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Effects of Elevation on Pressure Cooker Sterilization

LTC Khai Q Le

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ABSTRACT

Background: The Army operates all over the world. Medical and dental units must be fully functional to support operational and civil missions. Sterilization processing is critical to the safe continuous functioning of medical and dental assets. In established or fixed facilities, a steam autoclave is utilized for sterilization, which are heavy, cumbersome, and expensive. Previous research has shown that a portable and cost effective pressure cooker can achieve sterility under the right conditions. The purpose of this study is to further evaluate the ability to sterilize instruments with a pressure cooker by testing the effects of elevation. Materials and methods: Trials were conducted at three different elevations around Fort Carson, CO. Each trial consisted of using the Presto® 4-quart stainless steel pressure cooker with approximately 355 mL of tap water and a test packet, which contains one chemical indicator and one biological indicator. Each trial ran for 20 minutes at the pressure and temperature established by the manufacture of the pressure cooker. Results: At 6247 ft, there were no failures. At 8454 ft, the failure rate was 3.7%. And at 11,555 ft, the failure rate was 34.8%. The results indicate a negative correlation between the elevation and successful sterilization. Conclusion: It is evident that elevation has a significant effect on pressure cooker sterilization. However, this method could still provide a viable alternative to steam autoclave. Further research is needed to standardize a protocol that can predictably achieve sterility across elevations and environments.

INTRODUCTION

The Army operates in a multi-domain environment and would benefit from a method to sterilize medical and dental instruments that is portable, inexpensive, and can be utilized anywhere in the world.[1] Sterilization is essential for ensuring that medical and surgical instruments do not transmit infectious pathogens to patients. Therefore, sterilization is a critical aspect to performing surgical procedures down range. In dentistry, sterilization is essential to treat patients in a clean environment that minimizes infections. Sterilization, as defined by the Center for Disease Control (CDC), is a process that destroys all forms of microbial life, including bacterial spores, and is carried out by physical or chemical methods such as: steam under pressure, dry heat, EtO gas, hydrogen peroxide gas plasma, or other liquid chemicals. The preferred method to sterilize critical items is steam sterilization or autoclave.[2] The autoclave exposes the instrument to direct steam at a required temperature, pressure, and time. It is widely used because of its dependability, margin of safety, consistency, and lethality. Furthermore, steam sterilization is nontoxic, rapidly heats, and penetrates fabrics.[2] According to DENCOM PAM 40-5-1, the standard temperatures of 121°C (or 250°F) and 103.4kPa (15 psi) can reach sterility at 20 minutes. The Army uses three methods to ensure effective sterilization: mechanical, chemical, and biological. Mechanical parameters are measured using the gauges, settings, and printouts. Chemical parameters are monitored using internal and external indicators, such as the 3M Comply™ SteriGage™ Steam Chemical Integrator (1243A).[3] These indicators verify proper temperature, steam penetration, and time exposure has been achieved.[4] The 3M Attest™ Rapid Readout Biological Indicator (1292) is used to monitor the biological parameter, which contains the presence of *Geobacillus stearothermophilus.* If live *Geobacillus stearothermophilus* is present in the spore test vial after the completion of the 121°C steam sterilization cycle, that sterilization has failed.[5] *Geobacillus stearothermophilus* is the bacteria of choice for monitoring

steam sterilization because its spores are highly resistant to heat. Therefore in the absence of *Geobacillus stearothermophilus* spores, it can be inferred that lesser heat resistant bacteria have been eradicated and the sterilizer is working properly.[6] However, autoclaves are not ideal for all terrain, austere environments. They can be heavy, expensive, and require maintenance and a power source.[7] Previous research has used pressure cookers as an alternative. In general, pressure cookers are light weight, inexpensive, readily available, and require minimal maintenance. Swenson et al, tested four comm only available pressure cookers and verified that at the right conditions, sterility can be achieved for laboratory purposes with the Instant Pot. [8] Dr. Cook showed that a Presto 4-quart stainless steel pressure cooker can achieve sterilization under a controlled environment when run for 20 minutes at a pressure of 103.4kPa and temperature of 121°C.[9] Dr. Hong achieved the same results using the same parameters with the exception of the heat source. To replicate an austere environment, Dr. Hong used a propane burner outdoors instead of an electric hot plate used by Dr. Cook indoors. Their research was conducted at the same elevation of 300 ft above sea level.[7]

In order to be truly versatil e in all environments, elevation must be considered. At higher elevations, the atmospheric pressure decreases. Thus, the temperature is lower for the vapor pressure to reach the surrounding pressure, therefore water under lower pressure boils at a lower temperature.[10] Boiling is the vaporization of liquid into steam. This occurs at a temperature where the vapor pressure of the liquid is equal to the pressure that is exerted on the liquid by the external atmosphere. In the case of a pressure cooker, the surrounding atmospheric pressure is exerted on the excess pressure relief valve (EPRV), which determines the pressure within the pressure cooker. Subsequently for every 500 ft increase in elevation, there is a 0.03°C decrease in the boiling temperature of water.[7] The Presto manual states that at high elevation, cooking time needs to be increased by 5% for every 1,000 ft above the first 2,000 ft. Additionally, at elevation above 3,000 ft an additional half cup of water will be required .[11]

PURPOSE

The purpose of this study was to further evaluate the ability to sterilize dental and medical instruments processed in a pressure cooker under elevated outdoor conditions which mimic austere operational locations and to further validate a sustainable alternative to using an autoclave. The Presto 4-quart stainless steel pressure cooker is capable of achieving sterility at sea level. The hypothesis is that at higher elevations, the change in atmospheric pressure prohibits the pressure cooker from achieving 100% sterility at the proposed protocol of 20 minutes.

MATERIALS AND METHODS

This study and design advances Drs. Cook and Hong's studies with the addition of increased elevation. The study was conducted in various locations around Fort Carson, CO where the elevation is 5,814 ft. The test design was to utilize a pressure cooker (Presto® brand) in various locations outdoors, run for 20 minutes at the varied pressure and temperature produced within the pressure cooker. To confirm sterility, a steam chemical integrator (1243A, Comply, SteriGage; 3M) and a biological indicator (1292; Attest, Rapid Readout; 3M) were utilized. The 3M Comply SteriGage (1243A) steam chemical integrator consist; of a chemical pellet, paper strip for chemical wicking, and aluminum foil cover. It verifies that the temperature, steam and time

required for sterilization has been met. At the stated value of 121°C over at least 16.5 minutes, the chemical pellet melts and causes a progressive upward color change of the paper wick strip from white to black. If the black color change reaches the accepted mark this signifies that the stated values have been meet. 3M's stated values ensure that the chemical indicators are consistent between all temperatures and correlates with the performance of its biological indicator.[4] In other words, if the chemical indicators have met the conditions for sterilization so will the biological indicators. The 3M Attest 1292 Rapid Readout is a dual biological indicator designed to monitor the sterilization process in conjunction with the 3M Attest Auto-reader 390. The Attest 1292 auto-reader detects the presence of *Geobacillus s tearothermophilus* by identifying the fluorescence enzymatic breakdown of alpha-glucosidase. The biochemical activity of *G. s tearothermophilus* produces acid by-products that causes a color change from purple to yellow. A fluorescence and yellow color change both indicate a steam sterilization process failure.[5] For the purposes of this study, only the 3M Attest 1292 Rapid Readout was used to determine if sterility was achieved. To maintain consistency with previous studies, for it s portability, and to mimic austere environments without electricity, the heat source used was a 10-lb propane tank and a Camp Chef two 30,000 BTU's cast-aluminum burner.[7]

DETAILED METHODOLOGY

Data was sourced from three different elevations (6,247 ft, 8,454 ft, and 11,555 ft). These reflect the height above sea level of Manitou Springs, CO; Woodland Park, CO; and Hooiser Pass, CO, respectively. At Manitou Springs, 27 trials were conducted. At Woodland Park, 32 trials were conducted. At Hooiser Pass, 31 trials were conducted. Each trial utilized a test packet containing one 3M Attest Rapid Readout (1292) biological indicator and one 3M Comply SteriGage (1243A) steam chemical integrator strip enclosed in a 8.9 cm x 13.3 cm Henry Schein self-seal sterilization pouch with internal and external indicators.

Additionally, a Presto® 4-quart stainless steel pressure cooker was filled to the level of the metal grate or cooking rack with approximately 355 mL (1 2 ounces) of tap water. A metal grate was placed on the bottom of the cooker and a surgical towel was placed on the metal grate to prevent the heated metal from melting the test packet and preventing it from being submerged in the water.

For each trail, one test packet was placed on top of the surgical towel and the cooker was closed. The pressure cooker was placed on the propane burner, and the gas turned on and ignited. The pressure and temperature established by the manufacturer for the stock weight is 15 pounds of pressure and 121°C at sea level.11 In each trial, the pressure cooker was subjected to heat until the researcher could detect audible sounds and visually confirm the rattling movement of the excess pressure relief valve (EPRV) on top of the lid. The rattling of the EPRV indicates that the water inside the pressure cooker is boiling. The pressure cooker was then given 20 minutes to achieve sterility.

After each trial, the pressure cooker was allowed to cool for at least 2 minutes before the next trial was started. At the end of each trial, the readings from the Attest Rapid Readout pouch indicators and Comply SteriGage strips were recorded. The Attest vials were incubated in a 3M

Attest 290 auto-reader with a control vial for at least three hours, following US Army protocol and the manufacturer's recommendation.[5]

A Kruskal-Wallis test was used to assess the relationship between testing elevation and the ability of a pressure cooker to achieve sterility. Pairwise comparisons were made using a chi square test. Cramer's V was subsequently used as a measure of effect size. All analyses were conducted using SPSS version 25 (IBM, Chicago, IL).

RESULTS

Data revealed that of the 75 trials, only 9 (12.0%) failed to achieve sterility. Overall, a significant difference was found based on the elevation at which the samples were tested, $P < 0.001$. The measure of association, Cramer's V, for the relationship between elevation and sterility was 0.47. This indicates a strong relationship between the independent (elevation) and dependent (sterility) variables.[1] [2]

As Table 1 shows, the lowest testing elevation (6,247ft) yielded highest rate of sterility (n=25, 100%). In contrast, the highest elevation yielded the lowest rate of sterility (n=15, 65.2%). Pairwise comparisons revealed significant drops in the proportion of successfully sterile trials with both subsequently higher elevations (both $P < 0.05$). There were no cases in which a spore failure did not also include a SteriGage steam chemical integrator test failure. However the opposite was not true as among the 26 SteriGage steam chemical integrator test failures, only 9 (35%) were accompanied by a biological spore test failure. The SteriGage steam chemical integrator signifies that conditions for sterilization has been met but the biological spore test is the true indicator of sterilization.

Table 1. Sterility of samples by elevationaltitude, n(%)

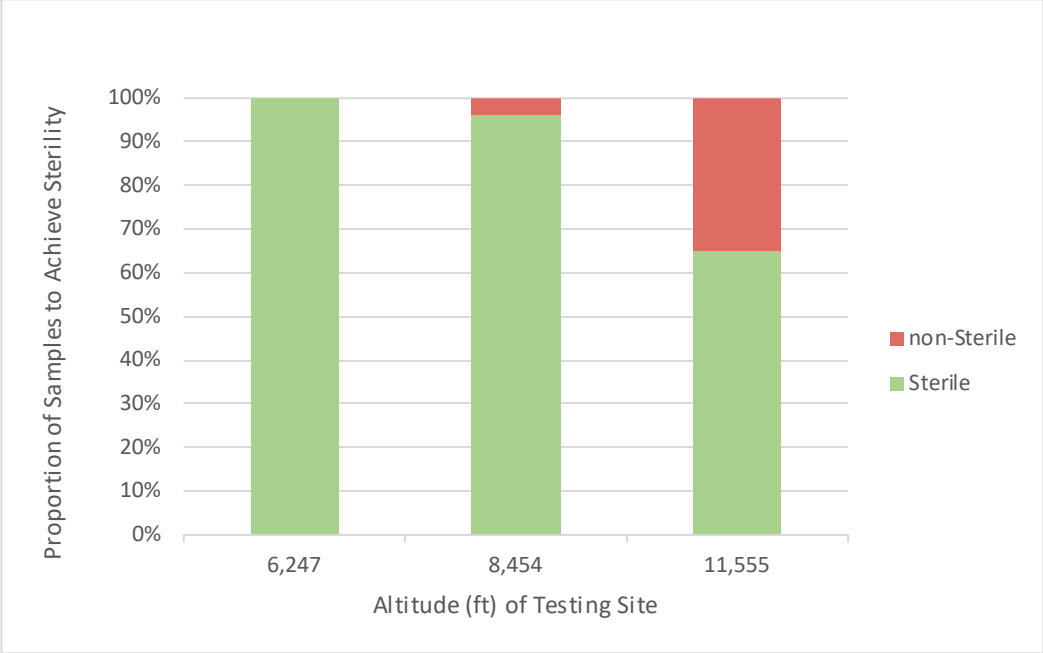
elevation Altitude (ft)	n	non-Sterile	Sterile
6,247	25	0 (0.0)	25 (100.0)
8,454	27	1 (3.7)	26 (96.3)
11,555	23	8 (34.8)	15 (65.2)

DISCUSSION

According to the results, it is evident that elevation has a significant effect on pressure cooker sterilization. As elevation increases, the atmospheric pressure and boiling point of water decreases. Similar to cooking food, turning up the heat will not help cook the food faster. No matter how high the temperature is, water cannot exceed its own boiling point unless using a pressure cooker. To compensate for this, the cooking time must be increased.[1] [3] Alternatively, pressure serves as a means to achieve higher temperatures.[2] Increasing pressure brings the boiling temperature of water higher and thus may decrease run time. Direct measurements of ambient temperature, humidity, atmospheric pressure, and wind speed w as not measured, which could have affected the results. Furthermore, the actual temperature and pressure within the pressure cooker was not measured or recorded. At sea level, the manufacture

established the temperature of 121°C, and pressure of 103.4kPa (30 psi of absolute pressure). The results show that elevation affects the conditions within the pressure cooker by decreasing the overall pressure resulting in lower boiling temperatures. Other factors such as water quality, load size in the pressure cooker, different heat sources, cleaning and maintenance of the pressure cookers, change of gaskets or leaks add to the limitations of this study. Further research is needed to test these variables and establish a protocol that will achieve 100% sterilization at all elevations.

Figure 1. Proportion of Samples to Achieve Sterility



CONCLUSION

The increase in elevation has a significant negative association with successful sterilization. There was a decline in the proportion of sterile t r ials from 6,247 ft to 8,454 ft and a greater decline between 8,454 ft to 11,555 ft. Showing a strong correlation between increased elevation and unsuccessful sterilization.

BENEFIT FOR THE DOD

Further research is needed to determine and establish standard protocols at different elevations . This will enable the DOD to preform sterile medical and dental procedures anywhere in the world. Pressure cooker sterilization is an easy, inexpensive, portable, readily available and light weight

alternative to an autoclave. Pressure cooker sterilization will facilitate cost savings and maneuverability for the fighting force in all terrains and environments.

DISCLAIMER

The views and opinions stated here are solely of the authors and are not official or reflect the views of the Department of Defense or US Government.

DISCLOSURE

The authors disclose that they have no financial gain or affiliations with any company or product used in this research.

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AUTHOR CONTRIBUTIONS

Khai Le, Ross Cook, and Seung Hong conceived the study concept. Khai Le collected the data and wrote the first draft. Thomas Beltran analyzed the data. Garrett Wood acted as a mentor to the project. All authors read and approved the final manuscript.

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