The diagnosis of renal artery stenosis in the coronary population. This is a very important subject since there are now a lot of cardiologists starting to perform renal artery procedures. There is a unique population of cardiologists that deals with the renal artery stenosis problem. This has been an interest of ours for several years. One of the first studies to examine the prevalence of renal artery stenosis in patients undergoing cardiac catheterization was done by Harding et al. Their study focused on 1,302 of 1,651 consecutive patients catheterized in a 5 month period where antero-posterior aortography was used to screen for renal artery stenosis. Ninety-five percent of these patients were deemed technically adequate to assess the presence of renal artery stenosis. There was some degree of renal disease present in 30% of that population. Fifteen percent of these patients were less than 50% stenosed, but 15% were more than 50% stenosed, out of which 11% were unilateral and 4% were bilateral. There is a direct relationship between the severity of coronary disease and the presence of significant renal artery stenosis; patients with 1-vessel disease had a 10% incidence of renal artery stenosis, those with 2-vessel disease had 20% incidence, and those with 3-vessel disease had a 30% incidence of renal artery stenosis. Forty percent of patients with left main disease were found to have some degree of renal artery stenosis.

Univariate predictors of renal artery stenosis are peripheral vascular disease and age. There is an interesting relationship between congestive heart failure and renal artery stenosis and the presence of elevated creatinine. The multivariate predictors of renal artery disease and peripheral vascular disease are age, extent of coronary artery disease, congestive heart failure and female sex.

The rate of progression of renal artery stenosis within the coronary artery disease population. We performed a large study at Duke University wherein we examined 27,000 patients who underwent cardiac catheterization and abdominal angiograms simultaneously. Patients who had undergone more than one abdominal angiogram, at least 6 months apart, were selected in order to look for the progression of the disease; this study group totalled 1,189 patients. Among this group, we found that 22% actually demonstrated a significant progression (defined as ≥ 25% progression between the baseline and follow-up angiograms, which were performed an average of 2.5 years after the initial procedure). The prevalence of any renal artery stenosis at the time of the first catheterization was 8.5%; the presence of significant renal artery stenosis was 2.8%, which is somewhat less than expected. However, the presence of any renal artery stenosis upon subsequent cardiac catheterization was 24% only 2.5 years later, with a significant renal artery stenosis being ≥ 50% in 13.5% of the population; this is much higher than would have been predicted. Therefore, renal artery stenosis seems to progress rapidly once it appears in
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Experience has shown a remarkable success rate. These procedures involved large vessels, and our expanded renal stent implantations we have performed to date. There were no procedural failures during any of the procedures using coronary stenting techniques for renal arteries. The follow-up results are currently undergoing analysis. We have already noted one remarkable result, the only thing in the peripheral artery that is not point, the only thing in the coronary population (ejection fraction, coronary artery disease index, etc.) and singled out only renal artery stenosis, the change was less dramatic. However, renal artery stenosis still remained a significant independent risk factor ($p = 0.0002$).

Treatment of renal artery stenosis. Stents have revolutionized the treatment of peripheral vascular disease. Our use of stents in the peripheral population and the changing pattern between 1993 and 1995 has remained at approximately 98% stent usage. At this point, the only thing in the peripheral artery that is not treated with stent implantation is fibromuscular dysplasia. We are approaching our 300th renal stent procedure; the follow-up results are currently undergoing analysis. We have already noted one remarkable result of using coronary stenting techniques for renal arteries: there were no procedural failures during any of the renal stent implantations we have performed to date. These procedures involved large vessels, and our experience has shown a remarkable success rate.

Complications. We had one patient who presented with massive myocardial infarction after malignant hypertension who had bilateral renal artery stenosis. When we were asked to treat the patient, he was already moribund and went on to die of a severely low ejection fraction later on in the hospitalization. We do not believe this was related to the successful renal procedure. There were 3 patients who began with an abnormal creatinine level (over 2.0) and eventually went to acute hemodialysis. However, all of these were temporary and none required chronic hemodialysis. There was one patient with bowel infarction; we felt this might be due to cholesterol emboli. The patient was taken to surgery and found that the patient had atrial fibrillation but had not been anticoagulated because of gastro-intestinal bleeding; large clots were recovered in the vessel to the bowel, but no cholesterol crystals were found. Therefore, we once again felt that this patient’s complication was not a direct result of the renal artery stenting procedure. In conclusion, there was a surprisingly low rate of complications in this study population.

Is renal artery stenosis under-treated? One would ostensibly treat renal artery stenosis for three reasons:

1) To prevent progression (preservation of renal mass). A recent study in the Lancet looked at the creatinine levels of patients who had abnormal creatinines before stent implantation and after. You can see the deterioration in renal function prior to implantation of the stent; after stent implantation there was no further deterioration in renal function.

2) To treat hypertension. Several similar reports have recently been published about the use of renal artery stenting to treat hypertension. One study that we performed, which looked at 18 months of follow-up on 67 patients, found a statistically significant reduction over the long-term in arterial pressures. There was no statistical difference in medication. It went from 2.7 to 2.2 drugs. Again, a lot of these subjects are cardiac patients and are therefore already on medications such as beta blockers and ACE inhibitors.

3) To aid in the management of congestive heart failure. A report from Rosenfield et al. examined 20 of 72 patients stented for renal artery stenosis who presented with episodic congestive heart failure. Sixty percent of these patients had global renal ischemia (bilateral lesions or lesion in a single remaining kidney). Thirteen patients had normal ejection fractions, despite the episodes of congestive heart failure and 12 had LVH, presumably representing diastolic dysfunction. It is important to note that 90% had no further episodes of congestive heart failure at 6 months after implantation of the renal stents. Despite the existence of these compelling anecdotal and single-center reports, I feel that a system for obtaining randomized control data is absolutely needed in this field.

Percutaneous transluminal renal angioplasty versus renal stent implantation. It is my belief that angioplasty does not work very well in ostial lesions and that stents are therefore the obvious choice in this case. However, my opinion is not necessarily shared by Medicare and other reimbursement sources; unfortunately, they are beginning to deny procedures because of a lack of randomized trial evidence. The Princess trial,
Renal artery stenosis is less common at the first presentation of coronary artery disease, but it becomes rapidly progressive in that population. Secondly, the prevalence of renal artery stenosis is directly related to the severity of coronary disease. Finally, renal artery stenosis appears to be an independent predictor of survival in the coronary population. Randomized trials are needed to compare percutaneous transluminal renal angioplasty versus stenting and medical therapy versus stenting for the management of hypertension, preservation of renal mass, the management of congestive heart failure, and survival rates.

**SUMMARY**

Renal artery stenosis is designed by Dr. Robert Safian, examining renal function after stent therapy compared to medical therapy. I believe we must study renal stenting versus medical therapy to ensure the survival of the renal stenting procedure, particularly if we can limit it to the coronary disease population where there would be a high endpoint.

**Panel Discussion**

**Patricia Thorpe:** I would like to congratulate Dr. Stack and his colleagues at Duke University for performing so many difficult procedures with 100% technical success. I think that result is possible with people who are very well trained, but it is very obvious in patients who have undergone renal angioplasty by physicians who don’t have the experience that there are technical differences that are very important. There are clinical indications, i.e., hypertension control and preservation of renal function. I believe that we are seeing an increased survival rate with patients treated with renal artery stenting and renal angioplasty because we are now addressing the issue of hypertension patients with coronary artery disease. I think we are also going to find that preservation in renal function might also prolong the life of patients with systemic vascular disease. However, I do not think that there is an indication to do renal angioplasty because of the lesions there. I am against performing a “drive-by angiography”, which is an angiogram done as you come out of the artery system without recognition of how much contrast media the patient has received. We have seen people actually go into acute renal failure due to additional contrast modes because practitioners wanted to do an angiogram of the pelvis and abdomen as they came out of the coronary system. Therefore, I think we must be very judicious about how we approach this procedure, and I agree that we need to take into account the technical expertise of the physicians who are doing these procedures.

**Richard Stack:** I think that is a great idea. One thing I would like to point out is that there is a group in Spokane, Washington that has treated 200 ostial lesions with stents. They have now treated 10 patients who are on dialysis. We have encountered cholesterol emboli before when performing other peripheral procedures, but not in this particular population.

**Kenneth Rosenfield:** You touched on the cholesterol emboli to be similar to that seen with coronary interventions. We base this opinion on our technique: after performing an abdominal angiogram, we simply and quickly take the guide into the ostium of the renal artery itself. The guide is inside the ostium for only a few seconds. That is basically the only thing we go near; we do not drag the wire up and down the aorta or anything of that nature, so a cholesterol embolism is extremely rare. We thought we had one; however, the case was extensively investigated, and the portion that was affected was completely resected and examined microscopically. There were no crystals present. I believe the diagnosis of cholesterol emboli is sometimes overdone in patients who have ATN following contrast load. I think it is important to meet all diagnostic criteria for cholesterol emboli before making that diagnosis.

**Moderator:** I have found that the nephrologists that I interact with at my own institution and at international meetings first consider cholesterol embolization when the topic of stenting and/or angioplasty of the renal artery is contemplated in a patient with both hypertension and some element of renal insufficiency. Were there any instances of cholesterol emboli in your series of patients?

**Richard Stack:** We expect the incidence of cholesterol emboli to be similar to that seen with coronary interventions. We base this opinion on our technique; after performing an abdominal angiogram, we simply and quickly take the guide into the ostium of the renal artery itself. The guide is inside the ostium for only a few seconds. That is basically the only thing we go near; we do not drag the wire up and down the aorta or anything of that nature, so a cholesterol embolism is extremely rare. We thought we had one; however, the case was extensively investigated, and the portion that was affected was completely resected and examined microscopically. There were no crystals present. I believe the diagnosis of cholesterol emboli is sometimes overdone in patients who have ATN following contrast load. I think it is important to meet all diagnostic criteria for cholesterol emboli before making that diagnosis.

**Moderator:** You had no cholesterol emboli in a group of 300 patients?

**Richard Stack:** We have encountered cholesterol emboli before when performing other peripheral procedures, but not in this particular population.

**Kenneth Rosenfield:** You touched on the issue of patients going into renal failure on the basis of renal vascular disease. What do you think about the possibility of studying patients as they go into renal failure or patients who are newly on dialysis who have evidence of vascular disease? Should you perform a routine angiogram on those patients to see if you might discover renal artery stenosis and reversible cause for their renal failure? This practice might be worthwhile in several ways even if it resulted in taking only one patient out of 100 off of dialysis.

**Richard Stack:** I think that is a great idea. One would first want to screen the patient population for those more likely to have renal artery stenosis.

**Patricia Thorpe:** I would like to address Dr. Rosenfield’s point. There is a group in Spokane, Washington that has treated 200 ostial lesions with stents. They have now treated 10 patients who are on dialysis.
STACK
dialysis; 4 of them have come off dialysis, although it is hard to attribute this to “residual renal function”. I believe there is still a lot to be learned in this area.

AUDIENCE: Dr. Stack, your study showed that 15% of the patient group had significant renal artery stenosis. If you examine subsets among the population that you studied, such as patients with hypertension or patients with baseline abnormal renal function, the incidence should be a great deal higher.

RICHARD STACK: It is.

AUDIENCE: Did you examine the prevalence of renal artery stenosis in that setting?

RICHARD STACK: Yes, we have examined the relative importance of the multivariate predictors of renal artery stenosis. However, we have not focused a study on predicting different incidences of renal artery stenosis based on hypertension, borderline renal function, extent of coronary disease or other predictors. Perhaps it would be possible to find a population that would be very predictive of renal artery stenosis. For example, a population study might show that a patient with 3-vessel disease who has a borderline creatine level and is hypertensive has an 80% chance of having renal artery stenosis. We have not done that sort of study, but I think it might yield important information.

AUDIENCE: Did you use a femoral approach in all cases?

RICHARD STACK: Yes, we happened to use a femoral approach in all cases. We used an RDC guide; if we could not cannulate (for example, in cases with extremely downward takeoffs), we cannulated an IMA guide. We then get the wire across. If we need to raise that vessel up, we can change to a Rosen wire — that actually provides a more favorable angle for approaching the vessel. We previously used a 0.035” wire-based technique; now that we are in vessels that are 6 mm or so, we can use the 0.018” wire systems. If the vessel is 7–8 mm, we use 0.035” wire-based systems. Perhaps the hardest part of screening patients populations without using angiography is that non-invasive studies contradict each other in terms of what constitutes stenosis.