THE EFFECT OF GAS STERILIZATION ON ANGIOGRAPHICALLY USED CORONARY CATHETERS

Thesis
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In Cardiology

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ABSTRACT

The study was done to know the efficiency of cleaning and sterilization using EO gas on the reused cardiac catheters.

500 catheters divided into two groups used for 158 patients were included.

EO was found to be effective method for different cardiac catheters resterilization and that there is no risk of cross bacterial infection provided that strict sterile and hygienic measures were followed in the catheterization procedure and cleaning and sterilization protocols were strictly followed.

Key words: Cardiac catheters, coronary catheters sterility, catheter reuse, cross infection.

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ABBREVIATIONS

PTCA	:	Percutaneous Transluminal Coronary Angioplasty
FDA	:	Food and Drug Administration
US	:	United States
EO	:	Ethylene oxide
AAMI	:	Association for the Advancement of Medical Instrumentation
SAL	:	Sterility assurance level
CFC	:	Shloroflourocarbon
HCFC	:	Hydrochlorofluorocarbons
OSHA	:	Occupational Safety and Health Administration
PEL	:	Permissible exposure limit
TWA	:	Time-weighted average
CO2	:	Carbon dioxide
EPA	:	Environmental Protection Agency
DNA	:	Deoxyribonucleic acid
RNA	:	Ribonucleic acid
B. subtilis	:	Bacillus subtilis
HIV	:	Human Immunodeficiency Virus
SCAI	:	Society for Cardiovascular Angiography and Interventions
CDC	:	Centers for Disease Control
CHG	:	Chlorhexidine gluconate
PCI	:	Percutaneous Coronary Intervention
VCDs	:	Vascular closure devices
CBC	:	Complete blood count
CAD	:	Coronary artery disease
TLC	:	Total leukocytic count
LV	:	Left ventricle
SWMA	:	Segmental wall motion abnormality
LVH	:	Left ventricular hypertrophy
LA	:	Left atrium
JR	:	Judkin right catheter
JL	:	Judkin left catheter
Staph.aureus	:	Staphylococcus aureus
E.choli	:	Escherichia coli
HTN	:	Hypertension
DM	:	Diabetes mellitus
MI	:	Myocardial infarction
UA	:	Unstable angina
NSTEMI	:	Non ST segment elevation myocardial infarction
DCM	:	Dilated cardiomyopathy

SA	:	Stable angina
STEMI	:	ST segment elevation myocardial infarction
Y	:	Yes
N	:	No

INTRODUCTION

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Cardiac catheters have become an essential element of current cardiovascular practice with several hundred thousands used each year in both diagnostic and intervention procedures.

By 1997, over one million angioplasties were performed worldwide, making angioplasty the most common medical intervention in the world. By 2001, almost two million angioplasties were performed worldwide, with an estimated increase of 8% annually.[1, 2, 3]

Cardiac catheters are increasingly being reused as hospitals attempt to cut costs. The general progression of device reuse seems to follow rather directly the rise in the expense of medical equipment and procedures. For example, in 1976, only 14% of United States hospitals reported reusing single-use devices, while in 1982, 90% of hospitals admitted practicing reuse. [4]

It is generally recommended that medical devices labeled "single use only" should not be reused, but controversy arises because of their high cost and the belief that using them once only is wasteful as well as environmentally unsound.[5,6]

The United States Food and Drug Administration (FDA) maintains that there is a lack of data to support the general reuse of disposable devices.[7] They consider that an institution or a practitioner reusing disposable medical devices should be able to demonstrate that they can be adequately cleaned and sterilized; and that the device will remain safe and effective for its intended use. In addition, the FDA believes that

institutions or practitioners who reuse devices must bear full responsibility for their safety and effectiveness. [8]

Reuse of various medical devices, labeled for single-use only, has become common practice in many countries of the world, especially in developing countries, where the primary motive is cost containment coupled with the possibility of treating a larger population of patients. Many hospitals reprocess and reuse disposable medical devices such as haemodialyzers, intra-aortic balloons, syringes, biopsy forceps, and various types of catheters.[9-15] This practice raised increasing concern regarding the additional risks to the patients due to contamination by infectious,[16-19] toxic[20, 21] or other possibly adverse substances,[21,22] or as a result of biological incompatibility or breakage of the medical devices. [23]

The decision to reuse such instruments should be taken openly and protocols giving precise details of all aspects of the process should be formally approved, kept available and regularly updated as new catheters and new materials come into use. [24]

AIM OF THE WORK

To study the efficiency of standard cleaning and sterilization using ethylene oxide gas on the elimination of infectious bacteria that can be transmitted by practicing reuse of cardiac catheters.

CHAPTER I

BENEFITS AND RISKS OF REUSING CARDIAC CATHETERS

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A) Benefits of reusing cardiac catheters:

Cost saving to hospitals and patients is the primary goal of reuse. It is estimated that five reuses of each diagnostic catheter and three reuses of each angioplasty catheter should result in net saving of approximately 5000$ and 100.000$ per hundred procedures respectively. [24]

If just 1% or 2% of all the disposable medical devices used in the US today were reused, the health care industry would save a billion dollars every year.[25]

Interestingly, reprocessors state that the reprocessing industry has forced manufacturers to lower the prices of new products to compete with reused single use devices, resulting in an additional cost savings for health care facilities. (The opposite, however could occur if the reusable device manufacturers increased prices to compensate for the lost revenue from reused single use devices). The manufacturers also could change or improve the product's design to compensate for the lost revenue, thereby increasing demand for the improved product, which raises the cost of the item. [26]

One source found that, if health care facilities took full advantage of the practice of reuse, they could save $ 700 million per year because the typical reused device costs approximately one-half that of a new