EFFECTIVENESS OF INTERNAL CHEMICAL INDICATOR IN THE FORM OF STRIPS FOR CLASS IV AND V USING STEAM STERILIZATION

Insan Sunan Kurniawansyah, Marline Abdassah
Faculty of Pharmacy Universitas Padjadjaran
Bandung, Indonesia
Phone number +628122320038
insan_fmunpad@yahoo.com
Villa Bandung Indah A6-9 Cileunyi-Bandung-West Java 40621 Indonesia

ABSTRACT

Infections through contaminated medical equipments are a serious threat to any patient's safety and can jeopardise this treatment or may lead to new illness. Such risk exposures has always been treated seriously by hospitals, to ensure every medical procedures are well monitored to mitigate any probability of such risk exposure. Sterilization process is a compulsory procedure to ensure sterility of medical equipments where chemical indicators are broadly used to monitor sterilization process. The purpose of this study is to determine the development of internal chemical indicators in the form of strips of class IV and V in the steam sterilization in order to obtain good and quality products. Internal chemical indicator strips able to provide visual verification on products that have passed through the sterilization process, with colour change on the indicator. The stages in this research has also included microbial contamination test Laminar Air Flow (LAF), dosage formulations NaCl 0.9% infusion, application of internal chemical indicator strips in the moist heat sterilization process and evaluation of NaCl 0.9% infusion that includes sterility test. This study was carried comprising 7 variations of time with data that shows a positive reaction for both indicators with a change of colour after 121 °C of sterilization. Sterility test shows no microbial growth starting from the sterilization time of 10.5 minutes. This research has successfully concluded that internal chemical indicator strips class IV and V are effective on steam sterilization at 121 °C for 10.5 minutes and can be used to monitor the sterilization process.

Key words: Internal Chemical Indicators Strips of Class IV and V, NaCl 0.9% Infusion, Steam Sterilization

INTRODUCTION

Since the 19th century, the developments on surgical science in European countries are advancing vastly. The main purpose of this development is to relieve symptoms and cure the disease, trauma and congenital abnormalities.[1] Surgery can only be performed in the presence of medical equipment such as syringes, needles, internal catheters, artificial heart valves, blood bags, scissors and many more.[2] The sterility of all medical devices must be maintained throughout the operation. The equipments must be cleaned and sterilized after usage. So, the cleanliness and sterility of the operating equipment must be taken care in order to avoid the occurrence of infections caused by microorganisms such as fungi, bacteria, spores and many more.[3] Central sterile supply department (CSSD) and the nurse in the surgical facility are responsible for cleaning, decontaminating and sterilizing medical equipment before and after usage. Sterilization of medical devices is important in wiping out all microbes and prevents further infection.[4]

Sterilization is the process of eliminating microorganisms physically, chemically and mechanically. This process is recommended to all medical devices such as surgical instruments, cardiac catheters, implantation tools, and needles used in surgery.[5,6,7] This process is very essential to ensure sterility of the instrument and to monitor the sterilization cycle.[8] The most common method used for sterilization of medical equipment is the steam sterilization process.[9] Steam sterilization which is also known as autoclave was first introduced by Charles Chamberland in 1880.[10]

Indicators are used in general to determine, validate and monitor tools which undergo sterilization process in order to obtain the quality assurance of the equipments used. Steam sterilization or autoclaving is not 100% effective in wiping out all microorganisms.[9] Thus, the effectiveness of each autoclave cycle should be monitored. Sterilization can be monitored by physical indicators, chemical indicators and biological indicators.[11]

Chemical indicators are divided into two types which are internal and external indicators. Chemical indicators use sensitive chemicals to assess physical conditions such as temperature during the sterilization process. Internal chemical indicator should be placed on each package to ensure sterilizing agent has penetrated the packaging material and actually reached the instruments inside the wrapped package. External indicators must be used when the internal indicator can't be seen from outside the package. These indicators changes color after being exposed to a certain temperature. Therefore these indicators can prove that sterilization has been achieved.[12]

According to Association for the Advancement of Medical Instrumentation, 1993 chemical indicators are divided into six classes. The classes are Class 1 (process indicator), Class 2 (Bowie-Dick test indicator), Class 3 (single-parameter indicator), Class 4 (multi-parameter Indicator), Class 5 (integrating indicator) and Class 6 (emulating indicator).[13]

A study was conducted by William A. Rutala in 1996 on the comparison between the four types of biological indicators and five chemical indicators using steam sterilization at 121 °C with the goal to monitor the effectiveness of steam sterilization.[14] In 2011, Marina Witari conducted a study to test qualification of the autoclave using indicators at temperature of 115 °C for 30 min and 121 °C for 15 min. This study showed no bacterial growth in the stock solution of NaCl 0.9% infusion. These studies also state that autoclave performance qualification test provides good results using sterilization process.[15]

Based on these findings, the aim of this study is to test the effectiveness of internal chemical indicator strips class IV and V using steam sterilization process.

MATERIALS AND METHODS

This study was conducted in several stages that includes preparation of equipments and materials, preparation of mediums consisting of Tryptic Soy Agar (TSA), Tryptic Soy Broth (TSB), and Fluid Thioglycollate Medium (FTM), microbial contamination test on Laminar Air Flow (LAF), preparation of NaCl 0.9% infusion, application of internal chemical indicator in the form of strip class IV and V using steam sterilization and sterility tests that includes fertility test and sterility test on NaCl 0.9% infusion and data analysis.

Preparation of equipments and materials

Equipments such as test tubes, measuring cylinder, glass beaker and rod sterile swabs are prepared. The glass tools that will be used were washed, dried, wrapped appropriately and sterilized at a temperature of 121 °C for 15 minutes. The entire process will be carried out aseptically in Laminar Air Flow (LAF) in which the room is sterilized using 70% alcohol and the room floor is cleaned using phenol. This LAF later irradiated with UV light for 2 hours before the usage.

Equipments sterilization

The glassware which will be used in this experiment are wrapped and sterilized by autoclaving at 121 °C for 15 minutes. Then, put the sterilized equipments in the oven at 150 °C for 1 hour.

Preparation of Test Mediums

Preparation of agar medium consists of:

1. Tryptic Soy Agar (TSA)
   A total of 10 grams of TSA was weighed and dissolved in 250 mL distilled water. Then, boiled and sterilize in an autoclave at a temperature of 121 °C, for 15 minutes.
2. Tryptic Soy Broth (TSB)
   A total of 15 grams of TSB were weighed and dissolved in 500 mL of distilled water. Then, boiled and sterilize in an autoclave at a temperature of 121 °C, for 15 minutes.
3. Fluid Thioglycollate Medium (FTM)
   A total of 14.75 grams of FTM weighed and dissolved in 500 mL of distilled water. Then, boiled and sterilize in an autoclave at a temperature of 121 °C, for 15 minutes.

Application of Indicators

1. Preparations of NaCl 0.9% infusion.

a) Formulation

Preparations which will be used for testing in this study are NaCl 0.9% infusions. This preparation will be prepared in the laboratory according to a formula contained in the Drug Formulation Manual. Based on the referred manual, each 100 mL contains sodium chloride 0.9%, activated carbon 0.1% and aqua pro Injectionum up to 100 mL.