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Cutting Balloon Angioplasty for Cardiac Transplant Vasculopathy

Yuzuru Takano, MD, PhD, Jesse W. Currier, MD, Lawrence A. Yeatman, MD, Jon A. Kobashigawa, MD, Alfred D. Rogers, CVT, Lisa J. Cianfichi, NP, Michael C. Fishbein, MD, and Jonathan M Tobis, MD

We performed Cutting Balloon angioplasty on 20 lesions in 11 heart transplant recipients 7.5 \pm 3.8 years after transplantation. The mean percentage of diameter stenosis decreased from 88.3% \pm 13.8% to 19.6% \pm 13.7% after Cutting Balloon angioplasty without complication. Seven patients underwent follow-up angiography at 4.9 \pm 1.7 months in a total of 12 lesions, and all lesions showed restenosis with a mean diameter stenosis of 84.4% \pm 19.2%. Cutting Balloon angioplasty can be used to treat obstructions in cardiac transplant coronary arteries; however, it may cause exacerbation and produce a high restenosis rate. J Heart Lung Transplant 2002;21:910–913.

Accelerated allograft vasculopathy significantly limits the survival of patients who undergo orthotopic heart transplantation.^{1–3} Balloon angioplasty, directional atherectomy, and rotational atherectomy have been used to treat this disease process; however, these techniques have higher procedural morbidity, mortality, and restenosis compared with their use in native coronary artery atherosclerotic disease.^{4–8} This may be because of the diffuse nature of transplant arteriopathy and its intense proliferative tissue response.

The Cutting Balloon is a relatively new device for treatment of coronary artery disease.⁹ The Cutting Balloon has been reported to be superior to conventional balloon angioplasty,¹⁰ especially in treating in-stent restenosis.¹¹ We hypothesized that there may be advantages to using the Cutting Balloon to treat transplant arteriopathy in which diffuse disease is commonly seen.

METHODS Study Population

A total of 11 consecutive patients with heart transplant arteriopathy were treated with Cutting Balloon angioplasty between June 2000 and March 2001. The mean age was 56 ± 11 years, and 9 were men. The indications for cardiac transplantation were idiopathic cardiomyopathy in 5 patients, coronary artery disease with ischemic myopathy in 4 patients, valvular heart disease in 1 patient, and right ventricular dysplasia in 1 patient. The mean time since transplant was 7.5 ± 3.8 years.

Cutting Balloon Angioplasty

We performed coronary angioplasty according to standard clinical practice, through the femoral artery with a 6F or 8F catheter. We treated 20 lesions with Cutting Balloon angioplasty. There were 13 de novo lesions, and 7 were restenotic (6 because of in-stent restenosis and 1 restenosis was secondary to conventional balloon angioplasty).

Quantitative coronary angiography measurements were performed with an automated computer-based system (CRS-PC+, General Electric Company; Fairfield, CT). Procedural success was defined as a post-procedural lumen diameter stenosis <50%without creatine kinase elevation, Q-wave myocardial infarction, emergency bypass surgery, or death related to the current Cutting Balloon angioplasty. We defined angiographic restenosis at follow-up as the return of >50% diameter stenosis.

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TABLE I	Angiographic results
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	Baseline	Post-CB	Final
MLD (mm)	$0.2 \pm 0.5 \\ 88.3 \pm 13.8$	2.2 ± 0.5	2.4 ± 0.4
% DS		19.6 ± 13.7	11.5 ± 8.3

Data are expressed as mean \pm SD. CB, Cutting Balloon; MLD, minimum lumen diameter; DS, diameter stenosis.

RESULTS Angiographic Results

Procedural success was achieved in all lesions with no complications during the Cutting Balloon angioplasty. Two patients underwent Cutting Balloon angioplasty as a bridge to repeat heart transplantation. One patient died 5 days after the procedure of heart failure caused by diffuse allograft arteriopathy and acute myocardial infarction that preceded the angioplasty. One patient died suddenly 3 months after Cutting Balloon angioplasty.

Table I shows angiographic results. We treated 9 of the 20 lesions with the Cutting Balloon only. Coronary stents were placed in 8 lesions, and adjunct balloon dilatation was performed in 3 lesions after Cutting Balloon angioplasty.

Follow-up Angiography

Follow-up coronary angiography was obtained in 12 lesions from 7 patients at a mean duration of 4.9 ± 1.7 months. The reasons for follow-up angiography were ischemia detected by non-invasive examination in 1 patient, heart failure caused by myocardial infarction in 2, and annual follow-up in 3. Eight lesions from 4 patients were not available for follow-up angiography because the patients underwent repeat transplantation (2) or death (1).

The mean percentage of diameter stenosis at follow-up was $84.4\% \pm 19.2\%$, and the minimum lumen diameter was 0.3 mm \pm 0.5 mm. Angiographic restenosis was present in all 12 lesions (100%). We observed a new significant stenosis outside of the target lesion or treated artery in 9 lesions (Figure 1). At the time of follow- up angiography, 2 patients (a total of 3 lesions) underwent target lesion revascularization with second Cutting Balloon angioplasties.

DISCUSSION

Accelerated graft arteriopathy is a major limitation to the long-term survival of cardiac transplant recipients.¹⁻³ The angiographic characteristic of allograft vasculopathy is defined as diffuse concentric narrowing in the epicardial medium and small arteries.¹² The only definite therapy for such diffuse disease is repeat transplantation, but the survival rate of retransplantation is worse than for initial transplantation and is limited by organ availability.¹³ Coronary artery bypass surgery also is of limited value in the diffuse, small-vessel disease manifested in these patients. Instead of surgical therapy, percutaneous catheter-based coronary revascularization has been used to attempt to reduce ischemic morbidity and mortality of cardiac transplant recipients.^{4–8}

Cutting Balloon angioplasty is a new treatment for coronary artery stenosis and has unique features.⁹ Three or 4 microsurgical blades, 0.010 inches in height, are bonded longitudinally to a traditional angioplasty balloon surface. During inflation of the Cutting Balloon, the atherotomes expand radially and incise the plaque, which facilitates a uniform longitudinal dissection. In this study, we evaluated the Cutting Balloon for its efficacy and safety in treating allograft arteriopathy. Although the number of lesions treated was small, transplant arteriopathy is a relatively rare disorder.

Cutting Balloon Angioplasty for Allograft Arteriopathy

In this unusual patient population, 20 allograft lesions in 11 patients were treated with Cutting Balloon angioplasty. Despite treating 9 total or sub-total lesions, immediate angiographic success was obtained in all cases and no complication occurred during Cutting Balloon angioplasty. Two patients underwent repeat orthotopic heart transplantation, 1 patient died of heart failure, and 1 patient died suddenly 3 months after Cutting Balloon angioplasty. These events were not related to the Cutting Balloon angioplasty itself but serve as an indication of the severity of disease associated with transplant arteriopathy. We had some initial concern that the stiff blades of the Cutting Balloon catheter could disrupt the luminal surface of the abnormal tissue seen in transplant arteries. However, the Cutting Balloon was used safely in these arteries despite the delicate tissue and propensity for spasm frequently seen with transplanted coronary arteries. The Cutting Balloon can be used effectively to treat long lesions with stent use reserved for those focal areas that remain underexpanded. In this study, we used this technique of IVUS-guided "spot stenting" to the transplant arteriopathy lesions.14

Unfortunately, the angiographic restenosis rate in the small group of patients who were restudied was

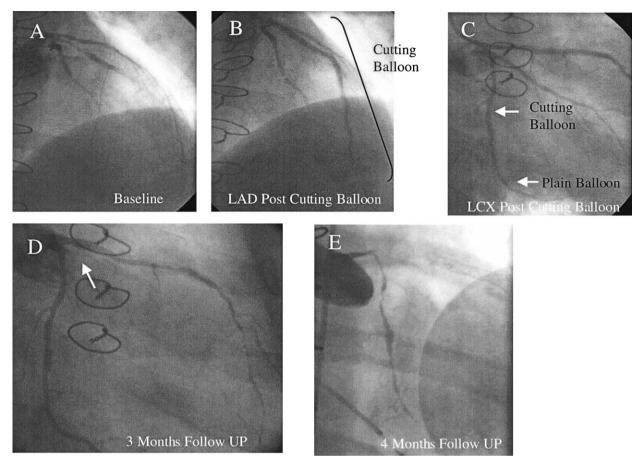


FIGURE 1 Cutting Balloon angioplasty for diffuse disease. Panel A: Baseline angiogram shows total occlusion of previous stent site in the left anterior descending artery (LAD). Panel B: Angiogram after Cutting Balloon was applied to the entire length of the LAD. Another significant focal stenosis is shown in the left circumflex artery (LCX). Panel C: After Cutting Balloon angioplasty in the LCX lesion, the diameter stenosis was improved to 13%. Panel D: Follow-up angiogram 3 months after Cutting Balloon angioplasty. There is a new total occlusion of the first obtuse marginal branch that did not appear to have a significant stenosis at baseline. No significant restenosis was found in either the LAD or LCX angioplasty sites at this time. Panel E: Follow-up angiogram just 1 month after Panel D. Occlusion of the LAD and stenosis of the left main in addition to severe restenosis of previous angioplasty sites in both the LAD and LCX. Because the patient had a cardiac arrest on the way to the laboratory, coronary revascularization was performed under percutaneous cardiopulmonary support.

100% at a mean of 4.9 months. This restenosis rate is high compared with conventional balloon angioplasty for cardiac allograft arteriopathy.^{4,5,8} We initially suspected the high restenosis rate associated with use of the Cutting Balloon was a manifestation of the aggressive proliferation seen with this patient population rather than a direct effect of Cutting Balloon angioplasty when used in transplanted arteries. However, the Cutting Balloon itself might exacerbate the aggressive tissue proliferation associated with transplant arteriopathy and result in a high restenosis rate. The true incidence of restenosis after Cutting Balloon angioplasty remains unclear because these results are obtained from only 12 lesions in 7 patients.

CONCLUSION

The Cutting Balloon can be used safely and effectively for the acute treatment of allograft arteriopathy. The diffuse nature of this disease process requires an efficient dilatation technique that can be used in association with focal application of coronary artery stents to minimize restenosis. However, the current restenosis rate is unacceptably high, which may be caused by stimulation of aggressive tissue proliferation associated with transplant arteriopathy. This implies that adjunctive therapy, such as brachytherapy or anti-metabolite eluting stents, may be necessary to effectively treat transplant arteriopathy.

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