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Radiofrequency Thermal Balloon Coronary Angioplasty: A New Device for Successful Percutaneous Transluminal Coronary Angioplasty

KATSUHIRO YAMASHITA, MD, SHUTARO SATAKE, MD,* HIROSHI OHIRA, MD, KENICHIRO OHTOMO, MD,

Yokohama and Tokyo, Japan

Objectives. The purpose of this study was to evaluate the effects of thermal balloon percutaneous transluminal coronary angioplasty using radiofrequency energy in the treatment of patients with failed coronary angioplasty and complex lesions. In addition, we evaluated restenosis after radiofrequency thermal balloon applications.

Background. The efficacy of coronary angioplasty is limited by the relatively low success rate in complex lesions and the high frequency of restenosis. Few reports have studied the combined effects of pressure and laser thermal energy. This study describes a new device for coronary angioplasty using radiofrequency thermal energy.

Methods. Thirty-two patients with failed conventional coronary angioplasty or complex lesions were treated with radiofrequency thermal balloon coronary angioplasty. Radiofrequency energy was delivered up to 11 times in exposures ranging from 30 to 60 s in duration. This combined effect allowed the vascular wall to be heated to temperatures ranging from 60 to 70°C. Follow-up coronary angiography was performed, on average, 6 months after the procedure.

Results. Successful radiofrequency coronary angioplasty was achieved in 28 (82%) of 34 lesions. There was one abrupt coronary artery occlusion (3%) and no death, perforation or dissection. Angiographic restenosis occurred in 14 (56%) of 25 lesions.

Conclusions. In patients with failed coronary angioplasty and difficult complex lesions, radiofrequency coronary angioplasty could potentially improve angioplasty success rates and may have important implications for bailout cases with abrupt occlusion. However, restenosis remains a significant problem.

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Percutaneous transluminal coronary angioplasty is an established, effective treatment for coronary vascular disease. However, its overall efficacy is limited by acute occlusion at the angioplasty site (1–4), the relatively low success rate in complex lesions (5–8) and the high frequency of restenosis (9–13). Recent reports of laser hot balloon angioplasty (14) have revealed that thermal treatment with balloon pressure was effective in improving lumen dimensions and arterial dissection caused by conventional balloon angioplasty. However, the restenosis rate has been reported to be higher with this method than with the conventional method. The purpose of this study was to assess whether the combination of radiofrequency thermal energy and low balloon pressure could improve angioplasty success rates and reduce the restenosis rate.

From the Cardiovascular Department, Yokohama Red Cross Hospital, Yokohama and *The First Department of Internal of Medicine, Tokyo Medical and Dental University, Tokyo, Japan.

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Address for correspondence: Dr. Katsuhiro Yamashita, Cardiovascular Department, Yokohama Red Cross Hospital, 2-85 Negishi-cho, Naka-ku, Yokohama, Japan.

Methods

Between July 1989 and October 1992, radiofrequency balloon coronary angioplasty was performed in 32 patients in medically unstable condition who were referred for elective conventional balloon angioplasty. All patients gave informed consent, and the institutional committee on human research approved the study protocol (July 1989). Twenty patients were treated initially with balloon angioplasty in a conventional manner that required balloon inflation up to 8 atm for 30 to 60 s in the stenotic segment at least twice in each case. Because of inability to achieve an optimal angiographic result with this conventional procedure, radiofrequency thermal balloon coronary angioplasty was performed in these patients immediately after conventional angioplasty (sequential radiofrequency coronary angioplasty group). Five of these 20 patients required a second radiofrequency treatment because of dissection or intimal flaps, as did 15 patients with an insufficient lumen diameter because of initial insufficient balloon dilation and elastic recoil. The remaining 12 patients underwent direct radiofrequency coronary angioplasty without a preceding conventional angioplasty procedure. These patients all had type B lesions as classified by the American College of Cardiology/American Heart Association Task Force (5).

A radiofrequency coronary angioplasty balloon catheter (Shutaro Satake Thermal Balloon Catheter, Japan Crescent)

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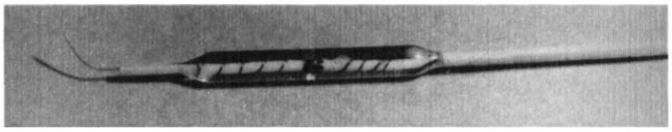


Figure 1. Radiofrequency balloon angioplasty catheter. This sample balloon is 3 mm in diameter and 20 mm in length. The balloon is made of polyethylene terephthalate. The monopolar electrode is inside the balloon.

is similar to a conventional coronary angioplasty balloon catheter except for its radiofrequency components (Fig. 1). The balloons used ranged in size from 2 to 3.5 mm in diameter and 15 to 20 mm in length, with a 4.3F shaft size. The balloon membrane is made of polyethylene terephthalate and the shaft is made of polybutylene terephthalate. A helical monopolar electrode is mounted around the shaft inside the balloon to deliver the radiofrequency energy. To monitor the temperature during radiofrequency energy delivery, a thermocouple sensor is conjoined proximal to the balloon marker. For each dilation attempt, the balloon was filled with saline solution and contrast medium (ioxaglic acid) and inflated to 3 to 6 atm with use of a standard angioplasty inflation device. When the balloon pressure reached the desired range, radiofrequency current (13.56 MHz) (Interbase 7A3000, Japan Crescent) was delivered between the helical electrode inside the balloon and the electric plate positioned on the body surface. The energy was delivered at an output of 10 to 40 W for 30 to 60 s. During radiofrequency energy delivery, the temperature inside the balloon was constantly monitored and maintained between 60 to 70°C by regulating the output of radiofrequency energy. These procedures were performed up to 11 times (average 3)/lesion until dilation of the stenosis was achieved.

Angioplasty success was defined as a residual stenosis <50% without major complications and restenosis as a diameter stenosis ≥50%. Percent diameter stenosis was calculated by computerized analysis of cineangiograms. Data are expressed as mean value ± 1 SD. A comparison between the groups was carried out by repeated measures analysis of variance. When statistical significance was obtained, group comparisons were performed using the Scheffé method. A p value < 0.05 was considered statistically significant.

Results

Patient characteristics. There were 24 men and 8 women, with a mean age of 62 years (range 44 to 80). Of these 32 patients, 2 had 2 lesions, for a total of 34 lesions. Eight patients had a history of restenosis of the lesion of interest after conventional angioplasty. Lesion characteristics are shown in Figure 2. Fifty-six percent of the patients had single-vessel disease, and 62% of the lesions were located in the left anterior descending coronary artery. Seventy-six percent of the lesions were classified as type B.

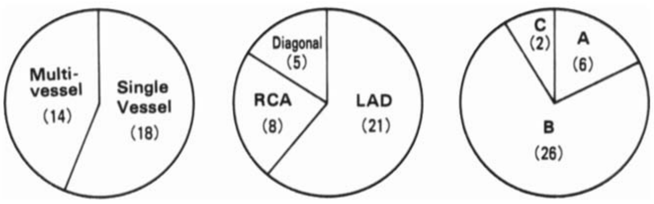


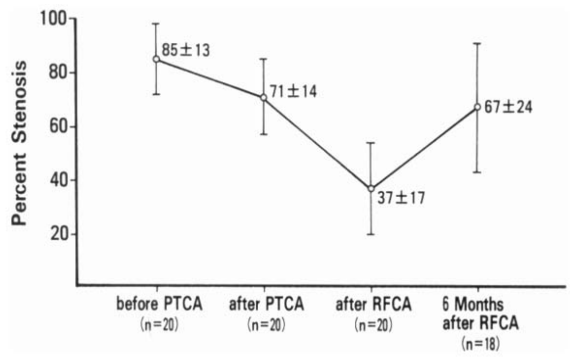
Figure 2. Baseline characteristics of coronary artery lesions in 26 patients (28 lesions). Left, Disease type. Middle, Lesion location. Right, Lesion type. A,B,C = types A, B and C lesion characteristics defined by the American College of Cardiology/American Heart Association Task Force. LAD = left anterior descending coronary artery; RCA = right coronary artery.

Primary angiographic success rates. Of the 34 lesions, 28 (82%) were successfully treated with radiofrequency coronary angioplasty. In the sequential radiofrequency angioplasty group, 17 (85%) of 20 patients were successfully treated. A significant reduction ($p < 0.05$) in mean percent stenosis was found after radiofrequency angioplasty compared with that after conventional angioplasty (Fig. 3). There was one acute occlusion (3%) caused by conventional coronary angioplasty; it was immediately thermally welded by radiofrequency angioplasty, and success was achieved (Fig. 4). In the direct radiofrequency angioplasty group, 11 (78%) of 14 patients were successfully treated.

Causes of unsuccessful angioplasty. Radiofrequency coronary angioplasty was unsuccessful in 6 of 34 lesions. In five of these six lesions, the residual stenosis ranged from 50% to 75%. There was one major complication entailing an abrupt coronary artery occlusion 8 h after radiofrequency angioplasty despite a satisfactory initial angiographic result.

Rate of restenosis. Follow-up angiography, averaging 6 months after radiofrequency coronary angioplasty, was performed in 28 patients (88%) with 30 lesions (88%). The angiographic study indicated that radiofrequency angio-

Figure 3. Percent diameter stenosis before and after radiofrequency coronary angioplasty (RFCA). A significant reduction in mean percent stenosis was found immediately after radiofrequency coronary angioplasty compared with that after conventional coronary angioplasty (PTCA). However, loss of the gain in lumen diameter was observed on follow-up angiography. Values presented are mean value ± 1 SD.



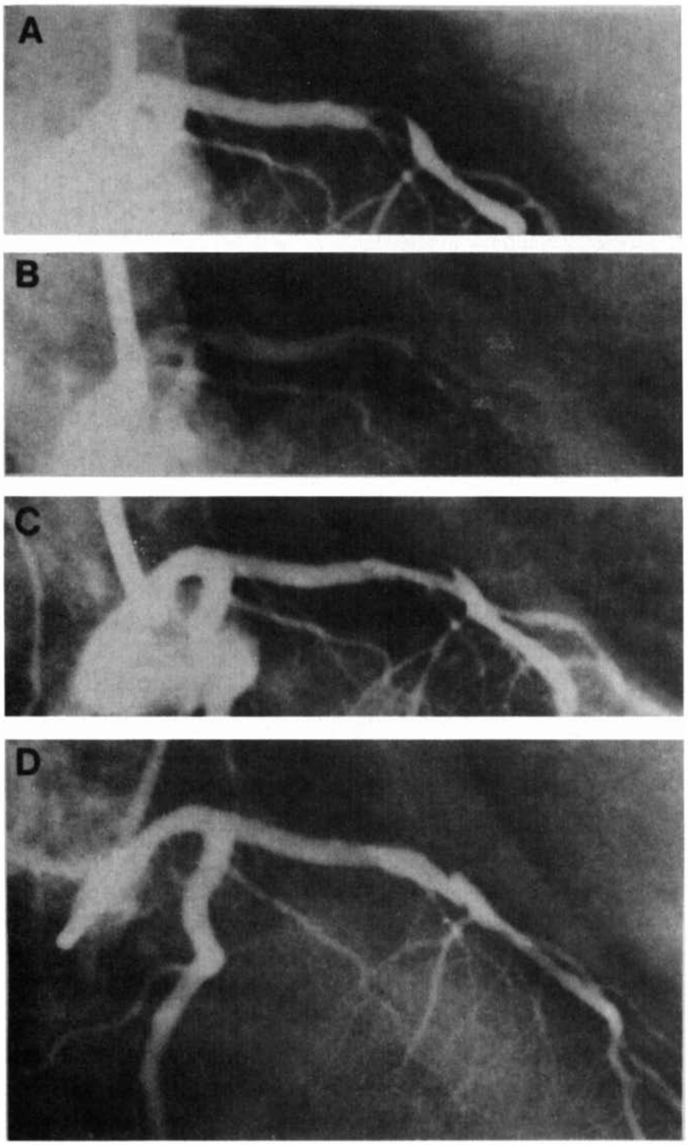


Figure 4. Treatment of acute occlusion with radiofrequency coronary angioplasty. Coronary angiography (30° right anterior oblique view) shows severe eccentric stenosis of the left anterior descending coronary artery (A). During conventional coronary angioplasty, acute occlusion occurred at the treated site (B). Immediately thereafter, a radiofrequency coronary angioplasty balloon was inserted into the coronary vessel, the stenotic site was thermally welded and success was obtained (C). The true lumen was obliterated after radiofrequency angioplasty with six radiofrequency exposures, and reentry occurred, resulting in a marked increase in false lumen diameter. Follow-up angiography after 10 months revealed a patent coronary artery (D).

plasty had achieved suboptimal success in 5 (17%) of the 30 lesions and that restenosis had occurred in 14 (56%) of the remaining 25 lesions. All four patients who were not restudied were asymptomatic with an average medication period of 10 months (range 6 to 18).

Complications. The most common complication of the procedure was the development of chest symptoms. Eight (25%) of 32 patients experienced a burning sensation in the chest during radiofrequency energy applications. Others complained of severe chest pain or discomfort similar to the severity of angina experienced during conventional balloon inflation. These symptoms were transient, and most patients could tolerate the pain once the temperature was lowered by reducing the level of radiofrequency energy. There was no perforation or dissection. All patients were hemodynamically stable during the procedure, and there were no malignant arrhythmias. However, one patient developed acute myocardial infarction secondary to late (8 h after radiofrequency angioplasty) abrupt coronary reocclusion despite an initial satisfactory angiographic result.

Discussion

Thirty-two patients were treated with a radiofrequency thermal balloon catheter. A total primary success rate was achieved in 28 (82%) of 34 lesions. The success rates in the sequential and direct radiofrequency coronary angioplasty groups were 85% and 78%, respectively. Thus, radiofrequency coronary angioplasty appears to be a highly effective treatment compared with conventional coronary angioplasty. It was unsuccessful in 6 of 34 lesions. Residual stenosis in five of these six lesions was <75%. Our results indicate that radiofrequency coronary angioplasty is highly effective for failed conventional coronary angioplasty and complex lesions. One major complication entailed an abrupt occlusion at the angioplasty site, with subsequent myocardial infarction. The lesion was eccentric and moderately angulated (type B) but had been initially successfully treated by direct radiofrequency coronary angioplasty (37% residual stenosis). However, 8 h later, the patient experienced abrupt coronary reocclusion and subsequent myocardial infarction. Anticoagulant therapy usually consisting of 200 to 300 mg/day of ticlopidine or 81 to 243 mg/day of aspirin administered orally before the procedure, and 8,000 to 10,000 U of intraarterial heparin were given at the start of the procedure, followed by 10,000 U of heparin administered intravenously for 24 h after the procedure. However, continuous venous heparin was not administered in this one patient, and the activated partial thromboplastin time was not measured. We speculate that the pathophysiology of abrupt closure in this case was thrombus formation.

In our study, 20 patients were successfully treated by radiofrequency coronary angioplasty after unsuccessful treatment with conventional coronary angioplasty at balloon pressures up to 8 atm. When the arterial wall is heated to a temperature >70°C, tissue shrinkage will ordinarily occur (15). However, Lee et al. (16) reported that the stretched vessel wall can be maintained at a constant pressure by an inflated balloon used in combination with radiofrequency energy. Elastic recoil of the arterial wall can therefore be reduced with thermal treatment. This reduction in arterial recoil by radiofrequency coronary angioplasty is one mechanism of improvement. Another mechanism is the increment of plasticity on the vessel wall, which is increased by denaturing protein, which forms an indurated vessel wall.

These mechanisms entail the application of high frequency energy such that the stenotic area of the vessel can be dilated satisfactorily. Recently, Spears et al. (14) reported that laser balloon angioplasty was an effective procedure in increasing the minimal lumen diameter after conventional coronary angioplasty.

A major mechanism of conventional coronary angioplasty is dissection of the arterial wall (17), which may lead to an abrupt closure of the vessel. In the lesions treated with radiofrequency coronary angioplasty, no arterial dissection was visible on angiography. Our results demonstrated that radiofrequency coronary angioplasty is also successful in thermally fusing tissue layers separated by conventional coronary angioplasty. Jenkins et al. (18) and Anand et al. (19) concluded that thermal tissue welding of arterial wall separation occurs at adventitial temperatures >80°C. Although the number of cases was small (Fig. 4), our study also revealed that adventitial temperatures <80°C with pressure can achieve similar effects. Radiofrequency coronary angioplasty could be important for bailout management of abrupt coronary artery occlusion, perhaps because of the unique capacitive heating mechanism of heating the vascular wall.

This capacitive-type heating mechanism (20) has a more uniform heating effect on the stenotic area of the vessel in contrast to a bipolar radiofrequency thermal balloon, which generates heat convection strictly within the balloon. Our experimental result in a human model demonstrated that there was little thermal difference between the fluid around the shaft inside the balloon and the inner surface of the vessel in contact with the balloon membrane. We kept the temperature around the shaft inside the balloon between 60° and 70°C by regulating the output of radiofrequency wattage such that the temperature of the inner surface of the vessels could be maintained between 60° and 70°C for 30 to 60 s. Our previous investigation, using the external iliac artery of a rabbit, revealed that radiofrequency heating at a temperature of 60° to 70°C at 3 to 6 atm for 60 s created a coagulation necrosis within both the elastic lamina and the smooth muscle cells of the tunica media. The inner surface of the dilated lesions was smooth and showed no visible evidence of intimal tear, dissection or thrombus formation.

We studied several frequencies and found that radiofrequency capacitive-type heating could not be produced by using lower frequencies, such as 350 to 700 kHz, which were used in the catheter ablation of Wolff-Parkinson-White syndrome.

Rate of restenosis. In our patients, the restenosis rate was 56%, which was relatively high compared with that of conventional coronary angioplasty (8–13). Several factors have been indicated as increasing the risk of restenosis. Complex coronary lesion morphology (21–23) and the severity of stenosis before coronary angioplasty (21,24,25) have been proposed as significant factors influencing restenosis. Residual stenosis (9,24,25), left anterior descending coronary artery lesions (21,23) and coronary artery dissection (arterial wall trauma) may all be associated with an increased rate of restenosis. Several studies have demonstrated that residual stenosis >30% (9,26) leads to higher percent stenosis immediately after the procedure. In our patients, residual stenosis averaged 37%. We used relatively undersized balloons to prevent trauma to the vascular wall, a factor (27) that might have correlated with the relatively higher rate of restenosis in our case studies.

In a report on the use of laser hot balloons, Spears et al. (14) noted that stenotic tissue was heated to temperatures >85°C in patients with a high rate of restenosis. However, their study revealed that the rate of restenosis was relatively low in patients treated at lower temperatures as compared with the rate in patients treated at higher temperatures. Given this report of lower temperatures with hot balloons, we speculated that lower temperatures might further reduce the restenosis rate. Therefore, we utilized lower temperatures (60 to 70°C) in our study and found that radiofrequency coronary angioplasty at lower temperatures was in fact effective in lowering the restenosis rate.

Study limitations and conclusions. Our study has several limitations. The patients in this study were highly selected and most had unsuccessful conventional coronary angioplasty and difficult lesions. Although primary success rates were favorable, patient numbers were small, and follow-up angiography was performed in only 28 patients. Because the profile of the radiofrequency coronary angioplasty balloon is larger than that of the conventional angioplasty balloon, use of the radiofrequency balloon as a primary device for tortuous lesions is limited.

Nevertheless, we conclude from our study of radiofrequency coronary angioplasty that many stenotic coronary arteries can be dilated effectively and safely by combining radiofrequency thermal energy with low balloon pressures.

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