

관동맥 풍선도자 재사용의 안전성과 유효성

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김 종 진

The Safety and Efficacy of Reusing Single-Use Coronary Balloon Catheter

Chong-Jin Kim, MD

Department of Internal Medicine, College of Medicine, The Catholic University of Korea, Seoul, Korea

ABSTRACT

A series of studies were reviewed to determine the safety and efficacy of reusing single-use coronary balloon catheters. The coronary balloon catheter is marketed as a single-use device. However, due to its high expense and the demands for containment of health care costs many medical institutions in various countries of the world are cleaning and resterilizing it for reuse. The US FDA does not prohibit reuse, but does place the burden on the physician and hospital to demonstrate that the balloon catheter is properly cleaned and sterilized, retains the physical characteristics of the original, and is safe and effective. The major concerns in the reuse of single-use balloon catheters regard the various potential risks to patients, in comparison with new balloon catheters, such as infection, toxicity, contamination, biologic incompatibility, decreased mechanical performance, device breakage, and poor clinical outcomes. To date, the risks for patients have been considered acceptable as long as the rigorous procedures related to cleaning, sterilization, and quality controls were well established. However, it is considered that further. The large sample sized, randomized, prospective, multicenter, multinational clinical trials need to be conducted to establish a rigorous, well-defined protocol for the validation of cleaning, sterilization, and quality control, in order to guarantee the safer reuse of coronary balloon catheters. Furthermore, the establishment of new, open door, standardized guidelines for the reuse of balloon catheters is urgently needed in Korea. (**Korean Circulation J 2002;32(5):381-384**)

KEY WORDS : Equipment reuse ; Angioplasty, balloon ; Safety ; Heart catheterization.

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E - mail : cjkim@sph.cuk.ac.kr

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중심 단어 : ; ; ;

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