Patency and Limb Salvage After Infrainguinal Bypass With Severely Compromised (“Blind”) Outflow

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Hypothesis: Infrainguinal graft patency and limb salvage are adversely affected by severely compromised outflow.

Design: Retrospective review of all infrainguinal bypass procedures performed at a single institution during a 5-year period.

Setting: University teaching hospital.

Patients: Two hundred seventy-four patients underwent infrainguinal bypass for limb salvage (351 grafts in 307 limbs).

Interventions: All infrainguinal bypasses originated from a femoral artery. The distal anastomosis in 279 grafts was located in an artery with at least 1 patent outflow vessel with anatomically normal end-artery runoff (Society for Vascular Surgery/International Society for Cardiovascular Surgery ad hoc committee runoff score, 1-9). The distal anastomosis of 72 grafts was located in an artery with only collateral outflow (“blind bypass”; runoff score, 10).

Main Outcome Measures: Perioperative morbidity and mortality, primary-assisted and secondary graft patency, limb salvage, and survival.

Results: All data are presented as mean±SEM. Patients undergoing blind bypass were older (age, 70±2 vs 66±1 years; P < .05) and had a higher incidence of hypertension (90% vs 70%; P < .05) and end-stage renal disease (24% vs 13%; P < .05). Comparing patients undergoing blind bypass to bypass with at least 1 patent outflow vessel, there were no differences in the use of nonautogenous conduits (50% vs 59%; P = .21) or postoperative warfarin (30% vs 32%; P = .69), or in perioperative mortality rates (2.7% vs 3.2%; P = .79). After a median follow-up of 13 months (range, 0-60 months), 2-year secondary graft patency for the entire group was 63% ± 4%. The secondary patency rate of blind bypass grafts was no different from that of grafts with at least 1 patent outflow vessel (67% ± 7% vs 64% ± 4%; P was not significant). However, the 2-year limb salvage rate in limbs with blind outflow was significantly worse than in limbs with at least 1 patent outflow vessel (67% ± 7% vs 76% ± 3%; P = .04).

Conclusion: Acceptable long-term patency rates can be achieved in infrainguinal bypass grafts with blind outflow, although blind outflow remains a marker for subsequent limb loss in the chronically ischemic leg.

Arch Surg. 2001;136:635-642

The favorable results of infrainguinal bypass grafting have promoted widespread application of these procedures to attempt limb salvage in patients with limb-threatening ischemia.1,3 These procedures have become increasingly complex in the current era,6 and the risks and costs associated with them are substantial.11 Therefore, it is important to identify factors that can predict outcome and allow better patient selection.

Anatomical factors influencing peripheral vascular bypass outcomes include inflow vessel quality, conduit quality, and the nature and quality of the outflow bed. Several studies have emphasized the importance of conduit quality over outflow as the primary determinant of graft patency and limb salvage.7,8 Previous studies examining the role of outflow status have used both anatomical and hemodynamic models but have failed to demonstrate conclusive results.9,10

Recent standardization of the angiographic runoff score by the Society for Vascular Surgery/International Society for Cardiovascular Surgery (SVS/ISCVS) ad hoc committee has facilitated the evaluation of outflow in predicting graft patency and limb salvage after peripheral vascular bypass grafting.11 Although several previous studies have attempted to define the role of outflow in predicting outcome, to our knowledge, no other series has fo-
PATIENTS AND METHODS

We performed a retrospective review of consecutive patients undergoing infrainguinal revascularization for limb salvage between December 1994 and January 2000 at a tertiary care medical center. During this period, 331 grafts originating from femoral arteries were created in 307 limbs in 274 patients. Of these grafts, 279 were anastomosed to patent outflow arteries (SVS/ISCUS runoff score, 1–9), whereas 72 terminated in arteries with blind outflow (SVS/ISCUS runoff score, 10).

PATIENT CHARACTERISTICS

Patients in both groups had risk factors commonly associated with atherosclerosis (Table 1). The patent outflow group included younger patients and a significantly greater number of smokers than the blind outflow group. Hypertension and end-stage renal disease (ESRD) occurred more frequently in the blind outflow group. All other comorbidities were similar between the 2 groups. The majority of patients in both groups had evidence of atherosclerosis in multiple vascular beds. Forty-four percent of patients demonstrated significant peripheral vascular disease in the contralateral extremity, which was manifested as contralateral claudication in 12% of patients, rest pain in 6%, and tissue loss in 7%. Twenty-two percent of patients had undergone prior contralateral bypass, and contralateral amputation had been performed in 9% of the patients.

Although all patients underwent revascularization for limb salvage indications (rest pain, ulceration, or gangrene), bypasses performed with blind outflow were more likely to be associated with concomitant tissue loss (36% with patent outflow vs 69% with blind outflow; \(P = .04\)). Operations for acute ischemia were performed in 8.6% of cases with patent outflow and in 8.3% of blind bypasses (\(P = \text{not significant [NS]}\)).

PREOPERATIVE EVALUATION

Prior to infrainguinal bypass, all patients underwent preoperative digital subtraction arteriography to fully evaluate the extent of arterial disease. Angiographic runoff score was calculated using the method recommended by the SVS/ISCVS ad hoc committee.15 The procedures were separated into those performed to outflow vessels with runoff scores between 1 and 9 (patent outflow) and those performed to outflow vessels with a runoff score of 10 (blind outflow).

RESULTS

Infrainguinal grafts to patent outflow vessels demonstrated similar postoperative complications compared with bypasses performed to blind outflow vessels (Table 4). Perioperative mortality rates remained low in both groups (3.2% with patent outflow vs 2.7% with blind outflow; \(P = \text{NS}\)). Major complications occurred in 47 (13%) of 351 procedures and did not differ between groups (13% with patent outflow vs 15% with blind outflow; \(P = \text{NS}\)).

After a median follow-up of 13 months (range, 0-60 months), the 6-month, 12-month, and 24-month cumulative primary graft patency rates were 63% ± 3%, 51% ± 3%, and 46% ± 3%, respectively. Primary-assisted patency rates were 72% ± 2%, 64% ± 3%, and 60% ± 3% at 6, 12, and 24 months. Secondary patency rates were 80% ± 2%, 71% ± 3%, and 64% ± 4% at 6, 12, and 24 months. Secondary patency at 24 months was 76% ± 4% for autologous grafts and 44% ± 6% for nonautologous grafts. When bypasses with patent outflow were compared with
blind bypasses, there was no significant difference in secondary patency rates (64% ± 4% with patent outflow vs 67% ± 7% with blind outflow; P = NS) (Figure 1). Because the frequency of suprageniculate vs infrageniculate distal anastomoses differed between the patent outflow and blind outflow groups, patency rates were further analyzed separately for these 2 distal anastomotic sites. Again, no difference between patent outflow and blind outflow was noted in 2-year secondary patency rates (Figure 2) for these 2 locations.

Limb salvage rates were significantly lower in the blind outflow group than in the patent outflow group (76% ± 3% with patent outflow vs 66% ± 7% with blind outflow; P = .02) (Figure 3). This difference in limb salvage between the groups was most remarkable in patients with above-knee bypasses (82% ± 7% with patent outflow vs 63% ± 10% with blind outflow; P = .01) (Figure 4). Bypasses to infrageniculate vessels demonstrated no difference in limb salvage at 2 years when comparing patent outflow with blind outflow (64% ± 4% with patent outflow vs 65% ± 9% with blind outflow; P = NS). Early amputation (within 30 days) was performed more frequently in the blind outflow group (4% with patent outflow vs 14% with blind outflow; P = .002). More patients in the blind outflow group also required amputation despite a patent bypass graft (2% with patent outflow vs 8% with blind outflow; P = .01). Overall survival rates at 12 months for the patent outflow and blind outflow groups were 85% ± 3% and 82% ± 6%, respectively (P = NS) (Figure 5).

Univariate analysis of clinical variables that differed between the patent and blind outflow groups (age, smoking, hypertension, and ESRD) was performed to identify other potential predictors of patency, limb salvage, and survival. None of the clinical variables predicted patency or overall survival rates. End-stage renal disease was the only variable that predicted limb salvage on univariate analysis (P = .01). Subsequent multivariate analysis of ESRD and blind outflow using a Cox proportional hazards model identified both variables as independent predictors of limb loss (P = .03 for ESRD; P = .04 for blind outflow). Patients with ESRD who underwent infrainguinal bypass to a blind outflow vessel demonstrated significantly lower limb salvage rates than patients without ESRD (71% ± 7% for non-ESRD with patent outflow vs 65% ± 9% with blind outflow; P = NS).
blind outflow vs 49% ± 12% for ESRD with blind outflow at 12 months; \( P = .04 \) (Figure 6A). There was no difference in patients who underwent bypass to patent outflow vessels (Figure 6B).

**COMMENT**

With the increased complexity of infrainguinal bypass procedures performed in the current era, accurate identification of anatomical factors predicting outcome would facilitate appropriate patient and procedure selection. Although recent studies suggest that conduit quality may influence infrainguinal graft patency more than outflow,\(^7,8\) the role of severely compromised outflow in determining outcomes has not been fully evaluated. The current study uses anatomical criteria to examine the effects of severely compromised outflow on infrainguinal graft patency and limb salvage.

Anatomical criteria to define peripheral vascular runoff have been standardized by the recently revised SVS/ISCVS runoff score.\(^9\) Although this score accurately incorporates anastomotic site, degree of occlusion, and pedal arch integrity, the use of this scoring system has not consistently predicted graft patency, limb salvage, or survival.\(^9,10,13\) All previous studies have attempted to stratify patients across the entire range of runoff scores, but none have focused on the ability of the worst score (SVS/ISCVS runoff score, 10) to predict outcomes.

Biancari et al\(^9\) have previously examined the ability of the runoff score to predict hemodynamic success, immediate graft patency, and overall graft patency. The patients in their series had a median runoff score of 3.5 (range, 1-9), but it did not include any patients with completely blind outflow (runoff score, 10). Although they demonstrated that the runoff scores in this range predicted hemodynamic success after infrainguinal bypass, these scores did not predict immediate or overall patency. A subgroup of grafts with widely patent outflow (runoff score, 1) did demonstrate excellent patency and limb salvage rates compared with all other runoff scores. Several other series have reported similar results using the SVS/ISCVS runoff score or modifications thereof.\(^10,13,14\)

Whereas previous studies have examined the results from bypasses to isolated popliteal segments,\(^16,17\) the current series focuses for the first time on grafts with completely blind outflow vessels (runoff score, 10) in the supragneciculate and infrageniculate positions as defined by the SVS/ISCVS criteria. Even at this extreme of outflow vessel disease, there was no difference in patency or overall patient survival rates when compared with grafts with patent outflow. The ability of these blind bypass grafts to remain patent, particularly in an infrageniculate location, may reflect a greater importance of conduit quality or inflow.\(^7,8\)

Hemodynamic measurements of outflow resistance provide another potential measure that may predict bypass outcomes. Peterkin et al\(^13\) examined the correlation between angiographic runoff scores (particularly...
with appropriate weighting of individual vessels) and in- 
traoperative measures of hemodynamic resistance. If this 
relationship is accurate, blind outflow such as that ex- 
amined in the current series should be associated with 
the highest outflow resistance values. Although this he- 
modynamic measurement was not performed in the cur- 
rent series, our results are consistent with most studies 
examining the effects of outflow resistance on graft pat- 
ency. Studies performed by Peterkin et al,12 Cooper et al,18 
and others19 have failed to demonstrate hemodynamic out-
flow resistance as a predictor of infrainguinal graft pat-
ency. Although Ascer et al20 maintain that outflow resis-
tance does predict graft patency, anatomically blind 
bypasses may not deliver adequate perfusion at the tis-
ue level in ischemic limbs. The amputation rate may also 
be affected by the slight preponderance of tissue loss in-
dications for operation noted in the blind outflow group 
and by the widespread occurrence of atherosclerotic dis-
ease in these patients.

Although blind outflow did not predict graft pat-
ency, it was a marker for limb loss in our series. Several 
previous studies have failed to demonstrate an overall cor-
relation between angiographic runoff score and limb sal-
vage.9,10,14 However, these studies did not include sub-
stantial numbers of patients with extremely compromised 
outflow (runoff score, 10). Ascer et al21 have demon-
strated inferior limb salvage rates with very high hem-
dynamic outflow resistance, a patient group that may be 
comparable with our patients who had completely blind 
bypass.

In addition to inferior overall limb salvage rates, pa-
tients with blind outflow had a greater proportion of acute 
amputations (within 30 days postoperatively) and a higher 
number of amputations despite patent grafts. Thus, blind 
bypasses may not deliver adequate perfusion at the tis-
ue level in ischemic limbs. The amputation rate may also 
be affected by the slight preponderance of tissue loss in-
dications for operation noted in the blind outflow group 
and by the widespread occurrence of atherosclerotic dis-
ease in these patients.

Seeger et al22 have recently used a modified SVS/ 
ISCVS runoff score to demonstrate results similar to those 
of our study. Their series separated 210 patients with tis-
ue loss into those with “good runoff” and those with “bad 
runoff,” with an arbitrary runoff score cutoff of 6 for pop-
liteal bypasses and a runoff score of 5 for pedal by-
passes. Bad runoff predicted death, limb loss, and am-
putation despite a patent bypass. Whereas the limb salvage 
findings were similar to ours, we did not demonstrate any 
difference in survival rates between our patent outflow 
and blind outflow groups. The study by Seeger et al dif-
fered from our series because it included only patients 
with tissue loss and because all bypasses were per-
formed using autogenous conduits.

Inferior limb salvage rates noted in the blind out-
flow group in the current series were most prominent 
when grafts were performed to the supragenulate pop-
liteal artery. No difference between blind and patent out-

Figure 4. A, Cumulative limb salvage for above-knee grafts. B, Cumulative 
limb salvage for below-knee grafts. Above-knee blind bypasses achieve 
significantly lower limb salvage rates than grafts with patent outflow 
(P = .01). There is no significant difference between groups for below-knee 
grafts. The number of grafts at risk per interval is shown below the x-axis.

Figure 5. Cumulative survival for bypass procedures with patent and blind 
outflow with no significant difference between groups. The number of grafts 
at risk per interval is shown below the x-axis.
flow groups was noted with distal anastomoses at the infrageniculate level. Above-knee bypasses to blind outflow vessels certainly offer a less direct reconstruction with a greater portion of the limb requiring collateral circulation. Such a bypass may be analogous to the indirect reconstruction offered by profundaplasty, a procedure that has been shown to have inferior limb salvage rates compared with direct peripheral bypass for limb-threatening ischemia. Additionally, because this is a retrospective review, limb salvage outcomes with above-knee bypasses may represent a selection bias of surgeons’ willingness to attempt this procedure even in marginally salvageable cases.

The prevalence of ESRD in the blind outflow group added another potential predictor of limb loss in this series. Several previous series, including a recent study by our group, have associated ESRD with an increased risk of limb loss. Multivariate analysis in the current series demonstrated both ESRD and blind outflow as significant predictors of limb salvage with equivalent weighting factors. In fact, the subgroup of patients with both factors achieved the lowest limb salvage rates as compared with either patients with blind outflow alone or patients with patent outflow who did or did not have ESRD. The combination of ESRD and blind outflow warrants careful consideration of the risk-benefit ratio of infrageniculate bypass in these patients.

Because of the retrospective design of the current study, differences in patient characteristics between the patent and blind outflow groups with respect to age, smoking, hypertension, and ESRD could influence our results. Although advanced age and a preponderance of ESRD and hypertension in the blind outflow group could affect results leading to inferior outcomes, the lower incidence of smoking in patients undergoing blind bypass could skew the results for this group favorably. Such differences in patient groups are inherent to the retrospective design of the study and potentially limit our conclusions.

Despite the possible association of blind outflow with generalized atherosclerotic disease, no differences in overall mortality or morbidity rates were noted in the current series. Furthermore, the cumulative survival rate of patients undergoing blind bypass was comparable with that of patients undergoing bypass to patent outflow vessels.

In summary, this study suggests that infrageniculate bypass with blind outflow yields patency and survival rates comparable with bypass performed with patent outflow. However, blind outflow does remain a marker for subsequent limb loss, particularly in dialysis-dependent patients and when the bypass terminates above the knee. Careful consideration is warranted prior to infrageniculate bypass grafting in these situations. Nonetheless, availability of only a blind outflow vessel should not preclude aggressive attempts at limb salvage in appropriately selected patients.

Presented at the 108th Annual Scientific Session of the Western Surgical Association, Dana Point, Calif, November 14, 2000.

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REFERENCES

William H. Baker, MD, Maywood, Ill: Congratulations to the University of Chicago for bringing a very important topic to our attention, and congratulations to Dr Desai for an excellent presentation. I now know where all of my patients to whom I recommended primary amputation have gone. This is a retrospective single-institution study, not a prospective randomized study. Nonetheless, there are many lessons to be learned. My questions attempt to further define the patients to whom we should or, perhaps more important, should not recommend operation.

Everybody can understand that a blind popliteal artery does not communicate directly with the tibial vessels. However, 36 (50%) of their patients had a blind tibial artery. I think that requires further definition. How long was this segment? Was it 10 cm or 20 cm? Were there notable collaterals, and do you require notable collaterals? Did you see any arteries, either named or unnamed, appear in the foot during angiography? Finally, all of these arteries have athroscerosis. Did some of them have a lot of scalloping or even multiple 50% stenoses? Where do you draw the line?

Secondly, we don’t operate on these patients in a vacuum. We use a variety of other preoperative tests. How do the ankle brachial index, transcutaneous Po2, laser Doppler imaging, ultrasonography, and similar tests fit into your therapeutic and diagnostic algorithm? The University of Chicago is one of the leaders in measuring intraoperative resistance or impedance. Did you measure it in these patients?

Finally, 69% of your patients had tissue loss. This means different things to different people. Does tissue loss consist of little black dots at the ends of the toes? Are there ulcerations over the bunion area? Are there smelly black eschars at the heel? To help me understand what you mean by tissue loss, how many of these patients had concomitant or subsequent minor amputations, foot infections, amputations, multiple debridements, or skin grafts?

I will limit my questions to these and let others raise additional questions as they choose. I congratulate you on bringing this subject to our attention. Too often this is a forgotten operation in our armamentarium to save the ischemic limb.

Jonathan B. Towne, MD, Milwaukee, Wis: There are several issues that I would like to know more about. Because 60% of their patients were diabetic, and because in diabetic patients the peroneal artery is often the major outflow to the foot, I would like to know how they categorized the peroneal artery. We have demonstrated in the past that peroneal artery bypasses, both in patients with branches to the dorsopedal and posterior tibial areas as well as in those without, had equal long-term results.

Secondly, I am troubled by any group that lumps prosthetic grafts with vein grafts. As I watched this presentation I wondered, Were there relatively more artificial grafts to the above-knee popliteal artery and more vein grafts to the lower limb? We have to stratify these grafts according to type of conduit and target outflow vessel.

Finally, I would like to ask the authors, who have a 14% early amputation rate, what they have learned. Is there a subset of patients for whom they would recommend primary amputation rather than a bypass?

James R. DeBord, MD, Peoria, Ill: In your below-knee group, was there any difference in outcome between the blind below-knee popliteal artery and the blind tibial grafts? Also, did you augment your polytetrafluoroethylene grafts with any vein cuffs or short segment vein composite grafts, or were they purely prosthetic? Finally, when do you anticoagulate these patients in the postoperative period?

Dr Gewertz: Regarding Bill Baker’s comments, we require an arterial segment that motivates us to operate, which will generally be at least 6 to 10 cm. Obviously we prefer extensive collaterals. We do evaluate the pedal arch, and we are influenced mostly by the nature of the foot lesion and what type of salvage can be expected. If we have very extensive forefoot gangrene with no pedal arch, a blind segment would be unat-
tractive to us, whereas if there is a pedal arch and the foot lesion is manageable, we would tend to be quite aggressive.

Regarding the other parameters, ankle brachial indexes are limited because many of these vessels are calcified; we did not find this parameter to have great predictive value. We do not routinely use transcutaneous oxygen determinations. Although there were measurements of intraoperative impedance in many of our bypass grafts, there was not a sufficient number in the blind outflow segment to allow us to do any statistical analysis. As far as the nature of the tissue loss in these patients, 31% in the patent artery group had gangrene, as opposed to 22% in the blind segment group. Ulcerations were present in 29% of the patent bypasses and in 43% of the blind bypasses. Therefore, about a third of the patients had advanced gangrene of the foot; for another 40%, ulceration was the nature of their limb-threatening ischemia.

Regarding Jonathan Towne’s comments, the peroneal artery was the site of distal bypass in 17% of the patent grafts and 8% of the blind grafts. We assumed that a peroneal artery was blind if we did not see the bifurcation at the ankle. If it was patent to that point and we saw a bifurcation where it filled the foot arch, obviously we would consider that to be a patent vessel.

I think that your point about polytetrafluoroethylene is very well made. We also were somewhat taken aback by the number of these grafts. I think that when you see the manuscript, Jonathan, you will note that approximately 25% of these patients had redo operations on that same leg and came to us following failures elsewhere, without usable vein. Although we used polytetrafluoroethylene grafts in roughly 45% of patients in the entire series, 25% of these were accounted for because the contralateral vein or ipsilateral vein had been used and the other veins were of insufficient caliber. There were a substantial number of venovenostomies in both groups, combining multiple segments of vein, which I think addresses Jim DeBord’s comments as well. Seventeen percent of the patients had multiple vein segments in the patent outflow bypass group, and 14% had multiple vein segments in the blind outflow group.

Anticoagulation was not routinely used after the perioperative period. Based on surgeons’ preferences, some did not reverse the heparin sodium in the operating room. About 30% of patients in both groups received long-term warfarin sodium anticoagulation. That was generally determined by a history of failure of previous bypass grafts at other institutions and/or a failure that occurred during the postoperative period with restoration of graft patency in which we felt that additional help was necessary.

There were certainly patients, particularly those with blind outflow and renal failure, who did very poorly irrespective of the nature of reconstruction. In fact, the worst group was nonautogenous conduits below the knee, in which there was a 22% patency rate. That being said, we often run into situations, as I know you all do in practice, where patients come to the “court of last resort” and ask you to maintain their leg. Although appropriate counseling about the likelihood of success is clearly indicated, we have generally proceeded with a bypass unless the foot lesion is such that no usable weight bearing could be restored.

Surgical Anatomy

The left and right vagus nerves descend with the esophagus as distinct trunks to the level of the tracheal bifurcation. The left vagus is anterior and the right vagus is posterior. The left vagus nerve divides into branches to the anterior lesser curvature, gastric and hepatic branches, which pass through the gastrohepatic ligament to the liver and biliary tract. The right vagus nerve divides into the posterior lesser curvature gastric branches and a celiac vagal division.