The Effects of Multiple Reprocessing of Radiofrequency Ablation Catheters on their Electrical Integrity

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Summary

Radiofrequency catheter ablation is a frequently used, first-line therapy for many tachyarrhythmias, and has won worldwide acceptance. However, clinical studies have detected problems, including a failure in the catheter's electrical integrity, after five to ten reuses. The present study analyzed the effect of multiple reuses and resterilizations of ablation catheters in a controlled experimental context. Five catheters were used the following way: electrical resistance was measured in all poles, ablation was performed (seven applications, power = 42 W, duration = 22 s), and the catheters were sterilized in 12% ethylene oxide. The same process was repeated 11 times for each catheter. By the end of the experiment, each had been used 12 times. All measurements during the study ranged in normal limits (< 5 Ω); the highest resistance found was 2.5 Ω. No difference was observed related to reuse. Also, no difference was observed comparing ablation (distal, 4 mm) and sensing (proximal, 2 mm) poles. In conclusion, the study showed that multiple reuses and sterilizations using 12% ethylene oxide does not damage the electrical integrity of these catheters in a controlled experimental environment.

Key Words

Catheter reprocessing, resterilization, radiofrequency ablation, electrical resistance

Introduction

Radiofrequency catheter ablation is a well-known procedure and first-line therapy for most tachyarrhythmias, including AV nodal reentrant tachycardia, Wolff-Parkinson-White Syndrome, and atrial flutter [1,2]. During this procedure, catheters are introduced into the heart for mapping and ablation; the number of applications, duration, and temperature vary according to the procedure performed and the medical center. Since many catheters are commonly used in these procedures, the issue of reusing them has continued to be an object of debate. Catheters are labeled as single-use devices because of the possibility that reuse could increase the risk of infection and catheter malfunctioning. On the other hand, this would decrease costs, and increase the cost-effectiveness of each procedure.

Although electrophysiologic catheters are intended for single-use only, they are nevertheless reused in numerous centers around the world, not just in developing countries [3]. Because of the importance of this issue, it has become a concern of NASPE as evidenced by its drafting of a policy statement on the subject [4]. NASPE adheres to the principle that the reuse of catheters is a safe and cost-effective practice, provided that they are meticulously cleaned, sterilized, and inspected. The exception is when catheters have been used in patients with human spongiform encephalopathies, such as Creutzfeldt-Jakob disease, since current reprocessing methods are not sufficient in eliminating contamination that is transmittable to other patients [5,6]. To assess catheter integrity, the physical (handle function, catheter shaft, deflectable tip), mechanical (deflection and torque), and electrical (resistance) aspects of the effects of reprocessing should be determined.

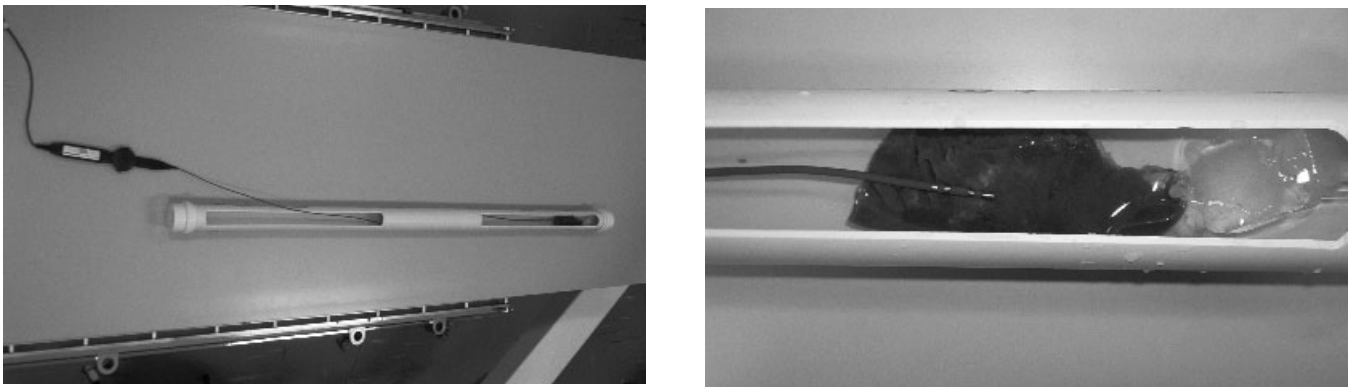

Figure 1. Panel a) Catheter and container; Panel b) amplified catheter tip, ice, and cow's heart.

Some studies have focused on analyzing the sterility and catheter integrity of diagnostic electrophysiology [7-9] and deflectable radiofrequency ablation [10] catheters used in clinical practice, revealing adequate results in most cases. However, catheters were frequently rejected after four to five uses, and electrical discontinuity was observed after ten uses [11-13]. The present study evaluated the effects of multiple reprocessing and reuse of modern deflectable catheters in a controlled environment.

Materials and Methods

For this experiment, five new radiofrequency ablation catheters (Alcath, Biotronik, Germany) were used. Each was inspected visually, resistance was measured in its four poles (digital multimeter MD-5770; LCEL-Gubintec, Brazil), the ablation procedure was performed, and then the catheter was reprocessed. Each of the catheters was subjected to these procedures twelve times.

Radiofrequency ablation was performed in vitro using a plastic container (5 cm diameter; 120 cm in height) containing a cow's heart. Because there was no circulating flow within the container, the temperature was kept at approximately 10 °C by filling it with saline and ice (Figure 1). The ablation catheter was positioned inside the container, and the distal electrode (4 mm tip) was placed horizontally over a section of cow's heart. A radiofrequency generator (AbControl MDS, Biotronik) was then connected to the catheter and programmed to the mean parameters found in 33 ablation procedures that were randomly chosen and performed at the Hospital de Clínicas de Porto Alegre, Brazil. The details of each procedure are as follows:

	Pole 1 (Ω)	Pole 2 (Ω)	Pole 3 (Ω)	Pole 4 (Ω)
Catheter 1	2.1	2.1	2.1	2.1
Catheter 2	2.2	2.2	2.1	2.1
Catheter 3	2.1	2.3	2.3	2.3
Catheter 4	2.1	2.1	2.1	2.1
Catheter 5	2.0	2.0	2.0	2.0

Table 1. Initial resistance measurements at each pole of each ablation catheter.

	Pole 1 (ablation)	Pole 2	Pole 3	Pole 4
Initial resistance (Ω)	2.1	2.1	2.1	2.1
Final resistance (Ω)	2.2	2.2	2.2	2.2
Λ resistance (Ω)	0.1	0.1	0.1	0.1
Maximum resistance (Ω)	2.4	2.5	2.5	2.5

Table 2. Mean results in resistance measurements at different poles.

- Number of applications: 7;
- Power: 42 W;
- Time required for each application: 22 s;
- Maximum temperature: 80°C

After each session, consisting of seven applications, the catheters were inspected visually for integrity, and impedance was measured at each electrode pole. Then, the catheters were cleaned and resterilized using ethylene oxide, the same process used for catheters in clinical practice. After reprocessing, this protocol was repeated eleven times. By the conclusion of the assessment, each catheter was used, reprocessed, and had

impedance measured 12 times for each electrode pole. Resistances measured over time were compared statistically. Whenever a change in resistance was ≥ 5 Ω, it was regarded as a problem [14].

Results

All catheters showed visual and mechanical integrity in the initial evaluation. Internal resistance measurements performed on each pole revealed that all catheters were in adequate condition. Results ranged from 2 to 2.3 Ω (Table 1), and resistance measurements over time revealed no significant change related to ablation and reprocessing. Initial, final, variation, and maximal impedance measurements remained in normal ranges (Table 2). Eventually, small variations were observed, probably related to the imprecision of some measurements. Another important discovery is that no difference was observed comparing the pole used for ablation (pole 1: 4 mm) and poles 2, 3, and 4, which were used only for sensing in clinical practice (2 mm). All catheters had appropriate electrical integrity at the beginning, and this was not affected by multiple reuses and reprocessing.

Conclusion

NASPE recognizes the practice of reprocessing ablation catheters, providing their integrity is checked. The present study demonstrated that in a controlled experimental environment multiple reuses and sterilization in 12% ethylene oxide does not damage the electrical integrity of these catheters. This conclusion was reached on the basis of no significant changes in measured impedance and no increase above 5 Ω. Also, no difference was observed between the ablation and sensing poles.

References

[1] ACC/AHA task force report. Guidelines for clinical intracardiac electrophysiological and catheter ablation procedures. A report of the American College of Cardiology/American Heart Association Task Force on practice guidelines (Committee on Clinical Intracardiac Electrophysiologic and Catheter Ablation Procedures), developed in collaboration with the North American Society of Pacing and Electrophysiology. J Cardiovasc Electrophysiol. 1995; 6: 652-679.

[2] Scanavacca M, et al. Diretrizes para Avaliação e Tratamento da Pacientes com Arritmias Cardíacas. Arq Bras Cardiol. 2002; 79 (Suppl V): 30-35.

[3] Mickelsen S, Mickelsen C, MacIndoe C, et al. Trends and patterns in electrophysiologic and ablation catheter reuse in the United States. Am J Cardiol. 2001; 87: 351-354.

[4] 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. PACE. 2001; 24: 1297-1305.

[5] Haywood AM. Transmissible spongiform encephalopathies. N Engl J Med. 1997; 337: 1821-1828.

[6] Klein R, Dumble LJ. Transmission of Creutzfeldt-Jakob disease by blood transfusion. Lancet. 1993; 341: 768.

[7] O'Donoghue S, Platia EV. Reuse of pacing catheters: A survey of safety and efficacy. PACE. 1988; 11: 1279-1280.

[8] Dunnigan A, Roberts C, McNamara M, et al. Success of reuse of cardiac electrode catheters. Am J Cardiol. 1987; 60: 807-810.

[9] Aton E, Murray P, Frasier V, et al. Safety of reusing cardiac electrophysiology catheters. Am J Cardiol. 1994; 74: 1173-1175.

[10] Avitall B, Khan M, Krum D, et al. Repeated use of ablation catheters: A prospective study. J Am Coll Cardiol. 1993; 22: 1367-1372.

[11] Grabsch EA, Grayson ML, Johnson PD, et al. Bactericidal efficacy of sterilizing protocol for reused cardiac electrophysiology catheters. Am J Cardiol. 2002; 89: 770-772.

[12] Bathina MN, Mickelsen S, Brooks C, et al. Safety and efficacy of hydrogen peroxide plasma sterilization for repeated use of electrophysiology catheters. J Am Coll Cardiol. 1998; 32: 1384-1388.

[13] Ferrell M, Wolf CE 2nd, Ellenbogen KA, et al. Ethylene oxide on electrophysiology catheters following resterilization: Implications for catheter reuse. Am J Cardiol. 1997; 80: 1558-1561.

[14] AlCath Technical Manual. São Paulo: Biotronik GMBH & Co. 2002.

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