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Study on Assessment of Sterility of Foley Catheters, Intravenous Cannulas and Intravenous Infusion Sets used in Peshawar, KPK

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To evaluate the microbiological sterility of selected disposable medical devices. Random samples of selected articles were obtained from open market and tertiary care hospitals in Peshawar, KPK. The Pharmaceutical sterility of these randomly sampled articles was assessed using United States Pharmacopoeia's standards for the sterility tests. The tests for evaluation of sterility were carried out in controlled aseptic environment using standard procedures and equipment. In case of Foley catheters 25% of total samples showed microbiological growth, intravenous cannula exhibited 33.3% microbial presence; while in case of intravenous infusion sets 83.3% samples appeared non-sterile. Foley catheters and intravenous infusion sets indicated bacterial growth while for intravenous cannula both bacterial and fungal growths were detected. Chances of microbiological contamination in disposable articles available in market are quite ample. It is therefore recommended that pharmaceutical manufacturers of such articles must strictly comply to GMP guidelines specially for sterilization in order to prevent local and systemic infection complications.

Key words: Foley Catheters, Intravenous Cannula, Intravenous Infusion Sets, Ethylene oxide sterilization.

Disposable medical devices or single use medical devices such as electro cardio graphic pads, catheters, glucose test strips, syringes, are meant are to be used upon single patient and for a single procedure[1]. As per guidelines of centre for disease control (CDC) for infection control in health care personnel, 1998; the medical devices that enter normally sterile tissues or the vascular system or through which blood flows should be sterilized before use. Sterilization is the use of physical or chemical means to destroy all microbial life, including highly resistant bacterial endospores[2].

Catheters are thin flexible tube extruded from medical grade materials that can be inserted in body tissues (cavity, duct or vessel) for multiple functions, like drainage and administration of fluids or access by surgical instruments[3]**.** Due to this reason they have become an essential part of hospital based, outpatient and home healthcare settings. Foley catheters are generally used to access the urinary tract, while intravenous cannula and intravenous infusion sets are most commonly used intravenous access devices in both hospital and pre-hospital services.

Ethylene oxide (EO) and ionizing radiations are the common methods of sterilization of medical devices are being used[4,5]. However, in Pakistan, especially Khyber Pakhtoonkhwa (KPK), mostly EO sterilized catheters and intravenous infusion sets are available in open market, although some imported gama sterilized brands are also available.

Since catheters and intravenous infusion sets are necessity of healthcare settings and most frequently used disposable devices; but if these

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devices are not properly sterilized, their use can put patients at risk for local and systemic complications; including local site infection, CRBSIs (catheter related blood stream infections), septic thrombophlebitis, endocarditis, lung abscess, osteomyelitis; depending on the body site where it is used. Epidemics of device-related infectious diseases appear to have increased in number since 1965, and most often have been related to Foley catheters, intravenous infusion devices (I/V Cannula, I/V Infusion Sets). Foley catheters and intravenous infusion devices represent major sources of nosocomial septicemia[6,7]. Since disposable medical devices like catheters and needles are in direct contact with human tissue and organs and they must be sterile prior to use in order to prevent related infectious consequences.

In Peshawar (KPK), various types of catheters are available in poly bag and blister packaging, with different sizes for adult and pediatric patients and are used in hospital and outpatient healthcare settings. The purpose of this study is to evaluate the sterility of these articles (Foley catheter, IV cannula, and IV Infusion sets) used in hospital and outpatient health care settings.

MATERIALS AND METHODS

Sampling

Samples in triplicate of Foley catheter, IV cannula, and IV Infusion sets of commonly used sizes were randomly purchased from open market and hospital pharmacies of all manufacturers available in Peshawar, KPK. Both poly bag and blister packed samples were collected that were either EO sterilized or gamma radiation sterilized. The details had been summarized in Table 1.

Media & other chemical substances

The sterility tests were carried as per guidelines of United States Pharmacopoeia[8] for the evaluation of pharmaceutical sterility of selected articles. Briefly, two media types were used i.e. Fluid Thioglycollate medium (FTM) and Soybean-Casein Digest Medium (SCD). Media were sterilized as per manufacturer guidelines and verified for sterility prior to use. Gram staining of the bacterial growth was done. Endospore presence was evaluated using Schaffer-Fulton method. Articles as whole or selected parts were aseptically immersed completely in prescribed media (FTM and SCD) simultaneously. Immersed samples were incubated at 37'C and observed for bacterial growth overnight and then after 48 hours. Similarly, samples were incubated at 25 ^{o}C for 7 days to check fungal growth. Blank media served as negative controls for both kinds of tests. All the tests were done in triplicate. Tests were repeated for the samples showing either bacterial or fungal growth as per pharmacopoeia guidelines.

Characterization of Microbial Growth

Gram's and Endospore staining[9] were carried out on the samples showing bacterial growth after 24 or 48 hours incubation.

RESULTS AND DISCUSSIONS

Foley Catheters

It was observed that 6 out of 24 samples (25%) of Foley Catheters showed microbiological (bacterial) growth, summarized in table 2.

The microbial growth was observed only in samples of foreign manufacturers. No fungal

Table 1. Description of selected samples for the study

S. no	Article description	Packaging material included	Sizes included	Claimed method of sterilization
1	Foley Catheters *(n = 8)	5 blister & 3 poly bag	8, 16, 18, 20 & 22 (French size)	5 EO & 3 radiation sterilized samples were included
2	I/V Cannula (n = 6)	Only blister pack	20, 22 & 24 (Gauge)	All samples were EO sterilized
3	I/V sets (n = 6)	2 blister & 4 poly bag	NA	All samples were EO sterilized

*Number of manufacturers
NA = Not applicable

growth was seen only bacterial growth (gram positive rods) was observed. Samples of only two manufacturers showed growth, of which one was blister packed EO sterilized while other one was blister packed radiation sterilized of different manufacturer.

Although no microbiological contamination had been observed in hospital samples (foley catheter), there are chances of contamination because all Foley catheters used in hospital setups are poly bag packaged, which are more prone to contamination during sealing stage of poly bag in pharmaceutical sterilization plant; as these catheters unlike blister packed materials are sterilized unwrapped because a conventional outer package (envelope or pouch) for use with ethylene oxide sterilization processes typically has a top clear polymer film which is gas impervious

Table 2. Description of Foley Catheter samples and developed microbiological growth after prescribed incubation period

S. No.	French size (Fr)	Manufac-turer	Bacterial growth after 24 hours (part)	Bacterial growth after 48 hours (part)	Gram Staining	Endospore Presence	Fungal Presence	Packaging	Claimed Sterilization method
1	8	Local	Absent	Absent	Negative	Absent	Absent	Poly Bag	EO
2	18	Foreign	Absent	Absent	Negative	Absent	Absent	Poly Bag	EO
3	8	Foreign	Absent	Absent	Negative	Absent	Absent	Poly Bag	EO
4	16	Foreign	Present (in Balloon part)	Absent	G +ve rods	Absent	Absent	Blister	EO
5	20	Foreign	Absent	Absent	Negative	Absent	Absent	Blister	EO
6	22	Foreign	Absent	Present (in middle tube)	G +ve rods	Absent	Absent	Blister	Radiation
7	20	Foreign	Absent	Absent	Negative	Absent	Absent	Blister	Radiation
8	22	Foreign	Absent	Absent	Negative	Absent	Absent	Blister	Radiation

Table 3. Description of Intravenous Infusion Set samples and developed microbiological growth after prescribed incubation period

S. No.	Manu-facturer	Bacterial growth after 24 hours (part)	Bacterial growth after 48 hours (part)	Gram Staining	Endospore Presence	Fungal Presence	Packaging	Claimed sterilization method
1	Local (in piercing device)	Present	Absent	G +ve cocci	Absent	Absent	Blister	EO
2	Foreign	Absent	Absent	Negative	Absent	Absent	Poly Bag	EO
3	Foreign (in drip chamber)	Present	Absent	diplococci	Absent	Absent	Poly Bag	EO
4	Foreign	Absent	Present (in needle assembly)	G +ve cocci	Absent	Absent	Poly Bag	EO
5	Foreign (in drip chamber)	Present	Absent	G +ve rods	Absent	Absent	Poly Bag	EO
6	Foreign	Absent	Present (in needle assembly)	G +ve cocci	Absent	Absent	Blister	EO

and then sealed. So chances of microbial contamination may happen if a sterile item is exposed longer in air.

Intravenous Infusion Sets

In case of Intravenous infusion microbial growth was observed in 15 out of 18 (83.3%) samples (table 3).

In case of intravenous infusion sets samples of 5 manufacturers, viz, four foreign and one local manufacturer developed microbial growth. Here as well no fungal growth was seen, only bacterial growth was observed. Samples of two manufacturers were blister packed and that of three manufacturers were poly bag packed; and claimed method of sterilization of all manufacturers was EO.

Intravenous Cannula

Microbial growth was observed in 6 out 18 samples (33.3%) of intravenous cannulas (3 samples bacterial and 3 fungal growth), summarized in table 4

Microbial growth was detected in samples of two manufacturers. In testing of I/V Cannula, it was observed that one of the manufacturer's samples developed fungal growth that reappeared when the sample was retested. Bacterial growth was observed in only one manufacturer's samples, however no growth was observed in local manufacturer's samples. All samples were blister packed and EO sterilized. No endospores were seen in any positive samples after prescribed incubation period. Its assessed that in case of intravenous cannula and foley catheters manufactured locally, no microbial growth was observed.

Most of the selected samples were claimed to be ETO sterilized, and its known that certain parameters such as gas concentration, temperature, relative humidity (as water molecules carry ETO to reactive sites) and exposure time influence the effectiveness of ETO sterilization[4, 10, 11]; and interestingly it was found in our study that all samples resulted in positive microbial growth were claimed to be ETO sterilized. The effectiveness of ETO sterilization can be altered by lumen length, lumen diameter, inorganic salts, and organic materials[12, 13]. For example, several studies have shown failure of ETO in inactivating contaminating spores in endoscope channels[14] or lumen test units[13], and residual ETO levels averaging 66.2 ppm even after the standard degassing time[15]; that's why cleaning of the items intended to be sterilized must be carried out before processing, because it reduces the bioburden and removes foreign material (i.e., organic residue and inorganic salts) that interferes with the sterilization process by acting as a barrier to the sterilization agent [16, 17].

Multiple studies in many countries have evaluated lack of compliance with established guidelines for disinfection and sterilization[18] and failure to comply with scientifically based guidelines has resulted in many outbreaks of infection[19, 20]. Biofilms have been found and reported in urinary catheters, central venous catheters, and numerous medical devices[21]. This argument also supports our findings and that their presence can have serious implications for immune-compromised patients and patients who have indwelling medical devices.

Table 4. Description of Intravenous Cannula samples and developed microbiological growth after prescribed incubation period

S. No	French size (G)	Manu-facturer	Bacterial growth after 24 hours (part)	Bacterial growth after 48 hours (part)	Gram Staining	Endospore Presence	Fungal Presence	Packaging	Sterilization method
1	20	Local	Absent	Absent	Negative	Absent	Absent	Blister	EO
2	22	Local	Absent	Absent	Negative	Absent	Absent	Blister	EO
3	24	Foreign	Absent	Absent	Negative	Absent	Absent	Blister	EO
4	20	Foreign	Absent	Absent	Negative	Absent	Positive, mold	Blister	EO
5	22	Foreign	Absent	Absent	Negative	Absent	Absent	Blister	EO
6	24	foreign	Absent	Present (in catheter tube)	G +ve cocci	Absent	Absent	Blister	EO

The shortcomings of this study include the limited pool of sample selection. Before this report no such work had been conducted in this regard in the region, so no comparison was made to such other studies. So additional research is needed for the evaluation of pharmaceutical sterility of such disposable medical devices which has been previously claimed as sterilized; as the non-sterility of such articles can lead to complicated infectious consequences

CONCLUSION

It has been concluded that there are chances of microbiological contamination in such disposable articles, so the pharmaceutical manufacturers of such articles must comply to the SOPs and GMP guidelines more precisely. Similarly before bulk purchase of such articles in hospital setups and even community setups, the quality control testing of random samples must be carried out to ensure the sterilization of these disposable items, and so to prevent the chances of local and systemic infections.

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