Failure of foot salvage in patients with end-stage renal disease after surgical revascularization

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Purpose: This report ascertained factors responsible for failure of foot salvage in patients with end-stage renal disease (ESRD) after undergoing infrainguinal bypass for critical ischemia.

Methods: A retrospective review of 69 distal arterial reconstructions performed in 53 patients with ESRD (hemodialysis [n = 37], kidney transplantation [n = 10], peritoneal dialysis [n = 6]) for foot gangrene (n = 28), nonhealing ulcer (n = 25), or ischemic rest pain (n = 16) was conducted. Endpoints of surgical morbidity, limb loss, and graft patency were correlated with extent of preoperative tissue loss and presence of diabetes mellitus.

Results: The 30-day operative mortality rate was 10%, and the patient survival rate at 2 years was 38%. The primary graft patency rate was 96% at 30 days, 72% at 1 year, and 68% at 2 years. Eleven of 22 foot amputations performed during the mean follow-up period of 14 months (range 3 to 96 months) occurred within 2 months of revascularization. Mechanisms responsible for limb loss included graft failure (n = 9), foot ischemia despite a patent bypass (n = 8), and uncontrolled infection (n = 5). Overall, 59% of amputations were performed in limbs with a patent bypass to popliteal or tibial arteries. Healing of forefoot amputations was prolonged, but all limb loss beyond 9 months of revascularization was due to graft failure. The limb salvage rate at 1 year decreased (p = 0.13) from 74% to 51% in patients admitted with gangrene. Only two of seven patients admitted with forefoot gangrene experienced foot salvage.

Conclusion: Failure of foot salvage in patients with ESRD and critical ischemia was due to wound healing problems rather than graft thrombosis. Earlier referral for revascularization, before development of extensive tissue ischemia and infection, is recommended. Primary amputation should be considered in patients admitted with forefoot gangrene, particularly if it is complicated by infection. (J VASC SURG 1995;22:280-6.)

Lower limb revascularization has been advocated to patients with end-stage renal disease (ESRD) when critical ischemia develops to improve quality of life. Surgical revascularization can be arduous because of comorbid heart and pulmonary disease, as well as anticipated difficulties with wound healing and infection resulting from uremia, malnutrition, diabetes mellitus, and long-term immunosuppression. A role for primary amputation has been suggested, but the patient cohort in whom the expense and manpower of revascularization can be avoided has not been clearly defined. With modern day techniques of lower limb revascularization and free muscle flap tissue transfer, even patients with forefoot or hindfoot gangrene are often deemed suitable candidates for limb salvage surgery if a suitable runoff artery and venous conduit are available. Unfortunately, in the patient population with ESRD and foot ischemia, these advancements in distal artery bypass grafting and tissue healing have not uniformly resulted in foot salvage, particularly in patients with long-standing insulin-dependent diabetes mellitus. Several authors have reported clinical failure with limb amputation despite a functioning bypass graft.[1-7]

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Table I. Patient demographics

Sex	
Male	27
Female	26
Age (yr.)	
Mean	59
Range	32-84
Risk factors	
Diabetes	43 (81%)
Hypertension	41 (77%)
Coronary artery disease	20 (38%)
Cigarette smoking	12 (22%)
Stroke	8 (15%)
Heart failure	8 (15%)
Prior myocardial infarct	4 (7.5%)

We have used similar criteria for revascularization in patients with ESRD as for other patients with critical ischemia from atherosclerosis obliterans because of a perceived similar outcome, particularly regarding early graft patency and surgical morbidity. Limb salvage in the patient population with ESRD often requires more than successful bypass grafting; control of infection and achieving adequate tissue perfusion for healing are also crucial for success. In this review, we have examined the factors responsible for limb loss in patients with ESRD diagnosed with critical lower limb ischemia who underwent infrainguinal bypass grafting.

CLINICAL POPULATION AND METHODS OF STUDY

The records of 53 patients with ESRD who underwent 69 infrainguinal bypass grafts from November 1983 to December 1994 for critical limb ischemia by staff of the Virginia Vascular Associates (M.H.G., Eastern Virginia Medical School, [n = 56]) or the Division of Vascular Surgery at the University of South Florida (D.F.B., [n = 13]) were reviewed. The two primary surgeons (M.H.G. and D.F.B.) in most of the procedures had completed surgical training together, therefore approaches to revascularization was similar. The patient populations with ESRD were alike because the institutions involved in the study were tertiary care centers. Patients receiving long-term hemodialysis (n = 37), peritoneal dialysis (n = 6), or a functioning kidney transplant (n = 10) were included. The group was composed of 27 men and 26 women with a mean age of 59 years (Table I). Eighty-one percent of patients had diabetes mellitus. Critical foot ischemia was the indication for revascularization in the 69 limbs and included nonhealing ulcer (n = 25), digit gangrene (n = 21), ischemic rest pain (n = 16), and forefoot gangrene (n = 7). Revascularizations performed solely for intermittent claudication were excluded. Primary amputation was performed in those patients whose preoperative angiograms showed extensive distal atherosclerotic disease not amenable to bypass (isolated popliteal segments were considered amenable to bypass). In general, patients had measured ankle/brachial pressure indexes (ABI) less than 0.5 and toe pressures less than 40 mm Hg or, when incompressible tibial arteries were detected, absent pulsatile arterial flow in the plantar or digital arteries.

Table II. Distribution of distal anastomosis for 69 infrainguinal arterial bypasses

Sites of distal anastomosis	*No.*
Popliteal artery	
Above-knee	7
Below-knee	12
Anterior tibial artery	20
Posterior tibial artery	11
Peroneal artery	6
Pedal arteries	13

The type of bypass grafting included in situ saphenous vein (n = 36), reversed saphenous vein (n = 26), polytetrafluoroethylene bypass (n = 5), and homografts in two instances. Most (65%) of the bypasses originated from the common femoral artery, but the popliteal artery was deemed a suitable inflow artery in 24% of cases. Table II lists the site of distal anastomosis for the 69 infrainguinal bypass grafts. Infrageniculate or pedal arteries were the graft outflow in 72% of the procedures.

Outcome analysis. Survival, limb salvage, and graft patency were analyzed by life-table methods. A Mantel-Haenszel test was performed to compare procedure outcomes. Graft patency was assessed by duplex scanning at 3-month intervals during the first postoperative year and at 6-month intervals thereafter. Any bypass that occluded or required a subsequent procedure (thrombectomy, thrombolysis, or graft revision) to restore or maintain functional patency resulted in loss of primary patency. Salvage of the foot was defined as relief of rest pain or healing of ischemia lesions or amputations at the digit or forefoot level. Outcome (death, graft patency, or foot amputation) was correlated with the presence of preoperative gangrene, diabetes mellitus, and type of revascularization. Failure of foot salvage via the mechanisms of graft thrombosis, persistent foot ischemia, and infection with a patent bypass or uncontrolled infection were tabulated for each postoperative interval.

Table III. Cause of limb loss during postoperative follow-up

Postoperative interval (mo.)	*No. of amputations*	*Bypass graft status*		*Reason for foot amputations*
		Patent	*Thrombosed*	
0-1	6	5	1	Foot ischemia-3 Infection-2 Graft failure-1
1-2	5	5	0	Foot ischemia-4 Infection-1
2-12	8	3	5	Foot ischemia-1 Infection-2 Graft failure-5
12-24	2	0	2	Graft failure-2
>24	1	0	1	Graft failure-1

Table IV. Cumulative limb salvage rates

Interval (mo.)	*No. of limbs at risk*	*No. of limbs lost*	*No. withdrawn*	*Interval limb loss*	*Cumulative salvage (%)*	*SE (%)*
0-1	69	6	8	.91	100	0
1-3	55	6	3	.89	91	3.7
3-6	46	3	8	.93	81	5.2
6-12	35	4	8	.87	75	6.3
12-18	23	1	4	.95	65	8.0
18-24	17	1	5	.93	62	9.3
24-30	11	0	1	1.00	57	11.3

RESULTS

The 30-day operative mortality rate was 10% (seven patients), with three deaths the result of myocardial infarction. The patient survival rate at 1 and 2 years was 58% and 38%, respectively. Postoperative wound complications developed in 20 (29%) limbs and included dehiscence as a result of dermal necrosis ($n = 10$), infection ($n = 6$), hematoma ($n = 3$), and seroma ($n = 1$). Two wound infections involved the bypass graft and required ligation followed by limb amputation. Persistent foot ischemia (nonhealing ulcer, extension of gangrene, or unresolved rest pain) and uncontrolled infection (progressive infection extending to deep tissues/joints or infection of the incision requiring graft ligation) despite a patent bypass graft were major causes of limb loss within the first 2 months of revascularization (Table III). Persistent foot ischemia was manifest in eight patients, all of whom had diabetes, as progressive tissue gangrene, unresolved rest pain, or the nonhealing and subsequent breakdown of a forefoot amputation site. Sites of distal anastomosis in the patients with foot ischemia despite a patent bypass were tibial ($n = 6$), pedal ($n = 1$), and below-knee popliteal ($n = 1$) arteries. The preoperative angiographic reports in three of these patients revealed an incomplete foot arch, whereas the bypass to the popliteal artery was to an isolated segment. Postoperative noninvasive hemodynamic assessment in these patients was limited by incompressible vessels and amputations precluding toe pressures, yet two patients had monophasic Doppler foot signals in bypasses to tibial vessels, and the patient with the bypass to the isolated popliteal segment had no change in the ABI (0.63 before operation; 0.63 after operation). Six of the eight patients underwent postoperative graft surveillance duplex scanning, with all showing normal systolic velocities with a range of 59 to 90 cm/sec and no areas of stenosis. Overall 13 (59%) of 22 amputations performed after revascularization were in patients with functioning bypass grafts. All amputations beyond 9 months of revascularization were due to graft failure. The cumulative limb salvage rate was 91% at 1 month and decreased to 57% by 2 years (Table IV). Limb salvage rates in patients with diabetes were similar, 88% at 1 month and 57% at 2 years.

Fourteen of the 69 grafts failed during a mean follow-up interval of 13 months (range 8 days to 72 months). Calculation of primary graft patency rates by life-table methods showed a cumulative patency rate of 96% at 1 month, 72% at 1 year, and 63% at 2 years (Table V). Graft thrombosis resulted in six immediate above-knee ($n = 1$) or below-knee ($n = 5$) amputations. Two patients underwent graft

Table V. Cumulative primary patency of all grafts

Interval (mo.)	*No. of grafts at risk*	*No. failed*	*No. withdrawn*	*Interval patency rate*	*Cumulative patency (%)*	*SE (%)*
0-1	69	2	14	.96	100	0
1-3	53	4	10	.91	96	2.6
3-6	39	4	7	.89	88	4.8
6-12	28	2	8	.92	78	6.9
12-18	18	1	2	.94	72	9.0
18-24	15	1	4	.92	68	9.9
24-30	10	0	1	1.00	63	12.1

Table VI. Clinical failure after revascularization in 53 ESRD patients (69 procedures)

		Failure of foot salvage		
Postoperative time	*Perioperative death*	*Graft thrombosis*	*Foot amputation**	*Clinical failure rate (%)*
1 month	7	2	5	20
1 year	7	8	13	41†

*Foot lost with patent bypass graft.
†Minimum failure rate because not all patients were monitored for 1 year (two patients lost to follow-up, seven patients monitored less than 1 year).

revision or a redo bypass, and four patients had adequate foot perfusion without ulceration or rest pain after graft failure.

Because the goal of revascularization in the 53 patients with ESRD was limb salvage and improved foot perfusion, operative death, graft thrombosis, and foot amputation were considered procedure failures. After 1 month, 14 (20%) of the 69 bypass grafting procedures failed to help the patient (Table VI). Although not all patients were monitored for 1 year, the calculated minimum clinical failure rate in the 53 patients with ESRD was 41% after this time interval. Failure of foot salvage was the most common adverse outcome. Only two of seven patients admitted with forefoot gangrene (gangrene extending beyond the web space of the toes) experienced clinical success beyond 5 weeks after revascularization. Two patients died, and three patients required early foot amputation. When the indication for limb revascularization was gangrene or gangrene complicated by infection, the foot salvage rate was 51% at 1 year versus 74% when patients were admitted with ischemic rest pain or nonhealing ulcers ($p = 0.13$). Ten patients with functioning kidney transplants underwent 13 bypasses without an operative death or early graft failure. Despite apparently successful bypass revascularization, four limbs required above- ($n = 2$) or below-knee ($n = 2$) amputation because of persistent ischemia.

DISCUSSION

Prior reports dealing with lower limb bypass grafting in patients with ESRD have emphasized an increased operative morbidity rate, but because of limb salvage rates in the range of 76% to 91% at 2 years, an aggressive approach toward revascularization has been advocated.[2-4] Most authors have acknowledged the limited the life-span of these patients and observed limb loss despite apparently successful bypass grafting. In our patients, 13 (59%) of 22 amputations were performed in limbs with patent, functioning bypass grafts. These results suggest that surgeons need better parameters to predict healing of ischemic foot lesions in the patient with ESRD. Our review found that failure of foot salvage was more common in patients diagnosed with gangrene, particularly if the ischemic tissue was also involved by infection. The limb salvage rate decreased to 51% at 1 year when gangrene was the indication for surgery. Early clinical failure (operative death, graft failure, amputation) after revascularization increased from 20% for the overall series to 71% for the seven patients admitted with forefoot gangrene. These observations suggest that earlier referral of patients with ESRD before development of major tissue loss could favorably influence outcome.

It appears that healing of ischemic lesions and amputation sites (i.e., tissue healing) rather than graft failure is the obstacle in achieving foot salvage. Our retrospective review cannot reliably identify patients in whom primary amputation would be the "best" treatment, but this alternative should be considered when extensive forefoot gangrene or infection is present. We found that early limb loss (< 2 months) was not due to graft thrombosis but to progressive gangrene, absence of wound healing, and infection. Of the 11 amputations in the first 2 months, 10 (91%) were in patients with patent bypasses with persistent foot ischemia or uncontrolled infection. Beyond 2 months from revascularization, eight (73%) of 11 amputations were the result of bypass failure. If the problem of limb loss despite a patent bypass could have been avoided, the limb salvage rate in our patients would have improved from 65% to 85% at 1 year. Therefore achieving higher early limb savage rates depends on better selection of patients for revascularization or improvements in wound healing and control of infection after surgery. Criteria for primary amputation in patients with ESRD and critical ischemia were suggested by Edwards et al.,[1] who found that the size (> 2 cm) of foot ulcers in patients with diabetes could predict failure of limb salvage. Subsequent studies have failed to confirm this, and in our study only three of 13 patients with a patent bypass when undergoing amputation had a nonhealing ulcer as the initial indication for surgery. Wassermann et al.,[5] in a study of 42 bypasses in patients with ESRD, believed that a preoperative ABI < 0.3 was predictive of poor limb salvage. Larger studies of patients undergoing infrainguinal bypass have failed to find preoperative ABIs statistically significant for predicting limb salvage.[8]

Our review highlights the problem of clinical failure despite successful bypass grafting that occurred in 13 patients in our series. Multiple studies have reported this problem, especially in patients with diabetes, large ischemic ulcers, and bypasses to isolated popliteal segments.[1,4,6,7,9] One reason for the failure of bypass grafting to prevent foot loss in patients with ESRD could be due to the incorrect placement of the distal anastomosis. In our study, seven of eight limbs with a patent bypass requiring amputation because of tissue ischemia had the distal anastomosis performed to a tibial or pedal artery. This should have provided adequate perfusion to prevent progression of gangrene or to achieve ulcer healing. The angiographic reports showed that three of these patients had an incomplete foot arch. One patient had a bypass to an isolated popliteal artery. Postoperative noninvasive hemodynamic assessment in these patients was limited by incompressible vessels, amputations precluding toe pressures and nonavailability of laser Doppler velocimeter and transcutaneous oximetry. When these data were available it showed monophasic Doppler foot signals in bypasses to tibial vessels in two patients and no improvement in the ABI of the patient with the bypass to the isolated popliteal segment. The increased percentage of limbs amputated with a patent bypass in patients with ESRD suggests that, although successful revascularization and foot salvage require operative technical precision, they also depend greatly on careful preoperative selection of operative candidates, with detailed angiographic assessment of foot vessels and consideration for primary amputation in those patients with only an isolated popliteal artery.

Even with adequate perfusion, failure of tissue healing in patients with ESRD could be explained by associated conditions such as anemia, malnutrition, and depressed immune function. Delayed wound healing occurs with uremia, which reduces formation of granulation tissue in wounds when compared with controls.[10] In addition, diabetes, a disease present in most patients with ESRD, is also associated with a deficiency of collagen content in granulation tissue. Although patients undergoing transplantation are not affected by uremia, they receive immunosuppressive medications that impair wound healing. It has been suggested that use of nonnephrotoxic antibiotics such as cefoperazone in patients with kidney transplants can reduce wound infection rates and thereby improve wound healing.[11] The use of recombinant human tissue growth factor may be needed in patients with ESRD to promote tissue regeneration and healing. This hormone has been shown to enhance protein balance and increase wound healing and immune function in the malnourished patient undergoing hemodialysis.[12]

Problems of impaired healing and resistance to infection often result in wound complications in patients with ESRD after they undergo lower limb bypass grafting. In this series, 20 (29%) procedures were associated with wound complications, of which eight required a return to the operating room for treatment. We used an in situ bypass technique in 52% of the procedures, which may have contributed to the high number of wound problems. Of note, both grafts that required ligation because of a wound complication were in situ saphenous vein bypasses. Wassermann et al.[5] reported a 36% incidence of wound complications with only reversed saphenous vein grafting but did not have any wound problems that resulted in graft ligation or rupture. These authors believed that tunneling the vein graft in an anatomic or subfascial plane was an important technical maneuver when operating on patients with ESRD.

It is important when considering any major operation to be cognizant of its overall outcome and benefit to the patient. Perioperative death, graft thrombosis, and amputations with patent grafts obviously do not benefit the patient with ESRD and critical ischemia. We found the clinical failure rate to be 22% at 1 month and 41% at 1 year. These sobering results occurred despite a high technical success rate with bypass grafting (30-day primary graft patency rate of 96%). If the most frequent cause of failure, amputation with a patent graft, could be eliminated, the outcome of surgical revascularization could be improved significantly. We continue to recommend infrainguinal bypass grafting to patients with ESRD when a multidisciplinary evaluation indicates that limb salvage is likely. In patients with gangrene and infection, consultation with plastic surgery and infectious disease are frequently obtained. Although we were not able to identify conclusively which factors will predict limb loss, we believe that referral at the first signs of foot ischemia and consideration for primary amputation in patients with forefoot gangrene or poor runoff (documented by angiographic assessment with complete foot films) should decrease the failures of foot salvage seen within the first 2 months after infrainguinal bypass grafting.

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DISCUSSION

Dr. Frank J. Veith (Bronx, N.Y.) I generally agree with the findings and conclusions of this study. My agreement is based on a recent 10-year analysis that Dr. Luis Sanchez[7] carried out on 141 threatened limbs in 112 patients with ESRD. When gangrene and infection were extensive and involved the mid foot, as was the case in 21 limbs, we performed a primary amputation. We attempted limb salvage by balloon angioplasty in 40 limbs and by bypass in the remaining 80 limbs. Our overall 30-day and late mortality rates were almost identical to Dr. Johnson's. Our results with bypasses were much better than those with balloon angioplasty, even though the bypasses were performed in the more difficult situations with worse arterial disease. The 6-month limb salvage rates were 83% ± 5% with bypasses and only 50% ± 11% with percutaneous transluminal angioplasty (PTA). Moreover, PTA often (seven limbs) delayed the rescue bypass so that, even when the bypass was successful, the limb was lost. We therefore believe PTA to be a poor option for treating limb-threatening ischemia in patients with ESRD. Like Dr. Johnson, we had a high incidence in these patients of limb loss despite a patent bypass and a palpable foot pulse. This always occurred in the face of extensive infection or gangrene as he found, and it is in this group of patients with ESRD that we believe primary amputation to be appropriate; however, if necrosis is limited, bypasses are worthwhile even in patients with diabetes and ESRD. Some good results can be obtained in this setting. Surgeons undertaking these procedures must, however, be aware that these patients with ESRD and diabetes have calcified, difficult arteries to deal with and high operative mortality and morbidity rates.

What are your views on the role of PTA in patients with ESRD? How precisely do you determine when forefoot infection and gangrene are extensive enough to justify primary amputation?

Dr. Brad L. Johnson. We have not used PTA in our patients very often and, given the severity of disease in this patient population, I do not believe that it would meet with much success, especially given the degree of gangrene seen in these patients.

We also have difficulty trying to choose those patients who should proceed to undergo primary amputation with forefoot gangrene, but given that only two of seven patients experienced clinical success, we believe that probably this group of patients should proceed directly to primary amputation.

Dr. James Seeger (Gainesville, Fla.). You stated that you performed some amputations even with patent bypass grafts presumably because you couldn't control the infection in the foot. What information do you have that documents good perfusion to the foot, even out into the toes in these patients? Did you have toe pressures that confirm the hemodynamics of the foot? Alternatively, do you have any information about the arterial anatomy in the foot, not whether there were patent pedal arches but rather whether digital arteries were present so that there was a potential of getting perfusion out to the area that was infected?

Dr. Johnson. Yes, we were concerned about whether we had adequate distal perfusion. No, we have not reviewed angiograms to assess patent arches or digital arteries.

Dr. William Suggs (Bronx, N.Y.). I have believed that the flow should be adequate for wound healing because of pulsatile flow coming from small digital calcified vessels, and yet in 2 days after what appears to be a clean wound, the muscle turns gray and the foot is unsalvageable. Has that been your experience, that even when the wound looks clean and the amputation looks adequate, 2 or 3 days later there is a local wound healing problem that then leads to a below-knee amputation?

Dr. Johnson. We had patients in whom we believed we had successful limb salvage with good perfusion but who continued to progress with gangrene. We had one patient who had an ulcer that eventually eroded into his ankle joint, which led to limb loss, so, yes, it still occurs when you believe you have adequate perfusion to the distal foot.

Dr. Timothy R. S. Harward (Gainesville, Fla.). I want to answer the question pertaining to small-vessel disease in the patient with diabetes. Dr. Strandness, among others, has shown quite nicely that small-vessel disease does not occur in the feet of patients with diabetes. In patients with diabetes and ESRD, tibial arteries are noncompressible because of medial calcinosis but one can still compress the digital artery. With a photoplethysmograph and a small cuff, one can very accurately measure toe pressures in the second, third, or fourth toes, whereas if you move up to the ankle or transmetatarsal areas, you are measuring pressure in the dorsalis pedis arteries, which are calcified; therefore you can't compress the artery.