Hypothesis: Female sex negatively affects the durability of percutaneous angioplasty of native arteries supplying the lower extremity.

Design: Outcome analysis of the results of percutaneous angioplasty of lower extremity arteries in a single vascular surgery practice.

Setting: University-affiliated community hospital.

Patients: All patients undergoing percutaneous intervention on lower extremity arteries during 10 years.

Interventions: Indication for intervention, anatomic site of intervention, placement of percutaneous stents, and length of lesion undergoing angioplasty were noted. Patient demographics and risk factors were identified.

Main Outcome Measures: Results were analyzed by sex. Kaplan-Meier life tables were plotted and differences between groups tested by the log-rank method. A Cox proportional hazards regression model was used to perform the multivariate analysis.

Results: During 10 years, 351 angioplasties were performed in 248 patients, 173 in women and 178 in men. There was no difference between men and women in indication for intervention, length and type of lesion treated, or quality of distal runoff. Univariate survival analysis identified a difference in duration of patency between men and women (P = .047). However, multivariate analysis demonstrated no significant difference in duration of patency between men and women (P = .18). Iliac angioplasty and adequate distal runoff were positive predictors of long-term patency (P < .001 for both).

Conclusions: There appears to be no significant difference in the durability of angioplasty between men and women. However, location of angioplasty and adequacy of distal runoff may be useful in determining when to use angioplasty.

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Dowter and Judkins pioneered the use of the coaxial catheter to perform arterial dilatation in 1964. In 1974, the creation of the balloon angioplasty catheter by Gruntzig and Hopff first allowed dilatation of vessels larger than 4 mm. Over the ensuing years, angioplasty has become an acceptable form of treatment for lower extremity arterial disease. It has been estimated that by 2030 there will be 76 million people 65 years or older and as the population ages, the prevalence of peripheral vascular disease will rise. Because catheter-based procedures are being used at an ever-increasing rate in the treatment of lower extremity arterial disease, a clear understanding of factors that may affect the success of percutaneous interventions would be beneficial in selecting patients for these procedures.

Age and sex have been shown to affect the success of percutaneous coronary arterial interventions and open cardiac bypass surgery. Studies documenting the effect of diabetes mellitus, hyperlipidemia, and hormone therapy on the success and durability of catheter-based peripheral interventions have been performed; however, results regarding the issue of patient sex have been conflicting. The objective of this study was to determine if patient sex can be used as a predictor of the success and durability of percutaneous interventions for lower extremity arterial disease.

METHODS

Medical records of patients who had undergone percutaneous arterial interventions within a single vascular surgery practice during 10 years were reviewed. Procedures had been performed by 1 (S.G.K.) of 2 vascular surgeons or by 1 of 4 interventional radiologists. Only interventions performed in native vessels were included in the study. Data were collected ac-
wise multivariate Cox proportional hazards regression model to determine individual significance in the presence of other factors. Statistical significance was assumed at \( P < 0.05 \).

**RESULTS**

During 10 years, 351 angioplasties were performed in 248 patients. One hundred seventy-three procedures were performed in women and 178 in men. The median age for women was 74 years, and for men it was 71 years. Men were more likely than women to have diabetes mellitus or coronary artery disease and to be taking warfarin sodium (Table 1). Follow-up ranged from 1 to 120 months (mean, 17 ± 22 months).

Fifty-two percent of patients had disabling claudication, 30.7% had gangrene or ischemic ulceration, and 17.3% had ischemic rest pain. The indication for the procedure did not differ between men and women. One hundred seventy-four procedures were performed in iliac arteries, 117 in the superficial femoral artery, 48 in the popliteal artery, and 12 in any of the tibial arteries. Women had more procedures performed in the superficial femoral artery, 48 in the popliteal artery, and 12 in any of the tibial arteries. Women had more procedures performed on the superficial femoral artery than men (\( P = 0.045 \)) (Table 1). All iliac lesions were TASC [Trans-Atlantic Inter-Society Consensus] classification A or B. Seventy-three percent of the lesions treated were less than 5 cm in length, and 4.3% of lesions were treated for occlusion. However, the length of the lesion (\( P = 0.89 \)) and the quality of the distal runoff (\( P = 0.37 \)) did not differ significantly between men and women.

The initial success of angioplasty was 97.2%. Patent rates at 1, 3, and 5 years were 49.6%, 37.3%, and 26.0%, respectively, for infrainguinal interventions and 77.9%, 71.1%, and 62.8%, respectively, for iliac interventions (Figure 1 and Figure 2). Univariate analysis then suggested that sex, smoking, quality of the distal runoff, and location of the angioplasty were significant predictors of overall patency (Table 2). When these factors were subjected to a multivariate analysis, only location of the angioplasty and quality of the distal runoff were found to be significant determinants of long-term durability of the interventions (Table 3).
Percutaneous interventions are increasingly being used to treat peripheral arterial disease. It is therefore important to understand factors that may affect the success and durability of catheter-based treatments. Female sex has been thought to adversely affect the success of angioplasty. However, other studies have not confirmed this and have found the success of percutaneous interventions to be related to other mitigating factors. Our data support the latter position.

The use of angioplasty in the treatment of aortoiliac occlusive disease has been well documented, and results of catheter-based interventions on the iliac vessels have approached those of open surgery. Unfortunately, angioplasty of the infrapopliteal vessels has not been as successful. Iliac angioplasty not only has been used as a stand-alone procedure but also has been demonstrated to be a viable option for improving inflow in patients requiring distal bypass procedures.

Studies by Timaran et al have reported that female sex negatively affects the success of iliac angioplasty. Their series differ from ours in several respects. While their studies focused on patients with suprainfundibular occlusions, our study included individuals with aortoiliac and femoropopliteal disease. In addition, a significant number of angioplasties included in their reports were performed on lesions of marked severity (TASC classification C or D). This contrasts with our series, in which most patients had short-segment disease and lesions that we believed were ideal for percutaneous angioplasty, closely mirroring the group of patients in the study reported by Orr et al that demonstrated no outcome difference following angioplasty based on patient sex. It is difficult to predict what factors will determine the durability of percutaneous interventions performed on vessels more severely diseased than those included in our report.

Although our study did not demonstrate a significant effect of patient sex on the durability of angioplasty, the site of the intervention (iliac vs infrapopliteal) was a crucial determinant of the success of the percutaneous procedures. Multivariate analysis in our study demonstrated that the location of the arterial intervention significantly affected the success and durability of angioplasty of the vessels supplying the lower extremities. Other authors have found that percutaneous interventions performed on the infrapopliteal vessels had poorer outcomes than those performed on the iliac arteries. Although the results of angioplasty of the infrapopliteal vessels have been somewhat discouraging, it is anticipated that future adjunct technologies, such as the primary use of self-expanding nitinol stents, cryoplasty, subintimal angioplasty, and atherectomy, will improve the durability of these procedures. It is interesting to note in our study that women had significantly more procedures performed on the infrapopliteal vessels than did men. This almost certainly accounts for the sex difference that was seen in the univariate analysis.

Our study demonstrates that, in addition to the location of the intervention, the adequacy of the distal runoff vessel is a significant determinant of the success of peripheral angioplasty. Patients with 1 or no runoff vessel distal to the site of intervention were significantly less likely to have a durable result from angioplasty than those with adequate runoff. This may account for the moder-
ate success of catheter-based interventions performed in patients with limb-threatening conditions, who often have compromised outflow vessels. This finding has been documented by others21,22 and would suggest that, in patients with inadequate runoff, angioplasty should be performed only in cases of critically ischemic tissue.

Encouraged by recent technologic advancements, such as the primary use of self-expanding nitinol stents, we have expanded our indications for catheter-based therapy. We attempt iliac angioplasty in patients with TASC classification A, B, or C lesions. In those with femoropopliteal disease, angioplasty is used as the first line of therapy in patients with at least 1 continuous runoff vessel to the ankle, as well as in most patients with limb-threatening ischemia regardless of the status of their runoff vessels. We continue to use operation as the primary therapy in most patients with extensive tibial artery disease.

Technologic advances in catheter-based procedures are occurring at an ever-quickening pace. It can be expected that the durability of these procedures will improve. Angioplasty offers the advantages of low morbidity, short hospital or outpatient stay, and saphenous vein preservation, and it may be used repetitively to treat arterial lesions. This will likely lead to its use in more patients with peripheral vascular disease. Delineating the factors that are significant in determining the success of these interventions will assume greater importance in the coming years. We conclude that patient sex does not significantly affect the durability of angioplasty of the peripheral vessels. While the location of the intervention and the quality of the distal runoff vessels may be useful in deciding when to use catheter-based procedures, sex should not be considered in determining the appropriateness of angioplasty in treating patients with peripheral arterial disease.

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REFERENCES
suggests equivalence of results of angioplasty in both men and women.

I have several questions for the authors. In the early phase of the study, the evaluation was generally clinical and ankle-arm indices. What were the confirmatory studies you performed? You mentioned duplex, but I wonder how many angiograms actually were performed. Since atherosclerotic disease is usually diffuse in these vessels, what were your criteria for a 50% recurrence by duplex in the iliac, femoral, and in the patients who had tibial and popliteal artery disease? Were you absolutely sure that the recurrence was in previously treated vessels, as opposed to new disease, either proximally or distally to the treated site by angioplasty?

Did the fact that women had more superficial femoral artery disease mean that men had more popliteal and tibial disease, and did this distribution skew the results in favor of women? Our experience has been that stents in the superficial femoral artery fail more quickly than angioplasty alone. Angioplasty tends to remodel with time, and I wonder if the number of stents placed in the superficial femoral artery is equal in both groups.

Were the differences between groups in the incidence of external iliac vs common iliac involvement the same? It is generally accepted that external iliac artery patency is less good than common iliac artery patency.

Finally, I would like to commend the authors for undertaking this study. Most of our information about the outcome of angioplasty is quite poor because of limited follow-up and lack of detailed patient information. Often, the data are published in radiology journals where follow-up is short and the definition of long-term follow-up is when the patient leaves the hospital. Now that vascular surgeons are involved in this field, we should begin to see results and more rigorous analyses, an example of which Dr Katz and his colleagues have presented today.

S. Eric Wilson, MD, Orange, Calif: The 95% high rate of initial success is excellent; however, I want to ask about the 1-year success rate after PTA of superficial femoral artery occlusions. With failure of an SFA PTA, reocclusion may occur and clot, in some patients, may extend more distally in the vessels, so that they may be worse off at the end of the year. Two randomized trials have shown that, in control patients without any intervention, there is no difference at the end of 2 years compared to those who have PTA of the SFA.

My question is, assuming a 50% failure rate of SFA PTA at 1 year, what are the appropriate indications? Also, can you advise us if the newer medicated stents have improved outcome?

Dr Katz: To answer Dr Dilley’s questions first, any patient who had an abnormal ankle-brachial index underwent duplex ultrasonography, and our criteria for significant stenosis were peak systolic velocity of 200 cm/s or greater, a 3:1 ratio across the lesion, and a change in the waveform below the area in question. We believe that our duplex scans were quite accurate in determining whether stenoses post angioplasty were located at the site of previous intervention. About 70% of the patients underwent repeat angiography. The remaining 30% remained relatively asymptomatic and did not wish to have any further therapy.

I don’t believe that I can explain why women were more likely to undergo angioplasty of the superficial femoral artery than men. I have changed the way I view stents in the superficial femoral artery. I have gone to primarily stenting superficial femoral arteries with self-expanding nitinol stents. Most of the original studies were performed with stainless steel, balloon-expandable stents, which were prone to fracture and early failure. Our preliminary results and those of others would suggest that primary nitinol stenting of the superficial femoral artery may significantly improve the durability of angioplasty alone.

I believe the numbers of angioplasties in the external and common iliac arteries were about the same for both men and women.

To answer Dr Wilson’s question, I do believe that there is a place for angioplasty of the superficial femoral artery. As previously mentioned, adjunctive measures, such as primary stenting, as well as cryoplasty and perhaps atherectomy, may hold promise in improving the results of infrapopliteal angioplasty. Drug-eluting stents, which have been so successful in the coronary circulation, are just beginning clinical trials in the periphery. Unfortunately, the results of these studies will not be known for several years.