial. After sterilizing, a slight pressure is applied to the indicator. This step crushes the glass ampoule of growth medium within the vial. Finally, the whole vial is incubated. In the event that the spores survive the sterilization process, spores will begin to grow when they come in contact with the nutrients contained in the growth medium and when incubated at the correct temperature. Absence o color change after incubation indicates that the sterilization conditions were achieved (no degradation of nutrients by the spores); otherwise the growth of the spores indicates that the sterilization process has not been successful (the degradation of the nutrients by the spores, which induce a modification in the PH, and thus color modification) indicate that the requirements for sterilization were not met.

3. Results and discussion

The results of the tests conducted on the pilot steam treatment system with no paddles show no survival of Bs spores after treatment at 144 °C during 10 min for dialysis tubes and syringes. On the contrary, Bs spores were not destroyed in the dialysis cartridges in these conditions, nor at 144 °C for 20 min. Spores destruction in dialysis cartridges and diapers was observed at 144 °C for 30 min (Fig. 6).

Fig. 5. Removal of the biological indicator from the dialysis cartridge.

The results of the tests conducted on the Hydroclave H25 that includes paddles and thus a pre-mixing/fragmenting step, show no survival of Bs spores after treatment at 144 °C for 10 min for dialysis cartridges in sharp containers and bags, and for dialysis tubes in sharp containers and bags. All Bs ampoules integrated in the syringes exploded during the experiment and consequently no conclusions can be derived for this material. However, Bs spores were not destroyed in diapers tightly rolled in a pad and then placed in thick plastic bags, and then integrated in jute bags, nor in diapers tightly rolled in pad and integrated in jute bags without plastic bags, nor in diapers tightly rolled in jute bags only. Nevertheless, spores destruction occurred in diapers rolled twice and

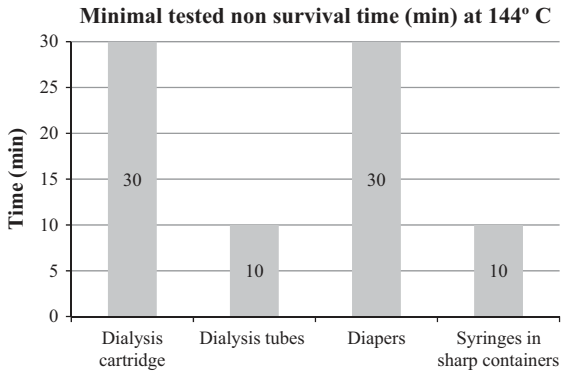

Fig. 6. Results of microbiological challenges for different types of simulated IHCW and different exposure times in the pilot steam treatment system without a pre-mixing/fragmenting step.

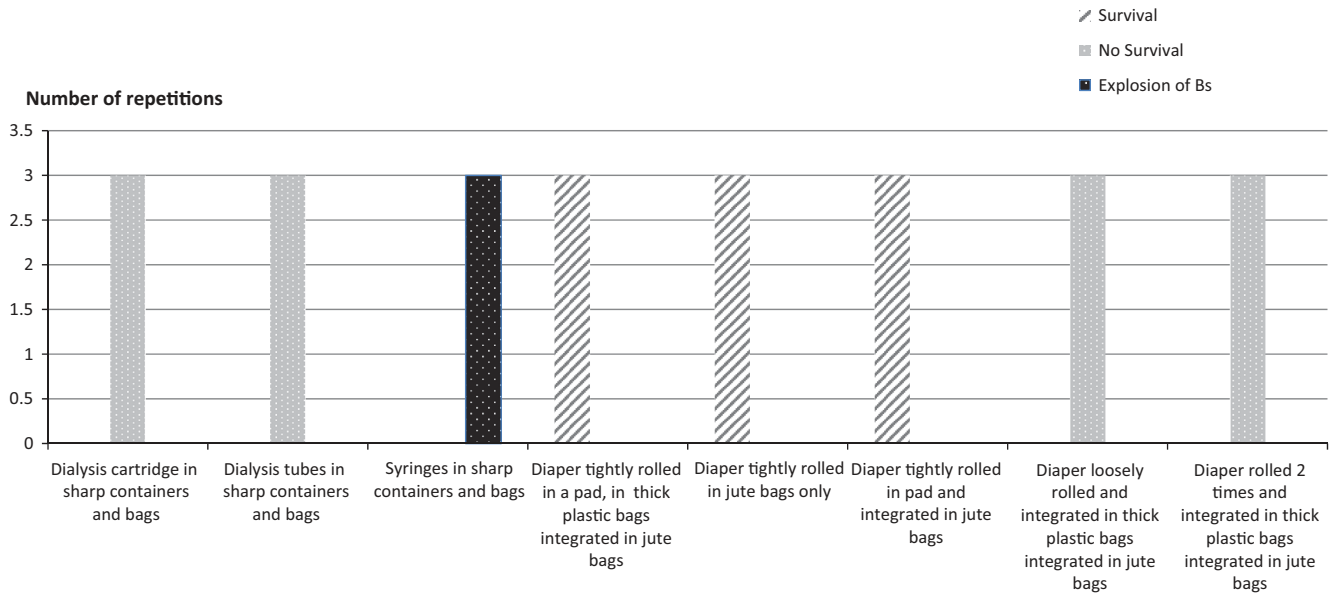

Fig. 7. Results of microbiological challenges for different types of simulated IHCW in the Hydroclave H25 including a pre-mixing/fragmenting step (144 °C to 10 min).

integrated in plastic bags and jute bags, and in diapers loosely rolled and integrated in plastic bags and jute bags (Fig. 7).

All biological indicators incubated without treatment as an untreated control showed spores survival.

Thus, dialysis cartridges and diapers are more difficult to sterilize than other types of IHCW. A contact time of 20–30 min at 144 °C is requested to achieve a proper sterilization of dialysis cartridges in a 60L steam sterilization system if no pre-shredding or pre-fragmenting step is applied. Thus, it is expected that higher exposure durations will be requested for larger volumes. However, these exposure times are not compatible with industrial IHCW treatment efficiency demand, in terms of energy and time optimization.

Steam sterilization with pre-mixing and pre-fragmenting paddles at 144 °C for 10 min is sufficient to sterilize IHCW proved to be sterilization challenges such as dialysis cartridges and diapers, in normal conditions of rolling. Only tightly rolled diapers could not be sterilized in these conditions, which indicated that this configuration limits heat transfer. Nevertheless, diapers are rarely considered as IHCW in hospitals. Besides, health care staff usually rolls diapers slackly.

These results confirm previous studies that showed that (1) parameters such as composition, density, and types of containers affect sterilization efficiency (Lemieux et al., 2006; Palenik et al., 1990), (2) standard operating parameters are not adapted for the proper sterilization of IHCW (Tiller et al., 2004; Lemieux et al., 2006; AFEC Solutions LLC New Jersey, 2007), and (3) Contaminated dialysis cartridges and diapers represent sterilization challenges (Tiller et al., 2004).

4. Conclusion

The results of this steam sterilization comparison experiment confirm previous studies showing that containerization and composition of waste material have an important impact on the exposure time required to achieve IHCW sterilization.

This study corroborates that standard sterilization parameters based upon minimum standards are not always sufficient to achieve proper sterilization where no pre-shredding or pre-mixing/fragmenting step is integrated. Thus, further scientific experiments should be conducted, with varying time, temperature and waste loads.

In addition, results confirm that a pre-mixing/fragmenting step using paddles integrated in steam sterilization systems allows for successful IHCW sterilization in normal operating conditions. In conclusion, pre-mixing/fragmenting with paddles can be an efficient alternative to shredders. Nevertheless, further scientific analysis such as cellular morphology alteration, as protein and enzyme denaturation, are required to confirm the microorganisms' inactivation.

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