Prospective screening for postoperative deep venous thrombosis in patients undergoing infrainguinal revascularization

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Purpose: **The incidence of deep venous thrombosis (DVT) in patients undergoing infrainguinal bypass graft procedures has not been well documented, and the need for routine prophylaxis remains controversial. The purpose of this study was to prospectively evaluate the risk of postoperative DVT complicating infrainguinal revascularization.**

Methods: **Seventy-four patients undergoing infrainguinal bypass graft procedures during a 12-month period were prospectively screened for DVT. Bilateral lower extremity venous duplex scan imaging was performed preoperatively and within 1 week and 6 weeks, postoperatively. Routine DVT prophylaxis was not used, with anticoagulation reserved for specific indications.**

Results: **Of the 74 patients screened, three patients (4.1%) had DVT identified on preoperative venous duplex scan imaging and were excluded from the study. Of the remaining 71 patients enrolled, only two patients (2.8%) had postoperative DVT. Postoperative DVT was ipsilateral to the bypass graft extremity in both patients, with involvement of the peroneal vein in one patient and the femoral vein in the other. Although routine prophylaxis was not used, 18 of these patients (25%) were anticoagulated for other indications, with DVT occurring in one patient (5.6%). Of the remaining 53 patients who did not receive postoperative anticoagulation, only one patient (1.8%) had DVT.**

Conclusions: **According to this prospective study, the risk of postoperative DVT in patients undergoing infrainguinal revascularization is low. Routine prophylaxis is not recommended, with postoperative anticoagulation reserved for specific indications. (J Vasc Surg 2000;32:669-75.)**

Venous thromboembolism is a significant cause of morbidity and mortality in the United States, with approximately 500,000 new cases of deep venous thrombosis (DVT) and an estimated 50,000 to 150,000 deaths from pulmonary embolism (PE) each year.[1] PE is the third leading cause of death from cardiovascular disease, exceeded only by ischemic heart disease and stroke, and may be the most common preventable cause of death in hospitals.[2]

Patients who require major surgical procedures are considered to be at a higher risk for venous thromboembolic complications. Previously identified high-risk groups include patients with major traumatic injuries and those undergoing orthopedic, neurosurgical, and intra-abdominal general surgical procedures. In these high-risk groups, the effectiveness of DVT prophylaxis has been clearly demonstrated, and its routine use in these patients is recommended.[3-5]

The risk of venous thromboembolic complications in patients undergoing peripheral vascular surgery is not well documented. Because patients undergoing vascular reconstruction receive intraoperative systemic heparin during the period of vascular clamping, the risk of DVT is assumed to be low. However, predisposing factors may possibly increase the risk of DVT in this population, including preop-

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erative limb ischemia, increased postoperative limb edema and pain, prolonged immobility, and associated hypercoagulable states.[6-8] Because the incidence of DVT in patients undergoing lower extremity revascularization is not well documented, recommendations for routine prophylaxis cannot be established. The purpose of this study was to prospectively evaluate the risk of DVT in patients undergoing infrainguinal revascularization.

METHODS

Patient enrollment. A prospective cohort study was designed to evaluate the risk of DVT in patients undergoing infrainguinal bypass grafting for lower extremity arterial ischemia. The Institutional Review Board approved the study, and informed consent was obtained before enrollment. Between January 1 and December 31, 1998, patients undergoing infrainguinal bypass grafting at the University of North Carolina Medical Center in Chapel Hill were approached concerning enrollment in the study and were assessed for eligibility. Those included were patients with chronic lower extremity arterial ischemia resulting from atherosclerotic occlusive disease who were electively scheduled for infrainguinal bypass grafting. Exclusion criteria included (1) acute lower extremity arterial ischemia requiring urgent intervention, (2) lower extremity arterial ischemia resulting from nonatherosclerotic disease, (3) the need for simultaneous multilevel reconstruction, and (4) an unwillingness to participate in the study.

Study protocol. Enrolled patients gave a preoperative comprehensive medical history and underwent a physical examination. In addition to routine laboratory and radiographic studies required for the operation, preoperative bilateral lower extremity venous duplex scan imaging was obtained to document the absence of DVT. Patients with DVT found before surgery were excluded from the study protocol. Serum laboratory tests to evaluate for a potential hypercoagulable condition were obtained just before operation. Serum tests included anticardiolipin antibodies (immunoglobulin G 0-23, immunoglobulin M 0-11), lupus inhibitor (lupus inhibitor screen, hexagonal phospholipid assay, and dilute Russell's viper venom time), antithrombin III (level 70%-118%), factor V Leiden (DNA polymerase chain reaction assay), homocysteine (total plasma serum level 5-16 μmol/L), protein C (activity 65%-178%), and protein S (activity 65%-178%, total level 78%-163%, free level 60%-161%).

Patients underwent infrainguinal bypass grafting for lower extremity arterial ischemia with the conduit and target vessels determined by the surgical team. During bypass graft operation, patients received standard heparin doses of 5000 units intravenously before vascular clamping, with additional doses of 1000 units received intravenously at approximately 1-hour intervals until completion of the final graft anastomosis.

Routine postoperative DVT prophylaxis with anticoagulation or sequential compression devices was not used. Postoperative anticoagulation with intravenous unfractionated heparin followed by warfarin sodium (Coumadin) was reserved for patients with preexisting hypercoagulable states, prior thromboembolic events, and previous bypass graft failures; for patients who required anticoagulation preoperatively for other indications; and for selected distal bypass graft procedures at the discretion of the operating surgeon. All other patients were treated with antiplatelet therapy, routinely aspirin, unless contraindicated.

During the postoperative period, repeat bilateral lower extremity venous duplex scan imaging was performed within 1 week and 6 weeks, postoperatively. If initial postoperative venous duplex scan imaging was inconclusive, an additional scan was performed 2 weeks after the operation. Patients in whom DVT was diagnosed during the postoperative period were subsequently treated with anticoagulation. Patients with abnormal hypercoagulable screening results reported during the postoperative period who had not been initially anticoagulated were subsequently anticoagulated after obtaining bilateral lower extremity venous duplex scan imaging, but they were included with patients who did not receive anticoagulation on the basis of intent-to-treat.

Venous imaging. Venous duplex scan imaging was performed by registered vascular technologists who used an Acuson XP-128 color flow duplex ultrasound scan (Acuson Inc, Mountain View, Calif). Femoral, popliteal, and calf veins (anterior tibial, posterior tibial, peroneal, and soleal veins) were routinely evaluated.[9,10] DVT was diagnosed with the criteria of incompressibility, abnormal or absent color flow images, and failure to increase flow with distal augmentation within an insonated vein segment.[11]

Statistical analysis. Sample size calculations were performed before enrollment on the basis of an estimate for a descriptive study of dichotomous variables ($N = 4z_\alpha^2 P(1-P)/W^2$, where N = estimated sample size, P = expected proportion, W = total width of CI, and z_α = standard normal deviate for a 2-tailed α where $[1-\alpha]$ is the confidence level). Assuming an expected proportion (P) of 0.05 with a total width of CI (W) of 0.10, a 90% confidence level would require

Table I. Preoperative medical problems and venous thromboembolic risk factors in 71 patients screened for postoperative DVT after infrainguinal revascularization for chronic lower extremity arterial ischemia

Medical problems	*No. of patients (%)*	*Risk factors*	*No. of patients (%)*
Tobacco abuse	61 (85.9)	Prior DVT/PE	2 (2.8)
Hypertension	53 (74.6)	Hypercoagulable state	1 (1.4)
Diabetes mellitus	48 (67.6)		
Cardiac disease	39 (54.9)	Prior limb surgery*	10 (14.1)
Hyperlipidemia	17 (23.9)	Prior limb trauma	6 (8.5)
Stroke	12 (16.9)	Immobility	6 (8.5)
Renal failure	10 (14.1)	Malignancy	5 (7.0)
Pulmonary disease	4 (5.6)	Morbid obesity	3 (4.2)
Prior abdominal surgery	33 (46.5)		
Prior CABG	11 (15.5)		
Prior vascular surgery†	30 (42.3)		
Leg bypass graft	19 (26.8)		
Major amputation	10 (14.1)		
Aortic bypass graft	3 (4.2)		
Extra-anatomic bypass graft	2 (2.8)		
Carotid endarterectomy	2 (2.8)		

*Prior limb surgery other than vascular operations.
†Number of prior vascular operations are listed for patients in the study (N = 71).
CABG, Coronary artery bypass grafting.

an estimated sample size (N) of 51 patients, and a 95% confidence level would require 73 patients.[12-15]

The presence of postoperative DVT in patients undergoing infrainguinal bypass grafting for lower extremity arterial ischemia was the primary prospective end point of this study. Secondary comparisons were made with the use of χ^2 analysis with statistical significance defined as a *P* value of .05 or less for preoperative risk factors, medical problems, surgical indications, operative technique, use of postoperative anticoagulation, and abnormal hypercoagulable screening.

RESULTS

Seventy-four patients undergoing infrainguinal bypass grafting for lower extremity arterial ischemia during the 12-month period met the inclusion requirements and were screened for enrollment into the study. Of these 74 patients, three (4.1%) had DVT revealed through preoperative venous duplex scan imaging and were excluded from the study. The remaining 71 patients were prospectively enrolled into the study protocol. The mean age of the patients was 69.1 ± 10.2 years (range, 36-87 years); 50.7% of the patients were men and 49.3% women. The associated medical problems and risk factors are shown in Table I, and the surgical indications and infrainguinal bypass graft operations performed are shown in Table II.

Bilateral lower extremity venous duplex scan imaging was obtained as per study protocol on all 71 patients within 1 week after the operation (mean, 4.9 ± 3.1 days). An additional venous duplex ultrasound scan was required at the 2-week interval in eight patients (11.3%) because of limited calf vein imaging in seven patients and femoral vein imaging in one patient due to leg edema, pain, or both during the initial venous duplex scan. Therefore, within 2 weeks of surgery, all patients in the study underwent a complete venous duplex ultrasound scan examination. Late follow-up venous duplex scan imaging 6 weeks after the operation (mean, 44.1 ± 6.2 days) was obtained in 60 (85.9%) of the 71 patients, with 11 patients (14.1%) lost to follow-up.

Of the 71 patients enrolled in the study, only two patients (2.8%) had postoperative DVT. Both were identified through venous duplex scan imaging within the 1-week interval. Postoperative DVT was ipsilateral to the bypass graft extremity in both patients, with involvement of the peroneal vein in one patient and the femoral vein in the other. Although routine DVT prophylaxis was not used in this study, 18 patients (25.4%) were anticoagulated during the postoperative period because of preexisting hypercoagulable states (1), prior thromboembolic events (2), previous bypass graft failures (8), preoperative anticoagulation for other indications (4), and selected distal bypass graft procedures at the discretion of the operating surgeon (3). Of these 18 patients, only one (5.6%) had postoperative DVT. Of the remaining 53 patients who did not receive postoperative anticoagulation, only one patient (1.8%) had DVT. There was no difference in post-

Table II. Surgical indications and bypass graft operations in 71 patients screened for postoperative DVT after infrainguinal revascularization for chronic lower extremity arterial ischemia

Surgical indications	*No. of patients (%)*	*Operation*	*No. of patients (%)*
Ischemic ulceration	46 (64.8)	Above-knee popliteal	6 (8.5)
Rest pain	19 (26.7)	Below-knee popliteal	15 (21.1)
Claudication	6 (8.5)	Tibial	37 (52.1)
		Pedal	13 (18.3)
		In situ vein graft	32 (45.1)
		Reversed vein graft	23 (32.4)
		Composite vein graft	9 (12.7)
		Synthetic graft	7 (9.8)

operative DVT between patients treated with and without anticoagulation. There was also no difference between patients with and without postoperative DVT in terms of preoperative risk factors, medical problems, surgical indications, and operative technique, although this lack of correlation may represent a potential Type II statistical error. Although not part of the study protocol, patients with DVT found preoperatively received postoperative anticoagulation, with no evidence of thrombus propagation on subsequent venous duplex scan imaging. No patients in this study experienced clinical symptoms compatible with PE.

Of the 71 patients in the study, 22 (31.0%) had abnormal results from a hypercoagulable serum-screening laboratory test, including one patient with a preexisting hypercoagulable state (protein C deficiency) (Table III). There was no statistical difference in postoperative DVT in patients with abnormal findings from hypercoagulable screening (4.5%) compared with patients with normal serum test results (2.0%). Nine (40.9%) of the 22 patients with abnormal findings from hypercoagulable screening had received postoperative anticoagulation before reporting of the abnormal results. The remaining 13 patients who had not been initially anticoagulated after the operation were subsequently anticoagulated after obtaining venous duplex scan imaging, but were included with patients who did not receive anticoagulation based on intent-to-treat. Of the two patients with postoperative DVT, one patient had a preexisting hypercoagulable state and was already anticoagulated. The other patient with postoperative DVT had not been anticoagulated and had normal results from the hypercoagulable screening serum laboratory test.

DISCUSSION

Patients who require major surgical procedures and are considered to be at increased risk for venous thromboembolic complications include those undergoing orthopedic, neurosurgical, and intra-abdominal general surgical procedures, and patients with major traumatic injuries.[3-5] The risk of venous thromboembolic complications in patients undergoing peripheral vascular surgery is not well documented.

Most of the previous studies on the risk of postoperative DVT in patients undergoing peripheral vascular surgery are after aortic reconstruction, with a reported incidence of DVT ranging from 1.5% to 26%.[12,13-23] This inconsistency may reflect variability in the diagnostic methods used for detecting DVT. Furthermore, although some of these series report a high incidence of DVT, this mostly represents a higher proportion of calf vein thrombosis. Olin et al[20] reported an incidence of 18% in 50 patients undergoing abdominal aortic aneurysm repair as documented through venography, with 78% of the thrombi confined to the calf veins. In contrast, Killewich et al[20] reported a 2% incidence of postoperative DVT identified with venous duplex ultrasound scan in a randomized prospective trial of 100 patients undergoing aortic reconstruction with and without DVT prophylaxis, although the venous duplex ultrasound scan protocol used in this study did not include insonation of calf veins. Because of the variability in these studies, the true incidence of DVT in patients undergoing aortic reconstruction remains uncertain, and recommendations for routine prophylaxis have not been established.

Although most studies in which the risk of venous thromboembolic complications in patients undergoing peripheral vascular surgery is evaluated have focused on aortic reconstruction, there have only been a few reports examining the risk of DVT in patients undergoing infrainguinal bypass grafting. Researchers investigating the cause of leg edema after lower extremity revascularization have suggested a variable incidence of DVT. Although Hamer et al[21] reported that 42% of 21 patients had DVT revealed through venography after femoropopliteal bypass

grafting, DVT more commonly was isolated to the tibial veins, and the incidence seemed to be higher in patients with increased lower extremity edema. Myhre et al[13] reported that in 25 patients with edema after lower extremity arterial reconstruction, only 8% had DVT revealed through venography. Similarly, AbuRahma et al[14] reported that six (8.3%) of 72 patients undergoing lower extremity bypass graft surgery had documented postoperative DVT and that venous thrombosis was not an important cause of leg edema.

Other studies in which the general risk of DVT after peripheral vascular operations is evaluated have included lower extremity infrainguinal bypass grafting as part of a larger study of other vascular procedures. Fletcher and Batiste[12] reported a total incidence of 9.8% in 146 consecutive patients after peripheral vascular surgery, which included a 9.2% incidence in 54 patients undergoing infrainguinal revascularization. In a randomized controlled trial in which low molecular weight heparin was compared with unfractionated heparin for DVT prophylaxis, 87 of 233 patients had undergone lower extremity bypass grafting with a 3.4% postoperative DVT rate.[15]

In this study, we prospectively evaluate the risk of DVT in patients undergoing only infrainguinal revascularization. Sample size determination was made assuming a 5% incidence of DVT with a total width of CI of 10%. Seventy-one patients with chronic lower extremity arterial ischemia resulting from atherosclerotic occlusive disease underwent infrainguinal bypass grafting during a 12-month period. Postoperative DVT was found in only 2.8%.

There are several limitations with this study that should be addressed. First, although venous duplex ultrasound scan is accurate in screening symptomatic patients for DVT, there is variable diagnostic accuracy in screening asymptomatic postoperative patients.[25] Because of this concern, in this study, if the venous duplex scan imaging obtained within 1 week of operation was inadequate, a repeat scan was performed within 2 weeks. With the use of standard venous duplex ultrasound scan criteria, the initial scan was technically adequate in imaging all lower extremity venous segments in 88.7% of patients 1 week after operation and in 100% at 2 weeks. Although historic data with radiolabeled fibrinogen have suggested that most early postoperative thrombi resolve rapidly, especially for DVT limited to the calf,[26] other studies have shown that limbs with more proximal DVT may have prolonged recanalization extending beyond 3 months.[27,28] In this study, a late follow-up scan was obtained at 6 weeks in 85.9% of the patients to confirm that a significant DVT, which may have been missed during the earlier scans, was not present. Because of these technical limitations and timing issues, the incidence of DVT in this study may be underestimated, although the clinical relevance of potentially missed DVT is questionable. Second, the presence of postoperative DVT in patients undergoing infrainguinal bypass grafting for lower extremity arterial ischemia was the primary prospective end point of this study. Although secondary comparisons were made with χ^2 analysis for preoperative risk factors, medical problems, surgical indications, operative technique, use of postoperative anticoagulation, and abnormal results from hypercoagulable screening, the lack of correlation may represent a potential Type II statistical error because of the patient population size relative to the low incidence of postoperative DVT. Finally, as a prospective cohort study designed to evaluate the risk of DVT in patients undergoing infrainguinal bypass grafting for lower extremity arterial ischemia, there was a mixture of patients included in the study, some of whom were treated perioperatively with antiplatelet therapy, whereas others were treated with anticoagulation during the initial postoperative period according to specific clinical criteria. An additional 13 patients required subsequent anticoagulation after abnormal findings from hypercoagulable screening, but for analysis were included with patients not receiving anticoagulation on the basis of intent-to-treat, with venous duplex scan imaging obtained before initiation of anticoagulation. Although exclusion of these patients would have created selection or confounding bias and in an ideal study design no

Table III. Abnormal hypercoagulable screening serum laboratory test results in 22 (31%) of 71 patients evaluated for postoperative DVT after infrainguinal revascularization for chronic lower extremity arterial ischemia

Abnormal serum laboratory test	*N* (%)*
Elevated plasma homocysteine	11 (15.5)
Anticardiolipin antibodies	6 (8.5)
Antithrombin III deficiency	3 (4.2)
Protein C deficiency	2 (2.8)†
Protein S deficiency	2 (2.8)†
Lupus inhibitor	1 (1.4)
Factor V Leiden mutation	1 (1.4)

*N = number of abnormal tests.
†Includes known preexisting protein C deficiency in one patient. Although seven patients had been concurrently anticoagulated with Coumadin during hypercoagulable screening, de novo protein C and S deficiency was found in three other patients who were not anticoagulated.

patients would have been anticoagulated during the postoperative period, this does not represent the clinical spectrum of patients undergoing infrainguinal revascularization.

Although the risk of postoperative DVT after infrainguinal revascularization is low, the potential for DVT in patients with peripheral vascular disease may be increased when compared with the general population. Libertiny and Hands[29] reported a 19.6% incidence of DVT in 136 patients screened with venous duplex ultrasound scan before arteriography, angioplasty, or arterial reconstruction, compared with 5% in 40 controls without peripheral arterial disease undergoing general surgical or urologic procedures. The propensity of patients with peripheral vascular disease for DVT may reflect preoperative limb ischemia, prolonged immobility, elevated plasma homocysteine levels, and associated hypercoagulable states.[6-8,30,31] Although our study was not intended to be a screening of patients with symptomatic peripheral vascular disease, three (4.1%) of 74 patients screened before undergoing lower extremity revascularization had incidental lower extremity DVT. Although there may be a higher prevalence of DVT in patients with peripheral vascular disease compared to the general population, according to our series, the risk does not seem to be increased in patients before or after lower extremity revascularization, with a 4.1% and 2.8% incidence of DVT, respectively. Because patients are not routinely screened for DVT in clinical practice, the combined potential for undiagnosed DVT in patients undergoing infrainguinal revascularization is 6.9%. Furthermore, despite 31% of patients in our study with abnormal results from hypercoagulable screening, the incidence of postoperative DVT remained low, with no difference in postoperative DVT in patients with and without abnormal hypercoagulable screening (4.5% and 2.0%, respectively).

Previously, because the incidence of DVT in patients undergoing lower extremity revascularization was unclear, recommendations for routine DVT prophylaxis have not been established. According to Fletcher and Batiste,[12] the incidence of DVT after lower extremity bypass grafting was 9.2% despite 5000 units of unfractionated heparin three times per day. According to Farkas et al,[15] there was no difference in postoperative DVT after infrainguinal revascularization in patients receiving prophylaxis with unfractionated heparin (2.5%) compared with enoxaparin (4.3%). In our study, patients did not receive routine DVT prophylaxis, although 25% required anticoagulation for specific indication including preexisting hypercoagulable states, prior thromboembolic events, previous bypass graft failures, preoperative anticoagulation for other indications, and occasionally distal bypass graft procedures at the discretion of the operating surgeon. There was no difference in postoperative DVT in patients who did and did not receive anticoagulation after the operation (5.6% and 1.8%, respectively). On the basis of this low risk of postoperative DVT, routine prophylaxis is not recommended, with postoperative anticoagulation reserved for specific indications. Although this question can only be truly settled with a prospective randomized trial, with such a low incidence of DVT, a large patient cohort would be required to detect minimal benefit with an increased risk of bleeding complications and cost.

CONCLUSION

According to this prospective cohort study, the incidence of postoperative DVT in patients undergoing infrainguinal revascularization is low (2.8%). Routine prophylaxis is not recommended, with postoperative anticoagulation reserved for specific indications independent of the risk of DVT.

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