JACC Vol. 30, No. 7
December 1997:1735–40

Initial Experience With Reuse of Coronary Angioplasty Catheters in the United States

KEVIN F. BROWNE, MD, FACC, REY MALDONADO, PHD, MARY TELATNIK, RN, RONALD E. VLIETSTRA, MB, CHB, FACC, ALAN S. BRENNER, MD, FACC

Lakeland, Florida

Objectives. **We sought to evaluate the performance of angioplasty catheters, restored under a strict manufacturing process, in patients with coronary artery disease.**

Background. **Most countries outside the United States routinely reuse disposable medical equipment, resulting in significant cost savings. Because of quality and legal concerns, reuse in the United States has been limited. We investigated the reuse of percutaneous transluminal coronary angioplasty (PTCA) balloon catheters, restored by a process strictly controlled for bioburden and sterility, in patients undergoing PTCA.**

Methods. **Used PTCA balloon catheters were shipped to a central facility and were decontaminated, cleaned and tested for endotoxin using the limulus amebocyte lystate (LAL) gel clot method. Physical testing and quality assurance were performed. The products were packaged and sterilized with ethylene oxide. Catheter performance was assessed in a pilot study powered to detect a 5% difference in the angiographic failure rates of new and reused balloons (beta 0.8).**

Results. **The study enrolled 107 patients. The indication for PTCA was stable angina pectoris in 69 patients, unstable angina in 22 and acute myocardial infarction in 16. Of the 107 patients enrolled, 106 had a successful laboratory outcome, and 1 required coronary artery bypass graft surgery after failed rescue stenting. There were 122 lesions attempted (American College of Cardiology/American Heart Association classification A, n = 32; B1, n = 43; ≥B2, n = 35; C, n = 12). Of the 110 lesions initially approached with restored PTCA catheters, 108 were crossed and dilated. Sixty-four required no further procedures. Stenting was performed in 37 patients (29 planned, 8 rescue). Thus, the angiographic failure rate was 7% (10 of 108, 95% confidence interval 2% to 12%), comparable to the 10% rate seen with new balloons in other studies.**

Conclusions. **Restoration of disposable coronary angioplasty catheters using a highly controlled process appears to be safe and effective, with success rates similar to those of new products and no detectable sacrifice in performance. Cost analysis suggests that implementation of reuse technology for expensive disposable equipment may offer cost savings for U.S. hospitals, without sacrifice of quality.**

(J Am Coll Cardiol 1997;30:1735–40)

Reuse of medical equipment, particularly in the surgical arena, has been commonplace for many years (1–3). Metal surgical tools have been cleaned, disinfected and sterilized many times until their performance has deteriorated (3). In the 1960s, with the dramatic impact of plastics technology, disposable medical devices became commonplace. Hospitals in the United States moved to single-use devices, particularly for products that appeared to be difficult to clean.

In the cardiac catheterization laboratory, disposable catheters rapidly supplanted reusable catheters. Biopsy forceps and the Brockenbrough needle, which are made of stainless steel, are two notable reuse exceptions. As disposable medical devices became a larger part of the catheterization laboratory's budget, reuse of these products became common in countries outside the United States (4). However, within the United States, interventionalists have not reused single-use disposable products because of concerns related to quality and liability. Recent publication of the Canadian experience of reusing angioplasty catheters has rekindled interest in the United States (5,6).

After using a newly developed method of restoring angioplasty products to the manufacturer's original specifications, coronary balloon angioplasty was performed under a protocol approved by the Investigational Review Board at a single hospital in the United States. The purpose of this study was to determine the safety and efficacy of restored angioplasty balloon catheters in a typical interventional practice.

Methods

Product cleaning. Angioplasty catheters were collected from the cardiac catheterization laboratory after coronary angioplasty, prepared for shipment and shipped to a central facility where they were inspected, decontaminated and cleaned using a novel proprietary process. Coronary angio-

From the Watson Clinic, Lakeland, Florida. This study was supported by the Watson Clinic Center for Research, Inc., Lakeland, Florida.

Manuscript received December 20, 1996; revised manuscript received August 19, 1997, accepted August 21, 1997.

Address for correspondence: Dr. Kevin F. Browne, Watson Clinic LLP, 1600 Lakeland Hills Boulevard, Lakeland, Florida 33805. E-mail: kbrowne@watsonclinic.com.

0735-1097/97/$17.00
PII S0735-1097(97)00362-8

Abbreviations and Acronyms

MI = myocardial infarction
PTCA = percutaneous transluminal coronary angioplasty
WBC = white blood cell

plasty balloon catheters were disinfected with a solution containing peracetic acid and hydrogen peroxide. Both of these components are recognized as potent disinfectants capable of inactivating bacteria, fungi and viruses, including human immunodeficiency virus and hepatitis. They disinfect by destroying proteins and other cell components that are essential for biologic activity (7,8).

As part of the cleaning procedure, all catheters are tested to assume that no measurable level of hemoglobin (<60 pg/ml) or protein (<600 pg/ml) remains after cleaning is completed. Testing for residual endotoxin is performed using the limulus amebocyte lysate (LAL) gel clot method (9). Removal of contrast agent is assured by measuring an extract from the balloon lumen using a proprietary process.

Product sterilization. Physical testing was performed using units that were cleaned, packaged and sterilized. The units were packaged in standard trays and pouches typical of those used in the industry. They are sterilized by exposure to ethylene oxide using a carefully validated protocol with measurement of bacterial kill and ethylene oxide residuals. This protocol is typical of new manufacturing requirements. Physical testing was performed according to the "Guidance for the Submission of Research and Marketing Applications for Interventional Cardiology Devices" (10). Sterilized units were submitted to a national testing laboratory for biocompatibility testing. Units intentionally contaminated with 10,000 times the typical viral burden of a patient with acquired immunodeficiency syndrome or hepatitis virus were processed and found to be sterile.

Product quality assurance. Devices were divided by product groups—namely, over-the-wire, monorail and perfusion—from the same manufacturer. Each product group was qualified for use by performing multiple tests, including, but not limited to, burst testing, fatigue testing, torque testing, tip strength, material compatibility testing, cytotoxicity, hemolysis, systemic toxicity, implantation, mutagenicity, sensitization and irritation. Each restored angioplasty catheter underwent individual performance evaluation, including, but not limited to, rated burst testing, deflated profile measurement to meet the manufacturer's original published data and balloon compliance testing. The products were then packaged, sterilized by ethylene oxide and returned to the institution for use.

Figure 1 shows the compliance curve for a restored catheter compared with a new catheter of the same type for two different manufacturers' products. Only those catheters whose compliance curve falls within 10% of the published compliance curve were returned to the institution for use. The 10% value was chosen because this is reported by manufacturers as the variation in compliance of new products (11).

Patient enrollment. All patients scheduled for coronary angioplasty were considered for enrollment in this trial, including patients experiencing acute myocardial infarction (MI).

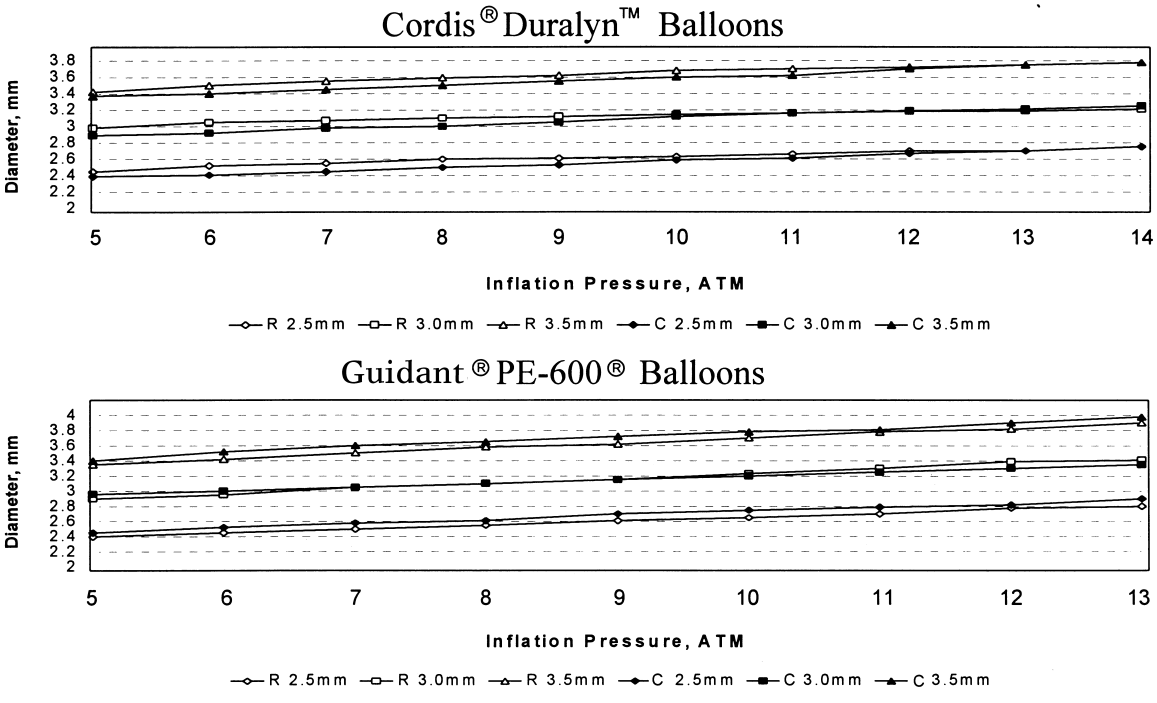

Figure 1. Balloon compliance data for restored balloon catheters compared with data from manufacturers' literature. C = new catheter; R = restored catheter.

The trial was approved by the Investigational Review Board of Lakeland Regional Medical Center, Lakeland, Florida. Each patient was required to give written, informed consent before enrollment. Once enrolled, a restored balloon angioplasty catheter was used during the procedure, providing the appropriate size and type were available. If not, a new catheter was used. If a subsequent balloon catheter was needed, the inventory would again be checked to determine availability. Given that this was a single-center safety evaluation, not all balloon sizes, lengths and catheter types were available at all times.

Angioplasty was performed in the standard clinical fashion. If atherectomy was performed as the initial intervention, the investigator was permitted to use a restored balloon before or after atherectomy. Coronary stenting was not restricted. If a restored product would not cross a lesion, the investigator had the option to either choose a new product of the same size as the restored catheter or downsize to a product that he or she believed would successfully cross the lesion.

On completion of the procedure, the angioplasty catheters were then prepared for return to the manufacturing facility for restoration.

Data collected. Temperature and white blood cell count (WBC) were obtained before and 24 h after the procedure to screen for pyrogen reactions. Monitoring for chills within 24 h after the procedure was required by the protocol. All patients were followed until hospital discharge for evidence of subsequent MI or requirement for emergent percutaneous or surgical revascularization of the target vessel. No long-term follow-up was performed.

Statistics. Earlier reports indicated that with new balloons, the angiographic failure rate is ~10% (5,6). This pilot study was designed to have an 80% chance of detecting a 5% difference in the failure rates of new and reused balloons (i.e., alpha 0.05, delta 0.05, beta 0.20) (12).

Results

Catheter types. During the evaluation, catheters manufactured by Guidant Corporation and Cordis Corporation were evaluated. Subsequent to this report, most major manufacturers' low and high pressure balloons have been validated and are in clinical trials. There were 18 over-the-wire balloon catheters, 76 monorail balloon catheters and 30 perfusion balloon catheters used in the trial. A large number of monorail catheters were used because of operator preference. Restoration of all three types of balloon catheters resulted in similar high quality devices.

Patient group. A total of 107 patients were enrolled in this safety and efficacy study. The clinical characteristics are shown in Table 1. The age of the patients was 64 ± 12 years (mean ± SD, range 29 to 87), and 56% were male. The indication for PTCA was stable coronary insufficiency in 69, unstable angina in 22 and acute MI in 16. Of the 122 lesions attempted during the study, 32 were type A, 43 were type B1, 35 were type ≥B2 and 12 were type C, as determined by the American College of Cardiology/American Heart Association classification (13).

Table 1. Clinical Characteristics

Elective PTCA	69
Unstable angina	22
Acute MI	16
ACC/AHA lesion class	
A	32
B1	43
≥B2	35
C	12
%DS	
Before PTCA	89 ± 6
After PTCA	20 ± 11

Data presented are mean value ± SD or number of patients. ACC/AHA = American College of Cardiology/American Heart Association; DS = diameter stenosis; MI = myocardial infarction; PTCA = percutaneous transluminal coronary angioplasty.

The minimal lumen diameter before angioplasty was 89 ± 6% and the minimal lumen diameter after angioplasty was 20 ± 11% by visual estimate.

Outcome. Figure 2 depicts the outcome of balloon angioplasty of coronary lesions that were approached initially with a restored balloon catheter. Of 110 lesions approached, 108 were crossed and dilated. Sixty-four lesions required no further procedures. Six patients required a 0.5-mm diameter larger balloon and one patient required a 30-mm long balloon to complete the procedure. Stents were placed in 37 patients. Of the 37 patients with stents, 29 had planned stenting and 8 required bailout stenting. Seven of the eight bailout stents were successful in resolving an unacceptable angioplasty result.

In two lesions (1.8%), a restored balloon catheter initially failed to cross a stenosis. This represented 2% (2 of 102) of restored catheters used as initial devices. In one of these lesions, a new balloon catheter identical to the restored catheter was then used but also failed to cross the stenosis. A catheter 1 mm smaller in inflated diameter successfully crossed the lesion, and the original restored catheter was then used to complete the dilation. The other case was successfully crossed with a new catheter 0.5 mm smaller from a different manufacturer and of a different type. The original restored balloon was used to complete the dilatation.

In 12 lesions, restored catheters (Fig. 3) were used after a new device. Six restored balloons were used after rotational atherectomy and one after directional atherectomy. In five lesions, a new balloon was used initially. In three of the five lesions, the initial balloon size requested was not available at the time of the procedure. A larger size restored balloon was used after the initial balloon (0.5 mm in one lesion and 1.0 mm in two lesions). In two other lesions, the restored balloon had been used on another lesion primarily, and then used secondarily on another lesion at the same setting.

Table 2 shows the in-hospital outcome data for patients in the study. Of the 107 patients enrolled, 106 had successful laboratory outcomes and one required emergency coronary artery bypass graft surgery as described earlier. Three patients returned to the laboratory for abrupt closure, two of whom

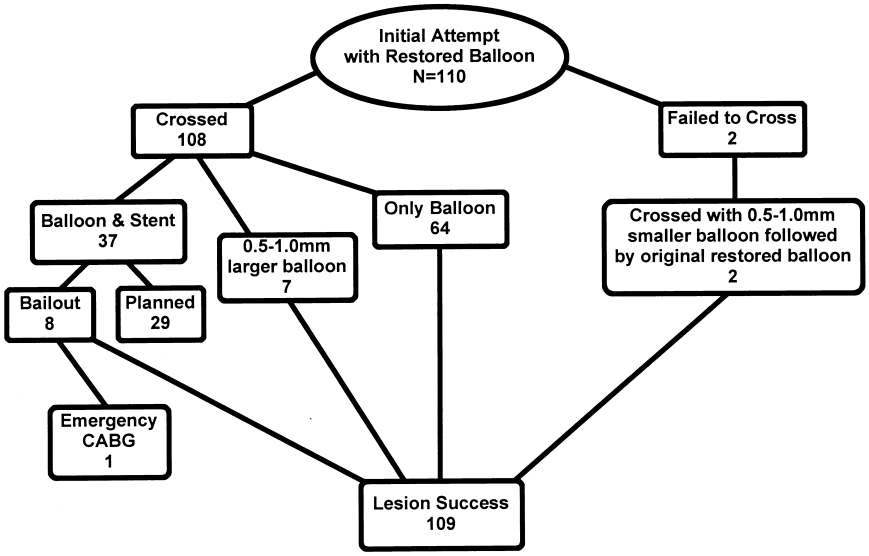

Figure 2. This chart shows the outcome after each procedure attempted in those lesions approached initially with a restored balloon angioplasty catheter. CABG = coronary artery bypass graft surgery.

underwent successful repeat PTCA. The third patient had elective coronary artery bypass graft surgery because of the inability to cross the lesion with any wire and persistent unstable angina. Three patients experienced non–Q wave MI—one after rotational atherectomy of a native vessel and PTCA of a graft, one after PTCA and a planned stent and one after routine PTCA. No patient died in the study. There were no new Q wave MIs. A newly elevated WBC was seen in 12 patients and was explained by other causes in nine patients (MI in 4, hematoma in 3, steroids in 1 and urinary tract infection in 1). The mean WBC in the 12 patients was 12,200 ± 700 cells/microliter. A newly elevated temperature within 24 h of the procedure was seen in 11 patients and was explained in 10 patients (urinary tract infection in 4, MI in 5 and hematoma in 1). One patient experienced chills lasting less than 5 min 16 h after the procedure. No etiology was found.

Comparison data. A case-matched control group of 108 patients was evaluated retrospectively from our data base of patients undergoing PTCA with new catheters. There was no significant difference in frequency of fever (11 vs. 12) or WBC (12 vs. 14). No patient in the control group had chills documented.

Procedure data. The mean procedure time was 67 ± 30 min compared with 83 ± 49 min in the comparison group. The mean fluoroscopy time for the procedures was 13 ± 10 min compared with 18 ± 15 min in the comparison group. The mean dye volume was 275 ± 125 ml compared with 307 ± 157 ml in the comparison group.

An average of 1.5 ± 0.7 balloons/lesion was used in the

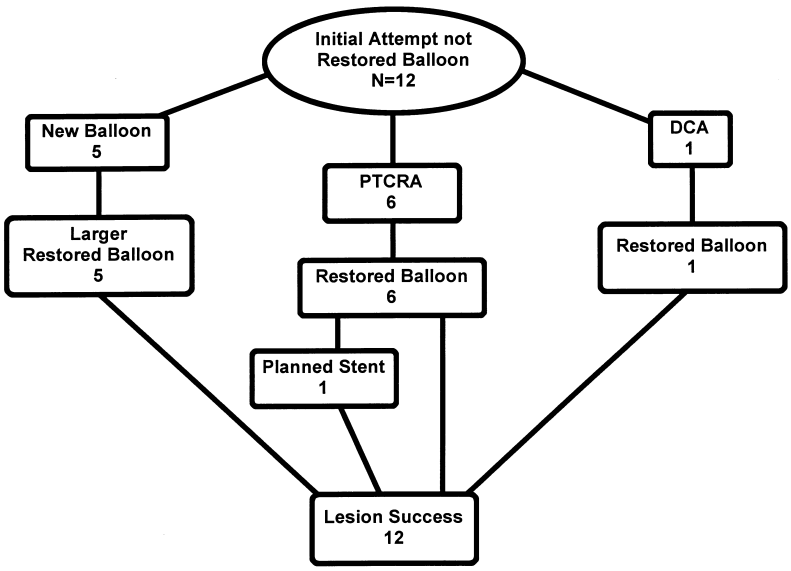

Figure 3. This chart shows the outcome after each procedure performed on the lesion when a restored balloon was not used in the initial attempt to cross a lesion. PTCRA = percutaneous transluminal coronary rotational atherectomy. DCA = directional coronary atherectomy.

Table 2. Patient Outcome

	No. of Patients
Enrolled patients	107
Patient success	106
Emergency CABG	1
Abrupt closure	3
Repeat PTCA	2
Elective CABG	1
Q wave MI	0
Non–Q wave MI	3
Death	0
New elevated WBC	12
Unexplained	3
New elevated temperature	11
Unexplained	1
Chills	1

CABG = coronary artery bypass graft surgery; WBC = white blood cell count; other abbreviations as in Table 1.

study, compared with 1.6 ± 0.6 balloons/lesion in the comparison group. The use of a high pressure balloon after stenting (34%) accounted for most second balloon requirements.

Discussion

Comparison with previous studies. Multiple previous studies have been performed to evaluate the safety of reused angiography (14–17) and angioplasty equipment (5,6,18). A nonrandomized clinical trial has been published (5) and a randomized trial has been reported (6), confirming the safety of these devices. Of note, the trials did not define whether the angioplasty catheters were returned to the original deflated profile and whether compliance curves and burst testing were performed on each catheter. Given that this quality requirement may have a substantial impact on success rate, this stricter approach to reuse may explain higher patient success rates seen in this trial than those reported in previous trials (99% vs. 83%) (5). If bailout stenting were considered as a failure (n = 8), the angiographic failure rate would increase to 7% (95% confidence interval 2% to 12%) in this evaluation. Abrupt closure occurred in 2.8% of patients, similar to the rate in other trials (5,6). Procedure time (67 vs. 68 min) was similar to the single-use center using new balloons (5). A larger randomized trial performed in western Canada confirmed the safety and efficacy of reused angioplasty catheters (6).

Performance. When restoration is performed in a very high quality fashion, performance of restored balloon angioplasty catheters can be expected to be similar to that of new devices. The subjective impressions of the investigators performing the procedures in the trial were uniformly that the products performed like new devices of equivalent type, and they currently use restored devices when available for any type of balloon angioplasty intervention.

To qualify for reuse, each balloon had to meet high performance testing levels, including compliance and deflated profile. These qualification requirements most likely represent the difference in the results of this trial compared with previous trials.

Safety. The trial demonstrates the safety of restored angioplasty catheters in patients undergoing PTCA. There were no episodes of catheter rupture under the rated burst pressure or of pyrogen reactions occurring in patients in the trial. Gensini (19) noted that a stringent protocol for cleaning and sterilizing would reduce the incidence of pyrogenic reaction to <1 in 1,000, no higher than the incidence with new products. Frank et al. (15) reported that reusing catheters, after careful cleaning and sterilization with ethylene oxide, was not associated with increased risk of infection. Further study will be required to determine the true incidence of pyrogen reaction. There was no evidence of catheter-induced infection in any patient in the trial. Because the trial is not randomized, small differences between new and restored balloons may not have been found.

Cost savings. Given that the main reason to consider restoration of angioplasty catheters relates to potential cost savings, it is expected that the restoration process used in this study would permit institutions to save 40% of the original invoice cost of the product to the hospital. In the laboratory at Lakeland Regional Medical Center, ~2,000 balloon angioplasty catheters are used per year at an average cost of $400. We expect to use the restored catheters in approximately half of the procedures. Reusing 1,000 catheters, with savings of $160 each, would thereby save the hospital laboratory $160,000. Higher use of restored products would create greater savings. Nationwide, 420,000 PTCA procedures were done in 1994 (20). Assuming 50% reuse and 1.5 catheters per procedure, the cost savings in the United States may surpass $50 million.

Cost efficacy of restoration was recently reported as very sensitive to the need for urgent revascularization (21). This trial suggests that urgent revascularization is similar to or better than that in reported trials for new products (0.9% vs. 1.9%) (5). However, the use of coronary stenting in this trial makes this comparison incomplete.

It is unknown how many cycles of restoration a single balloon angioplasty catheter can tolerate. In this trial, all catheters had been restored once. This is the subject of ongoing study with a data base designed specifically to evaluate the degradation of these products with each subsequent cycle. Early observations have already confirmed that some products are more durable than others and may lead laboratories to preferentially choose these products.

Grimandi et al. (22) published a review of methods of sterilization of single-use devices recently and concluded that using simple methods of cleaning and decontamination followed by radiation sterilization does not offer enough of a guarantee of safety to permit reuse. When comparing the process of restoration used in this study with those reported by Grimandi et al., the differences in methods would account for a difference in outcome. An accompanying editorial by Feldman (23) emphasized the important differences between in vitro evaluation and in vivo evaluation, and editorials by both

Turi (24) and Bourassa (25) emphasize that methods of restoration must be highly controlled and reproducible. It is unlikely that any single hospital would experience a significant cost benefit from in-house reuse given the complexity and expense of the process and the changing products, each requiring validation.

Future trials. A larger trial (Reusing Specialized Types of Resterilized Equipment [RESTORE]-PTCA trial) will evaluate, in double-blinded, randomized manner, new versus restored angioplasty catheters in a multi-institution format. This trial is expected to begin in 1998.

Conclusions. Restoration of disposable coronary angioplasty balloon catheters to the manufacturer's original specifications results in a high quality product that can be used alone or with adjunctive devices on all types of coronary angioplasty lesions. Operators should expect to achieve success rates equivalent to those published with new coronary angioplasty balloons.

The U.S. health care community stands on the threshold of a new era in which high quality restoration of disposable products can be accomplished without sacrifice in quality or performance and measurable cost savings can be achieved.

We thank Verna Kirk for diligence in the preparation of the manuscript and Barbara Seeger, PharmD for statistical input.

References

1. Spaulding EH. Alcohol as a surgical disinfectant. AORN J 1964;2:67–71.
2. Garner JS, Favero MS. CDC guidelines for handwashing and hospital environmental control, 1985. Infect Control 1986;7:231–43.
3. Black SS, editor. Disinfection, Sterilization and Preservation. 3rd ed. Philadelphia: Lea & Febiger, 1991:2.
4. Rozenman Y, Gotsman MS. Reuse of balloon catheters for coronary angioplasty. J Am Coll Cardiol 1995;26:840–1.
5. Plante S, Strauss BH, Goulet G, Watson RK, Chisholm RJ. Reuse of balloon catheters for coronary angioplasty: potential cost-saving strategy. J Am Coll Cardiol 1994;24:1475–81.
6. Burton J, Tymchak W, Dzavik V, et al. Randomized controlled trial of reuse of PTCA balloon catheters [abstract]. Circulation 1995;92 Suppl I:I-661.
7. Schroeder W. Peracetic acid disinfectant for the food stuff industry. Brauwelt Int 1984;1 Suppl:115–20.
8. Turner FJ. Hydrogen peroxide and other oxidant disinfectants. In: Block SS, editor. Disinfection, Sterilization and Preservation. 3rd ed. Philadelphia: Lea & Febiger, 1991:240–50.
9. USP 23/NF 18 Bacteria/Endotoxin Test. United States Pharmacopeia 23/National Formulary 18, Chapter 85. Rockville (MD): U.S. Pharmacopeial, 1995:1696–7.
10. Guidance for the Submission of Research and Marketing Applications for Interventional Cardiology Devices. International Cardiology Devices Branch, Division of Cardiovascular, Respiratory and Neurology Devices, Office of Device Evaluation. Washington (D.C.): U.S. Department of Health and Human Services, May 1993.
11. ACS product literature. Santa Clara (CA): Guidant Corp., Advanced Cardiovascular Systems, 1996.
12. Glantz SA. Primer of Biostatistics. 3rd ed. New York: McGraw-Hill, 1992.
13. Ryan TJ, Faxon DP, Gunnar RM, et al. Guidelines for percutaneous transluminal coronary angioplasty: a report of the American College of Cardiology/American Heart Association Task Force on Assessment of Diagnostic and Therapeutic Cardiovascular Procedures (Subcommittee of Percutaneous Transluminal Coronary Angioplasty). J Am Coll Cardiol 1988;12:529–45.
14. Comis J. Reusing single-use cardiac catheters. Dimensions in Health Service 1991;68:8–9, 34–5.
15. Frank U, Herz L, Daschner FD. Infection risk of cardiac catheterization and arterial angiography with single and multiple use disposable catheters. Clin Cardiol 1988;11:785–7.
16. Bauer E, Densen P, Faxon D, et al. Endotoxic reactions associated with the reuse of cardiac catheters—Massachusetts. MMWR 1979;28:25–6.
17. Jacobson JA, Schwartz CE, Marshall HW, Conti M, Burke JP. Fever, chills and hypotension following cardiac catheterization with single- and multiple-use disposable catheters. Cathet Cardiovasc Diagn 1983;9:39–46.
18. Conseil d'Évaluation des Technologies de la Santé du Québec. The reuse of single-use cardiac catheters: safety, economical, ethical and legal issues. Can J Cardiol 1994;10:413–21.
19. Gensini GG. Reuse in angiography, cardiac catheterization, and pacing: summary and recommendations. In: Institute for Health Policy Analysis. Reuse of Disposable Medical Devices in the 1980s. Washington (DC): Georgetown University Medical Center, 1984:139–41.
20. U.S. markets for diagnostic and interventional cardiovascular catheters and supplies. Biomedical Business International, Rep No. 4215, 1994.
21. Mak K-H, Eisenberg MJ, Eccleston DS, Brown KJ, Ellis SG, Topol EJ. Cost-efficacy modeling of catheter reuse for percutaneous transluminal coronary angioplasty. J Am Coll Cardiol 1996;28:106–11.
22. Grimandi G, Sellal O, Grimandi F, Crochet D. Risks of reusing coronary angioplasty catheters: results of an experimental study. Cathet Cardiovasc Diagn 1996;38:123–30.
23. Feldman T. Reuse of coronary angioplasty catheters [editorial]. Cathet Cardiovasc Diagn 1996;38:131–2.
24. Turi ZG. Reuse of disposables: let's not embrace waste [editorial]. Cathet Cardiovasc Diagn 1996;38:133–4.
25. Bourassa MG. Is reuse of coronary angiography catheters safe and effective? [editorial]. J Am Coll Cardiol 1994;24:1482–3.