Distribution Statement

Distribution A: Public Release.

The views presented here are those of the author and are not to be construed as official or reflecting the views of the Uniformed Services University of the Health Sciences, the Department of Defense or the U.S. Government.

The author hereby certifies that the use of any copyrighted material in the thesis manuscript entitled:

Use of a Pressure Cooker to Achieve Sterilization for an Expeditionary Environment

is appropriately acknowledged and, beyond brief excerpts, is with the permission of the copyright owner.

Ross K. Cook
2-yr AEGD Program, Fort Bragg, NC
Uniformed Services University, Bethesda, MD
Date: 01/10/2020

UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES
POSTGRADUATE DENTAL COLLEGE
SOUTHERN REGION OFFICE
2787 WINFIELD SCOTT ROAD, SUITE 220
JBSA FORT SAM HOUSTON, TEXAS 78234-7510
https://www.usuhs.edu/pdc

THESIS APPROVAL PAGE FOR MASTER OF SCIENCE IN ORAL BIOLOGY

Title of Thesis: "Use of a Pressure Cooker to Achieve Sterilization for an Expeditionary Environment"

Name of Candidate: MAJ Ross K. Cook
Master of Science Degree
June 05, 2020

THESIS/MANUSCRIPT APPROVED: DATE:

Erik Reifenstahl — *05 June 2020*
Erik Reifenstahl, LTC, DC
ASSISTANT DIRECTOR, AEGD-2, FORT BRAGG
Committee Chairperson

Charles Lambert — *05 June 2020*
Charles Lambert, LTC, DC
PROGRAM DIRECTOR, AEGD-2, FORT BRAGG
Committee Member

Manuel Pelaez — *05 June 2020*
Manuel Pelaez, LTC, DC
RESEARCH ADVISOR, AEGD-2, FORT BRAGG
Committee Member

Use of a Pressure Cooker to Achieve Sterilization for an Expeditionary Environment

Cook RK, McDaniel J, Pelaez M, Beltran TA,

Abstract

Background: Sterilization of medical and dental instruments in an expeditionary environment presents a myriad of logistical challenges to include portability, cost, and the need for adequate electrical power. The off-label use of pressure cookers to sterilize instruments presents a low-cost, easily procured option for sterilization in military prehospital settings. The objective of this project was to determine if sterility can be achieved using a commercially available pressure cooker.

Methods: Presto 4-Quart stainless steel pressure cookers were heated using Cuisinart CB-30 cast-iron single burners. Sterility test packs consisted of a 3M Attest 1292 Rapid Readout Biological Indicator and a 3M Comply SteriGage chemical integrator strip inside a Henry Schein Self Seal Sterilization Pouch. Each test pack was placed in a pressure cooker and brought to a pressure of 15 psi. After 20 minutes at pressure, sterility was verified. The Attest vials were incubated in a 3M Attest 290 Auto-Reader for at least 3 hours with a control Attest vial from the same lot as the autoclaved vials.

Results: Sterility using the pressure cooker was achieved in all tested bags, integrator strips, and Attest vials (n=128). The mean time to achieve the necessary 15 psi was 379 sec (SD = 77). Neither the ambient temperature nor humidity were found to affect the pressure cooker's time to achieve adequate pressure nor the achieved depth on the integrator strip (all $P > 0.05$).

Conclusions: This study provides evidence that sterilization is a device agnostic process which can be accomplished with off-the-shelf alternatives capable of achieving the required pressure and temperature. Though lacking FDA approval, the use of commercially available pressure cookers may provide a fast and reliable method of sterilization requiring minimal resources from medics, physicians, and dentists working in expeditionary environments.

Introduction

Sterilization of medical and dental instruments allows healthcare providers to minimize the transmission of HIV, Hepatitis C, Hepatitis B, or bacterial infections from one patient to another. The Centers for Disease Control and Prevention (CDC) defines sterilization as a process that destroys or eliminates all forms of microbial life and is carried out in health-care facilities by physical or chemical methods[1]. Sterilization in an expeditionary environment presents a myriad of logistical challenges including weight, cost, and power requirement. Tabletop autoclaves can weigh between 60 and 200 lbs. with a power requirement ranging from 1.5 to 3kW. The cost of tabletop units, ranging from $1,500 to $2000, combined with the cost and weight of the generators needed to power the autoclaves, can also be prohibitive. Forgoing the use of an autoclave and opting for single-use medical and dental instruments can be helpful in expeditionary or austere environments. However, the packing and transport of single use items can be impractical in scenarios of high patient volume or separation from a supply chain.

Liquid chemicals for sterilization come with a comparatively lower cost than tabletop autoclaves and no power requirement for use. The use of liquid chemicals for "cold sterilization" have the drawbacks of requiring contact times from 3-12 hours and the inability to verify sterility using a biological indicator[1]. Shorter contact times are considered high-level disinfection, meaning they eliminate all pathogenic microorganisms, except bacterial spores and prions, on inanimate objects[1]. Alcohol lacks sporicidal action and can't penetrate protein-rich materials found on instruments[1]. Chemicals like chlorine and glutaraldehyde have sporicidal activity, but the World Health Organization (WHO) does not recommend their use for sterilization because of the risk of contamination while rinsing[2]. In addition to potentially not achieving sterility, and the long contact times required, these chemicals have other concerns. Chlorine is corrosive to metal instruments in high concentrations and, like formaldehyde and glutaraldehyde, can be dangerous or hazardous to transport[1]. Like single-use instruments, the use of chemicals also makes a provider or facility dependent on a supply chain.

The World Dental Relief advocates for the off-label use of pressure cookers as autoclaves in austere environments[3]. Off-the-shelf pressure cookers, at a cost of less than $50 and weighing less than 10 lbs. can provide a fast and portable solution only requiring a consistent source of heat to operate. The objective of this project was to determine if sterility can be achieved using a commercially available 4-quart stainless steel Presto pressure cooker for use as an autoclave for an expeditionary environment.

Methods & Design

Two Presto 4-quart stainless steel pressure cookers were filled with 12 ounces of tap water. The metal grates included with the pressure cookers (National Presto Industries, Inc., Eau Claire, WI) were placed and verified to not be submerged in the water. Both

pressure cookers contained a test packet composed of a 3M Attest 1292 Rapid Readout Biological Indicator vial (3M Health Care, St. Paul, MN) and 3M Comply SteriGage Steam Chemical Integrator strip (3M Health Care, St. Paul, MN) sealed within a 3.5”x5.25” Henry Schein Seal Seal sterilization pouch (Henry Schein, Inc., Melville, NY). A surgical towel was placed between the grate and the test pack to ensure the Attest vials did not melt from contact with the metal grate. Two pressure cookers were run simultaneously on two Cuisinart CB-30 cast-iron single burner hot plates (Cuisinart, Stamford, CT). A total of 128 trials were run with 64 trials on each pressure cooker. Each run consisted of one test packet. The pressure & temperature established by the manufacturer 15 psi and 250 ^{o}F[4] and established US Army sterilization protocols require 20 minutes to achieve sterility at this pressure and temperature[5]. After each trial, the pressure cookers and hot plates were allowed to cool for at least 5 minutes before the next trial was started.

At the end of each trial run, the readings for the pouch indicators and SteriGage strips were recorded. The Attest vials were incubated in a 3M Attest 290 Auto-reader (3M Health Care, St. Paul, MN) with a control vial for at least 3 hours following US Army protocol and the manufacturer’s recommendation[5,6]. The Attest vials were labeled to identify the day, trial, and in which pressure cooker the vials were used. Positive or negative incubation was verified by a blinded observer. The ambient temperature and humidity at the beginning of each day was measured using an Acurite digital thermometer and hygrometer (Chaney Instrument Co., Lake Geneva, WI).

Exploratory data analyses were conducted on the all continuous data. The Shapiro-Wilk test was used to assess the normality of the data distributions. Measures of central tendency are presented as means with associated standard deviations. Multiple regression analyses were used to test if the ambient temperature and humidity affected either the pressure cooker’s time to achieve 15 psi or the achieved depth on the sterility integrator strip. All analyses were weighted and conducted using SPSS Complex Samples (SPSS version 25, IBM, Chicago, IL).

Results

Sterility using the pressure cooker was achieved in all tested bags, integrator strips, and Attest vials (n=128). The mean time to achieve the necessary 15 psi was 379 sec (*SD* = 77). The mean depth on the test strips was 6.4 mm (*SD* = 1.7). Ambient temperature and humidity during the tests was 69.3F (*SD* = 8.8) and 64.6 mmHg (SD = 2.9) respectively. Neither the ambient temperature nor humidity were found to affect the pressure cooker’s time to achieve adequate pressure nor the achieved depth on the integrator strip (all $P > 0.05$). Figure 1 summarizes the observed times to achieve pressure for the pressure cookers.

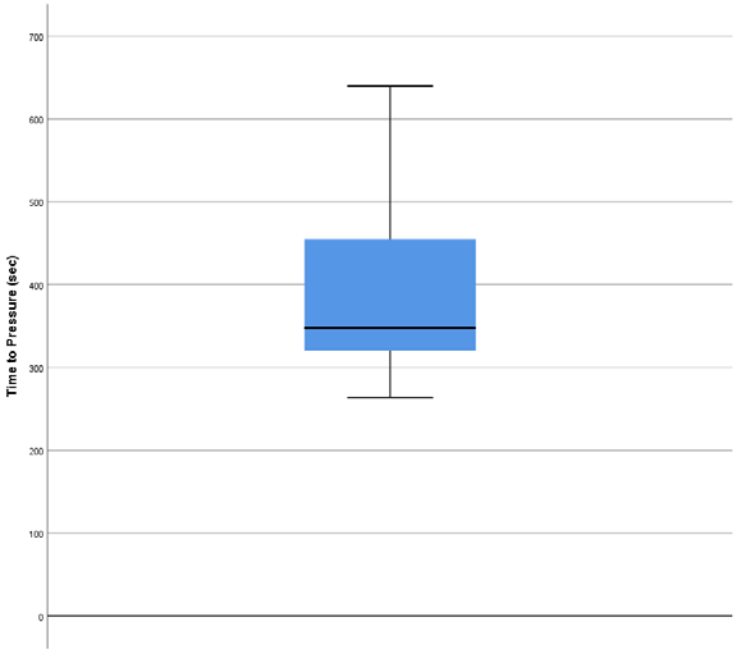

Figure 1. Boxplot of Time to Pressure

Movement of the weight after the pressure pot had reached 15 psi was observed to stop in 56 of the 128 trials. However, interruption of weight movement had no effect on the outcome.

Discussion

This benchtop study only tested one pressure cooker model's ability to achieve sterilization under controlled conditions with a consistent heat and power source at 20 minutes. Further studies are necessary to develop a proper protocol for the pressure cooker's use as an autoclave. Several questions not addressed in this study need to be answered before the use of a pressure cooker as an autoclave can safely be recommended. Primarily, what is a reliable protocol for precleaning instruments in an expeditionary environment to achieve sterilization in a pressure cooker? Sterilization is compromised if the instruments are not first meticulously cleaned of the bioburden and foreign materials that act as a barrier to the process[1]. A simple method tested by Knox et al., using chlorhexidine sponges and UVC lights on instruments was found to decontaminate instruments in austere environments[7].

Another limitation of this study is that the conditions tested were controlled and at approximately 341ft above sea level. For every 500 feet gained in elevation, the boiling point of water is lowered by 1 ^{o}F[8]. The effect of atmospheric pressure and humidity on a pressure cooker's ability to achieve sterility needs to be measured to provide an appropriate protocol for differing locations. Other models of pressure cookers should be investigated for their ability to function as autoclaves. A study by Swenson et al., tested

four different electric pressure cookers and found that only the Instant Pot was able to inactivate G. stearothermophilus spores[9]. Other limitations of this study and further areas to be investigated include the effect of water quality, the number of instruments that can be processed, and the effect of different heat sources.

Despite numerous questions remaining regarding the proper use of a pressure cooker as an autoclave, the need for cheap and simple methods of sterilization in austere and prehospital settings exists. The review by Fast et al., of sterilization practices in the Republic of Congo, Madagascar, and Benin highlights the struggle of resource limited areas with the infrastructure required for autoclaves[10]. Similar struggles with infrastructure can be expected among expeditionary healthcare providers who will be tasked with providing a reliable, agile, and responsive sustainment capability necessary to support rapid power projection, Multi-Domain Operations, and independent maneuver[11].

Conclusion

This study provides evidence that sterilization is a device agnostic process and a Presto 4-quart stainless steel pressure cooker can be used to create the conditions for sterility with a run time of 20 minutes at a pressure of 15 psi. All 128 trials in this study, each confirmed by a 3M Comply SteriGage chemical integrator strip, a Henry Schein Self Seal sterilization pouch, and 3M Attest 1292 Rapid Readout biological indicator, achieved sterility. Though lacking FDA approval, the use of commercially available pressure cookers may provide a fast and reliable method of sterilization requiring minimal resources from medics, physicians, and dentists working in expeditionary environments.

References

1. Centers for Disease Control. Guideline for Disinfection and Sterilization in Healthcare Facilities. http://www.cdc.gov

2. World Health Organization. Decontamination and Reprocessing of Medical Devices for Health-care Facilities. http://www.who.int

3. World Dental Relief. Portable Autoclave and Sterilization. http://www.worlddentalrelief.com

4. Presto Pressure Cookers Instructions & Recipes, National Presto Industries, Inc. 2009.

5. DENCOM Pam 40-5-1, Appendix J, Instrument Processing and Sterilization, June 2015.

6. 3M Attest 1292. 3M health Care, St. Paul, MN, 2016.

7. Knox, R.W., Demons, S.T., Cunningham, C.W. 2015. A Novel Method to Decontaminate Surgical Instruments for Operation and Austere Environments. *Wilderness Environment Med.*, 26(4), pp. 509-513.

8. United States Department of Agriculture Food Safety and Inspection Service. High Altitude Cooking and Food Safety. http://www.fsis.usda.gov

9. Swenson, V.A., et al. 2018. Assessment and verification of commercially available pressure cookers for laboratory sterilization. *PLOS One Online*, https://doi.org/10.1371/journal.pone.0208769

10. Fast, O., et al. 2017. Limited sterile processing capabilities for safe surgery in low-income and middle-income countries: experience in the Republic of Congo, Madagascar and Benin. BMJ Global Health 2017; 2:e000428.

11. United States. Department of the Army. The US Army in Multi-Domain Operations 2028. TRADOC Pamphlet 525-3-1, 2018.