Guest Editorial

Is It Safe to Reuse Single-Use Catheter for Diagnostic and Therapeutic Electrophysiological Procedures?

HUNG-FAT TSE, KATHY LAI-FUN LEE, RAYMOND HON-WAH CHAN, CHU-PAK LAU

From Cardiology Division, Department of Medicine, Queen Mary Hospital, The University of Hong Kong, Hong Kong

Clinical cardiac electrophysiological (EP) procedures have been increasingly used for the diagnosis and treatment of cardiac arrhythmias. During the procedure, 3-6 cardiac catheters, which incorporate platinum electrodes are used to record electrical signals or pace the heart. These EP catheters are solid nonluminal designs without any hollow inner core. Some special EP catheters have deflection mechanisms used to deflect the tip to help guide the catheter to a specific target for mapping and/or delivering radiofrequency energy for curative ablation procedure. The early experience showed that EP catheters were quite durable and could be sterilized for reuse, as has been the practice for many surgical instruments. The obvious motives was to reduce cost and eliminate the waste of catheters that could be reused without compromising patient safety. However, reusing catheters can potentially lead to several adverse consequences, including introducing infectious organisms, pyrogens, or toxin or particles into the patients' body. There is an inherent risk of catheter breakage and bioincompatibility. Therefore, it is important to balance against the risks and cost-effectiveness of reusing EP catheters.

Address for reprints: Dr. Hung-Fat Tse
Cardiology Division, Department of Medicine, The University of Hong Kong, Queen Mary Hospital, 102 Pokfulam Road, Hong Kong

Tel: (852) 2855 3598, Fax: (852) 2855 1143

O'Donoghue et al[1] performed a retrospective study in 12 medical centers to evaluate the risk of infection associated with reusing EP catheters. The incidence of infection related to a total of 14,640 EP procedures involving 48,075 catheter uses was reported. The prevalence of superficial skin infections (0.018% vs. 0.03%) or bacteremia (0.002% vs. 0.03%) was not significantly different in the catheter reuse group compared to the single use group. In a prospective study, Dunnigan et al[2] evaluated catheter reuse over a five-year period during which 178 catheters were used 1,576 times for 847 EP procedures. Detailed records of catheter testing and use were maintained. No complications were encountered during the study period. All reused catheters functioned for cardiac pacing and recording of cardiac electrical signals. Surveillance cultures and biologic indicators revealed that adequate sterilization procedures were used. The results of these studies demonstrated that the risks of infection related to EP studies was extremely low, sterilization and reuse of the catheters did not result in any increase in the risk of infection and the practice of reusing catheters would result in substantial cost savings to hospitals.

The studies mentioned above were conducted in patients undergoing diagnostic EP studies before the advent of deflectable catheters and arrhythmia ablation procedures. Avitall et al[3] prospectively investigated the time course of electrical, physical and mechanical changes in ablation catheters to determine the effect of reuse of such catheters on safety and efficacy. The study included 69 ablation catheters made by a single manufacturer that were used in 336 procedures. Testing of physical integrity consisted of visual and stereoscopic examination of handle function, catheter shaft and the deflectable tip. The electrical integrity of the catheters

was measured by electrical resistance from the handle connector to the recording rings and to the tip electrode. Deflection and torque measurements were made to assess mechanical integrity. During this study, 52% of catheters were rejected due to mechanical or electrical failure. The most common reasons for catheter rejection were tip electrode glue separation after an average of 4.3 uses and loss of deflection after an average of five uses. Electrical discontinuity was observed after an average of 10 uses. There was no significant decrease in catheter torquing ability that determines the steering responsiveness of the catheter. Aton et al[4] evaluated the effects of reprocessing on mechanical integrity, sterility, and chemical residuals of EP catheter. A total of 12 commercially available catheters were randomly selected from the catheter inventory of the clinical EP laboratory after being used one to four times. They were manually cleaned, repackaged, and gas sterilized with ethylene oxide. To assess the sterility of reused catheters, three were cut into two-inch segments, placed in bacterial culture media, and incubated for five days. The catheters were analyzed for chemical residuals after gas sterilization and evidence of component failure. Visual inspection and microscopy were used to determine mechanical integrity of the catheter surface, and X-ray inspection was performed to assess interior structures. The results showed no bacterial growth detected on any of the cultures, which indicated that reprocessed EP catheters are effectively sterilized. Microscopic examination of reprocessed catheters demonstrated inconsequential metal and fiber particulates on the catheter surface and at some electrode-catheter interfaces. The shaft of the catheters and the electrodes remained intact. There was no evidence of electrical discontinuity, and the integrity of internal structures was confirmed by X-ray inspection. Blomstrom-Lundqvist[5] evaluate the safety of reusing ablation catheters with temperature control which are commonly used for catheter ablation. The catheters were tested for surface defects using a magnification glass, impedance measurements, evaluation of the catheter deflection capability, and the integrity of the thermistor and thermocouple. A total of 41 (55%) catheters were rejected after a mean of 9 uses (range 1-31). The main reasons for rejection were inaccurate temperature measurements by the thermistor or thermocouple (19%), breakage of, or defect in the internal pulling wire (12%), loss or disturbance of electrogram (9%), and loss of deflection capability (8%). The reuse of the catheters has not resulted in any major catheter failures or any major adverse clinical complications. There were no local or systemic infections. In Queen Mary Hospital, Hong Kong where the first radiofrequency catheter ablation was performed in Asia in 1990,[6] catheter reuse has been practiced for the last 13 years, and with nearly 5000 EP and catheter ablation procedures, we have not had issues on catheter breakage or patient infection due to the reuse of EP catheters.

As discussed above, both retrospective and prospective studies have demonstrated that both EP diagnostic and ablation catheters can sustain repeated uses and resterilizations without untoward harm to the patient. The risk to patients associated with reusing EP catheters is inconsequential relative to the overall risk of these procedures. Policies that prohibit the reuse of EP catheters will not have an appreciable impact on the risks of these procedures, but they will certainly increase the costs. However, for those centers which catheters are reprocessing, it is important that a thorough validation protocol and guidelines for quality control and rejection of catheters are used. This is to ensure that all the reuse EP catheters are meticulously cleaned, sterilized, and inspected in accordance with accepted standards of practice.[7]

References

1. O'Donoghue S, Platia EV. Reuse of pacing catheters: a survey of safety and efficacy. Pacing Clin Electrophysiol 1988;11:1279-80.
2. Dunnigan A, Roberts C, McNamara M, et al. Success of re-use of cardiac electrode catheters. Am J Cardiol 1987;60:807-10.
3. Avitall B, Khan M, Krum D, et al. Repeated use of ablation catheters: a prospective study. J Am Coll Cardiol 1993:22:1367-72.
4. Aton EA, Murray P, Fraser V, et al. Safety of reusing cardiac electrophysiology catheters. Am J Cardiol 1994;74:1173-5.

5. Blomstrom-Lundqvist C. The safety of reusing ablation catheters with temperature control and the need for a validation protocol and guidelines for reprocessing. Pacing Clin Electrophysiol 1998; 21:2563-70.
6. Lau CP, Tai YT. Transvenous radiofrequency catheter ablation of atrioventricular accessory pathways. Singapore Med J 1991; 32:52-7.
7. Lindsay BD, Kutalek SP, Cannom DS, et al. Reprocessing of electrophysiology catheters: clinical studies, regulations, and recommendations. A report of the NASPE Task Force on Reprocessing of Electrophysiological Catheters. North American Society of Pacing and Electrophysiology. Pacing Clin Electrophysiol 2001;24(8 Pt 1):1297-305.