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A comparative study on non-woven fabric and rigid container-based packaging system used in Central Sterile Supply Department: Experience from a cancer research centre in Eastern India

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Abstract:

The purpose of packaging materials used in health-care sterilisation processes is to provide a sterile barrier to protect the medical devices from outside contamination and maintaining sterility until it is used. The objective of this study is to inform the Central Sterile Supply Department technicians and infection control practitioners about the two different types of packaging system with their speciality, advantages and disadvantages so that an informed decision could be taken place before the procurement of these systems. The procurement of these systems would depend on the assessment of various factors such as material compatibility with sterilisation processes, safety features, microbial barrier efficacy, environmental impact and cost (initial investment and consumable cost).

Keywords:

Advantages and disadvantages, cost involvement, discussion on packaging materials, environmental impact, shelf life

Introduction

Packaging materials in Central Sterile Supply Department (CSSD) plays a very important role in the delivery of sterilised materials to the end users. The integrity and quality of the packaging are integral for safe delivery of sterilised items to the patients. Although a lot of emphasis is given to cleaning, disinfection and sterilisation of various materials in CSSD, not enough attention or information is available with regard to packaging of items to be sterilised.

The objective of this study is to review a comparison of two different types of packaging materials used for surgical set

packaging purposes so that an informed decision could be taken before procurement of these systems.

For example, rigid containers are basically made of by anodised aluminium and stainless steel (cover [lid], pressure valves and safety locks are made of by stainless steel). The boxes are fitted with gaskets, pressure valve and drain valve for steam penetration and draining purposes. There are no packaging materials required to wrap the container because it has a unique heat-sensitive locking system called 'thermo-lock'.^[1-3]

In addition, other containment devices such as stainless steel wire mesh baskets and

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polypropylene-based sterilisable plastic container also have been used for surgical set packaging purposes. However, these types of baskets are required to cover-up by non-woven fabrics for sterilisation purposes.^[1,2]

Case Report

Case study on two different types of packaging materials

1. For rigid container, there are two types of mechanisms used in sterilisation purposes such as reusable pressure valve mechanism and filter paper mechanism. The advantage of this packaging system is safety and security of surgical instruments and also reducing the reoccurring cost of packaging materials as consumable. Besides, a separate inner wire mesh basket helps to protect surgical instruments from severe damages and aseptically opening of the set.^[4]

There are several disadvantages of having rigid systems such as they are suitable only in vacuum assist steam sterilisation processes, continuous monitoring is required for cracks or damaged areas of the container, there is a need of changing valves and gaskets when required and they are of higher weight and high initial capital cost [Table 1].

Moreover, wet pack occurrence within the container is another problem due to poor sterilizer condition, humidity or temperature differences between inside and outside of the set especially when immediate unloading is done.^[5,6] To overcome the wet pack occurrences, it is required to either make sure that the absolute humidity at programme end is lower (cold and dry air to bring the sterilizer back to ambient pressure after load dryness) or have specially designed sterilisation programme for rigid container with deep vacuum and expanded drying time or by wrapping the insides of containers by non-woven fabric that resist re-condensing humidity to enter inside the container.

2. Non-woven fabrics are basically petroleum based and made of by polypropylene fibre with multilayer technology. Often, this fabric sheet has been called by Spun bond-Melt blown-Spun bond wrapper.^[7]

The term 'spun bond' implies where long endless filament with multiple crossover point which gives the product durability and puncture resistance. The term 'melt blown' implies uncrushable fibres providing a denser filtration barrier against microbial contamination of this wrapper. Finally, the two different sheets are mechanically compressed and used in different sterilisation purposes. In central processing, double wrapping of surgical set by non-woven fabric is required for aseptic opening of the surgical sets in OR areas.^[8,9]

There are certain advantages of sterilisation wrappers such as their sterilisability by all three types of sterilisation system. The standard pore size of this wrapper is 0.3 microns (similar to high-efficiency particulate air filter) that gives excellent barrier filtration from outside environment. Several test methods are performed to check the effectiveness and quality of the packaging materials such as (a) sterilising agent penetration and air removal test, (b) resistance of fibres to abrasion, (c) microbiological barrier test that consist of 'event-related sterility assurance' and 'dry spore challenge test', (d) tensile strength of the fibre, (e) liquid repellency test, (f) tear resistance include 'internal tear resistance' and 'burst strength', (g) test of elongation peak strength and (h) chemical tests such as 'pH of hot water extract' and 'chloride and sulphate content test'.^[10]

Disadvantages of packaging materials include problems related to waste disposal (being petroleum-based products unless they are disposed as per the regulatory requirement of local pollution control boards they may represent significant environmental pollution hazards).

Table 1: Cost involvement of both types of packaging materials used in Central Sterile Supply Department at Tata Medical Centre, Kolkata

Cost of instrument baskets		Cost in INR (per container)	
One time cost			
Stainless steel wire mesh baskets (e.g., Aesculap)			50,000
Polypropylene-based plastic container (e.g., Johnson and Johnson)			20,000
Rigid container (e.g., Wagner)			200,000
Disposable non-woven fabric	Cost in INR (per piece)	Cost of rigid container accessories	Cost in INR (per piece)
Recurrent (consumable) cost			
SMMS wrapper 91 cm × 91 cm	20.5	SMMS wrapper 101 cm × 101 cm	31.5
SMMS wrapper 101 cm × 101 cm	31.5	Filter paper	28.9
SMMS wrapper 121 cm × 121 cm	49.5	Gaskets and reusable valves	Rarely used

INR: International normalised ratio; SMMS: Spun bond-Melt blown-Melt blown-Spun bond

Sterility for these two types of packaging system is event related. Estimation of shelf life is a complex method that depends on many factors as follows: (a) stability of medical devices that has been packed, (b) quality of packaging materials, (c) method of sterilisation, (d) handling and transport system, (e) storage condition and (f) number of times the sterile materials have been touched. According to a Dutch study, it has been observed that container-based packaging system is comparatively better than disposable wrappers to increase shelf life when the all above parameters are the same.^[11]

Discussion

Packaging materials are of paramount importance in maintaining sterility of products until they are used. We have observed that wrapping of surgical set by non-woven fabric is a better alternative than rigid container because that can be used in different sterilisation processes (though rigid container system is better for modern autoclave-based technology, reducing consumable cost, better shelf life, good for storage and transport and also safety and security of the instruments). However, continuous monitoring of the expensive sterilisation containers for any damages, unavailability of costly accessories and limited warranty are the allied problems that affect rigid sterilisation containers. Moreover, in many coastal areas of the Indian subcontinent, ambient air is full of moisture that increases wet pack occurrences and compromises the sterility assurances in rigid sterilisation containers. Finally, most of the hospitals in India are overcrowded with plenty of surgeries where prolonged shelf life is not required because sterile sets are used within a week. Therefore, in our opinion, non-woven fabric is a better and cost-effective selection among the two options discussed in the India context, where high initial investment may not be economically feasible for most health-care institutions.^[12]

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Conflicts of interest

There are no conflicts of interest.

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