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The Effectiveness Comparison of Class VI Internal Chemical Indicator Strip with Rapid Readout Biological Indicator in Wet Heat Sterilization

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Abstract

Objective:
The objective of this study was to find out the effectiveness of the class VI internal chemical indicator strip in comparison with the effectiveness of the 3M attest 1292 rapid readout biological indicators.

Methods:
The laboratory experiment was done by proceeding stages of the research including formulation of the sodium chloride 0.9 % infusion, an application of both class VI internal chemical indicator strip and rapid readout biological indicator in the wet heat sterilization process and evaluation of the sodium chloride 0.9 % infusion which included sterility testing. The timing of sterilization used was 5, 7, 9, 10.5, 12, 13.5 and 15 min. The data were analyzed by means of descriptive statistics.

Results:
The class VI internal chemical indicator strip indicated color changes after 12 min of sterilization and the rapid readout biological indicator showed no color changes after 7 min of sterilization. The sterility test on the sodium chloride 0.9 % infusion had no microbial growth starting from sterilization time 10.5 min onwards.

Conclusion:
The class VI internal chemical indicator strip was more accurate as compared to the rapid readout biological indicator. The sterility level shown by the class VI internal chemical indicator strip was more effective compared to sterility level of rapid readout biological indicator.

Keywords: class VI internal chemical indicator strip, rapid readout biological indicator, wet heat sterilization, sodium chloride 0.9 % infusion

INTRODUCTION

Wet heat sterilization which utilizes the autoclave is an effective and fast method of sterilization. The purpose is to ensure sterilized products, material, and medical equipment, and not only for producing sterilized goods. All goods which have been sterilized must have a sterility assurance.[1-3]

Sterility testing can be done based on the usual combination of mechanical, chemical and biological indicators as sterilization parameters.[2] Upon use of the equipment, we initially have to validate and state that the equipment is utilizable. This can be achieved using the rapid readout biological indicator and chemical strip indicator.[2,4]

There are two types of chemical indicators, which are the external chemical indicator and internal chemical indicator. The chemical indicator uses a sensitive chemical compound to assess physical conditions such as temperature throughout the sterilization process. The internal chemical indicator should be placed in each sterilization packaging to ensure that the sterilization agent penetrates and truly reaches the instruments. An external chemical indicator is used when the internal chemical indicators could not be observed from outside the package. These indicators change color after being exposed to a certain temperature. Resulting from this, the chemical indicator can verify that temperature is achieved and the sterilization process is successful.[4-6] The advantages of the chemical indicator are that it can give immediate information whether an object has undergone sterilization and whether the parameters or conditions required for sterilization is achieved.[4] Besides that, the chemical indicator can indicate specific information on each packaging. The disadvantage of the chemical indicator is that it cannot assure a sterile condition, but can only indicate that if an object has undergone sterility conditions in a process cycle.[4,5]

The biological indicator is a component in a through quality assurance program for sterilization in hospitals and health facilities as well as aseptic equipment installation qualification, process cycle development, quality assurance of sterilization programs and decalcification of sterilization equipment.[7] Until this moment, this indicator is the basic reference to determine if a sterilized condition is achieved. Taking into account the fact that the purpose of sterilization is to kill microorganisms. Therefore, there is no other clearer way of demonstrating the killing of microorganisms than the biological indicator.[6]

Rutala *et al.* have conducted research by comparing four types of biological indicator and five types of chemical indicators for wet heat sterilization at 121 °C to monitor the effectiveness of sterilization. The results show that after 48 h of incubation, the conventional biological indicators attest 1262, proof plus, assert and biosign each showing 100 %, 95 %, 88 % and 93 % percentage of spores living after 5 min of sterilization, 0 %, 0 %, 0 % and 8 % percentage of spores living after 10 min of sterilization and all 0 %