

Reporting standards in venous disease

Prepared by the Subcommittee on Reporting Standards in Venous Disease, Ad Hoc Committee on Reporting Standards, Society for Vascular Surgery/North American Chapter, International Society for Cardiovascular Surgery.

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This report comprises suggested reporting standards for publications dealing with (1) acute lower extremity venous thrombosis, (2) chronic lower extremity venous insufficiency, (3) upper extremity venous thrombosis, and (4) pulmonary embolism. Attempts have been made to set forth numeric grading schemes for disease severity, risk factors, and outcome criteria. Some of the recommendations had to be arbitrary of necessity, but they were judged the most generally acceptable by members of the committee. They are offered not as binding rules but as guidelines whose observance will serve the clarity and precision of communication. (J VASC SURG 1988;8:172-81.)

ACUTE LOWER EXTREMITY VENOUS THROMBOSIS

Risk factors and predisposing conditions

The following should be considered in reports of acute lower extremity deep vein thrombosis (DVT) as factors that may influence the frequency of occurrence, clinical course, and response to treatment. Relative risk factors have been assigned to permit derivation of an overall risk factor index, which, although as yet unproved, may be of value in more accurately assessing the efficacy of various means of DVT prophylaxis and treatment by allowing comparison of more homogeneous patient groups.

Prior history of DVT. A prior episode of lower extremity DVT is the greatest single risk factor for a subsequent episode of DVT.¹ The diagnosis of DVT has traditionally required phlebographic documentation. However, in recent years noninvasive vascular laboratory examinations performed by experienced technologists using such proven methods as phlebography, impedance plethysmography, Doppler examination, and more recently duplex scanning have proved sufficiently accurate in diagnosing proximal DVT to replace phlebography in most cir-

cumstances. Accordingly, either a history of an abnormal phlebogram or an abnormal vascular laboratory examination is sufficient to establish prior episodes of lower extremity DVT. In the assignment of risk factor grades in this category, a patient with clinical postthrombotic syndrome with no history of prior DVT should be classified as grade 1 (suspected).

Assign grade

- 0 = none
- 1 = suspected
- 2 = proven
- 3 = multiple

Immobilization. Most DVT occurs in patients immobilized by trauma, operation, or disease.² Both duration and cause of the immobilization appear to have a role in determining the subsequent likelihood of DVT.

Assign grade

- 0 = none
- 1 = 1-3 days
- 2 = >3 days
- 3 = immobilization caused by acute paraplegia³

Postoperative state. A significant number of episodes of DVT develop postoperatively. Both the duration of operation and type of anesthesia appear related to development of postoperative DVT.⁴

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Assign grade

- 0 = local anesthesia
- 1 = <45 minutes, regional or general
- 2 = >45 minutes, regional or general
- 3 = extensive major (>3 hours) and/or pelvic operation⁵

Age. Increasing age increases the risk of DVT.⁶

Assign grade

- 0 = <40 years
- 1 = 40-70 years
- 2 = >70 years

Extent of malignancy. The extent of associated malignancy may influence the development of DVT.⁷

Assign grade

- 0 = none
- 1 = nonrecurrence or local recurrence only
- 2 = extensive regional tumor
- 3 = metastatic

Tissue type of malignancy. Tissue type of associated malignancy may also influence development of DVT.

Assign grade

- 0 = other than adenocarcinoma
- 1 = adenocarcinoma

Cardiac disease. Cardiac disease of whatever cause increases the risk of DVT in immobilized patients.⁸

Assign grade

- 0 = New York Heart Association (NYHA) class 1
- 1 = NYHA class 2
- 2 = NYHA class 3
- 3 = NYHA class 4

Limb trauma. The presence of extensive soft tissue injury or fracture increases the likelihood of DVT.⁹

Assign grade

- 0 = none
- 1 = soft tissue injury including bruise, contusion, and sprain
- 2 = fracture of tibia and/or fibula
- 3 = fracture of femur
- 4 = fracture of hip or pelvis

Prethrombotic state. Several coagulation abnormalities predispose to *abnormal clotting*, including venous thrombosis. These include but are not limited to antithrombin III deficiency; protein C or protein

S deficiency; myeloproliferative disorders, especially thrombocytosis; lupus anticoagulant; and plasma hyperviscosity states.¹⁰⁻¹⁴

Assign grade

- 0 = none suspected
- 1 = suspected
- 2 = proven, treated
- 3 = proven, untreated

Hormonal therapy. After years of controversy, it now appears that prolonged exogenous *ethinyl estradiol in a dosage in excess of 50 µg daily* in certain oral contraceptive preparations is associated with an increased risk of venous thrombosis.^{15,16} Neither low-dose estrogen therapy nor any other hormonal therapy has such a clear relationship to DVT, although others are suspected and may be proved in the future.

Assign grade

- 0 = no
- 1 = yes

Pregnancy and postpartum state. Venous thrombosis is five times more likely in a pregnant or postpuerperal woman compared with a nonpregnant, nonpuerperal woman not taking oral contraceptive medication.¹⁷

Assign grade

- 0 = absent
- 1 = present

Obesity. The precise role of obesity as a risk factor in DVT has not been defined but appears slight.¹⁸ The following risk assignment is suggested:

Assign grade

- 0 = normal to 175% ideal body weight
- 1 = >175% ideal body weight

Summary. The factors listed represent our impression of the risk factors relevant to the development of DVT. A total score of 28 is possible. With the relative risk assessment weighting scheme described, future studies of DVT prophylaxis and certain response to therapy studies may be meaningfully stratified by the DVT risk factor scores of the patient groups being studied. If, for example, the placebo limb of a DVT prophylaxis trial happened to have a mean risk factor score of 14 and the therapeutic limb had a mean risk factor score of 8, outcome appearing to favor the therapeutic limb may be in error.

Clinical presentation

Extent of thrombus and site involvement. Consistent and accurate descriptions of anatomic sites of

involvement are essential for interpretation of clinical reports of DVT. The following sites or segments should be specified in reports of lower extremity DVT: tibial-soleal veins, popliteal vein, common femoral or superficial femoral vein, deep femoral vein, iliac vein, and vena cava. Suggested superficial sites include greater saphenous vein and its branches; lesser saphenous vein and its branches; or unnamed cutaneous veins, in which case the location of the veins should be specified, if relevant for individual case reports. Each of the six deep vein segments and two superficial veins may then have grades assigned as follows:

Assign grade

- 0 = patent
- 1 = subsegmental, nonocclusive thrombus
- 2 = subsegmental, occlusive thrombus
- 3 = occlusive thrombus throughout length of segment

Thus the maximal thrombotic score for a single limb is 24. To date the thrombus grading system has required detailed phlebography. It appears likely that in the future duplex scanning may accomplish this task with an accuracy equaling or exceeding phlebography.

Clinical description. The subjective descriptive terms in this section are useful and important for clinical reports but must not be considered an alternative for objective diagnostic tests when applicable.

Superficial venous thrombosis. The site and extent of involvement as already described should be specified. The presence of tenderness, erythema, induration, or suppuration should be noted. In addition, it is essential that the patency status of the deep veins be documented in reports dealing with superficial venous thrombosis because the coexistence of DVT may confuse both the clinical presentation and response to therapy of superficial venous thrombosis. The patency of the deep veins may be assessed either phlebographically or by appropriate noninvasive vascular laboratory examinations.

DVT. The site and extent of involvement as described should be specified. The presence and location of pain and the extent of swelling should be noted in case reports.

Definitions

With respect to DVT, the following terms continue to be used often enough to require a uniform definition.

Phlegmasia alba dolens. This term implies marked swelling of the lower extremity without cyanosis. It refers to a characteristic clinical picture and

does not imply the existence of DVT at a precise site. However, most, if not all, of these patients have thrombus obstructing the common femoral vein, and many have extension to the iliac vein.

Phlegmasia cerulea dolens. This term refers to massive limb swelling and cyanosis. The venous thrombotic involvement in this condition is more extensive than in phlegmasia alba dolens. This may be associated with arterial insufficiency, compartmental compression syndrome, or venous gangrene. No role for "reflex" arterial spasm has ever been convincingly demonstrated, and the diminished limb arterial flow in these patients apparently results from the markedly elevated venous pressure.

Venous gangrene. This requires the occurrence of areas of full-thickness skin necrosis, which usually occurs in the setting of tense limb edema with bleb formation and cyanosis. Compartment syndrome(s) may coexist.

Diagnostic testing

These are best separately considered as either functional or anatomic studies. Technical details and criteria for interpretation of noninvasive tests are being prepared by a subcommittee on noninvasive vascular diagnostic studies.

Functional tests. These tests are considered valid only if performed by an experienced vascular laboratory technologist and usually only under the following conditions: (1) absence of prior history of deep vein thrombosis of the same extremity and (2) absence of causes of extrinsic venous compression such as pregnancy or hematoma because external venous compression may markedly decrease the specificity of the test.

The recognized vascular laboratory tests for the diagnosis of DVT include (1) venous Doppler examination usually performed with a continuous-wave Doppler probe with the use of flow interruption or augmentation maneuvers but no imaging; (2) plethysmography—impedance, air/volume (e.g., phleborheography), and strain-gauge; (3) duplex scanning—imaging of venous segments with compression maneuvers and Doppler confirmation of flow.

Anatomic tests. The contrast phlebographic technique should be described in detail, specifically the use of a tourniquet, head or foot table elevation, and volume and type of contrast media. A positive phlebogram must be described as directly or indirectly positive. A directly positive test is one in which thrombus is outlined by contrast medium. Nonfilling of deep vein segments without visualization of thrombus is an indirect sign of DVT.

Uptake of iodine 125-labeled fibrinogen is considered a research test because of practical limitations and its notoriously low specificity. It should not be used alone as the basis for therapeutic decisions in reports describing patients with venous thrombosis. If the test is used for epidemiologic screening purposes, the author must include concurrent experience in his own hospital comparing the accuracy of the test to standard contrast phlebography in a representative number of patients. The test does appear useful in diagnosing recurrent venous thrombosis because neither vascular laboratory nor phlebographic studies can reliably detect a new thrombus occurring in a postthrombotic limb.

Functional and anatomic tests. Ultrasonic duplex scanning combines direct and indirect ultrasound image data with Doppler-derived flow data. The criteria for positivity of this test must be specified by the author. Direct image positivity requires actual visualization of the thrombus. Indirect image positivity consists of the absence of normal venous wall coaptation during the respiratory cycle or with external pressure. The Doppler flow data must presently be considered indirect and are considered positive for DVT in the absence of a normal intraluminal venous flow signal.

Treatment

The choices of treatment of DVT include non-operative mechanical treatment, drug treatment, and thrombectomy.

Nonoperative mechanical treatment. Reports should specify the use and duration of bed rest, leg elevation, and elastic compression hosiery. If the latter is used, specify the length of the garment (whether below-knee, above-knee, or waist-high), whether the garment is of gradient construction, and the amount of compression measured in torr.

Drug therapy. Drug therapy for DVT focuses on anticoagulation, thrombolysis, and other unconventional forms of drug treatment.

Anticoagulation. If heparin sodium is used, the rate of administration, dosage, and duration of therapy should be specified. If low molecular weight heparin is used, the molecular weight and source of the heparin must be specified. The type and frequency of monitoring to determine anticoagulant effect must be reported. If the route of drug administration is other than by continuous intravenous administration, the timing of blood sampling for monitoring tests in relation to prior dose of heparin must be specified. The usual tests for monitoring heparin anticoagulant activity include partial thromboplastin time (PTT) and activated clotting time (ACT).

Whatever test is used, it should be related to the PTT to allow readers a normative reference. Similarly, the dose, frequency, type of monitoring, and duration of therapy for warfarin anticoagulation must be specified. In addition, when a patient is switched from heparin to warfarin, the timing and duration of the drug overlap should be described. The intensity of warfarin anticoagulation, as well as the test reagent used in performing the prothrombin time test (rabbit thromboplastin [Simplastin] vs human brain thromboplastin [Manchester Comparative Reagent]) should be specified. The intensity should be expressed as a prothrombin ratio (e.g., $1\frac{1}{2}$ to $2 \times$ control).

Thrombolytic therapy. The drug, dosage, route of administration, and laboratory method of monitoring thrombolytic activity must be specified. Since the goal of thrombolytic therapy is total clot dissolution with preservation of venous valve function and restoration of patency, the frequency and results of sequential contrast phlebograms must be specified. A perfect result requires both complete phlebographic patency and vascular laboratory determination of valvular competency, as determined by measurement of venous recovery time (VRT). Ambulatory venous pressure and duplex determination of valvular competence may be included as desired but do not currently represent substitutes for VRT.

The phlebographic results of lytic therapy should be reported as the percentage of patients experiencing total clot resolution with preservation of valve function. There is no benefit in reporting percentage clot resolution, if less than 100%. Incomplete clot resolution should be reported as failure of thrombolytic therapy. The current practice of reporting outcome of thrombolytic therapy as a percentage of thrombus resolution as compared with heparin anticoagulation with the implication of benefit from thrombolytic therapy should be abandoned. On occasion, restoration of patency in large veins, such as the vena cava or iliac veins, may be the goal of lytic therapy, and in these select cases restoration of valvular competency is irrelevant. Restoration of patency of distal veins without valvular competence should be noted.

Unconventional drug therapy. The use of unconventional drugs such as antiplatelet agents in the treatment of DVT should include an explanation as to why the particular agent was selected as well as the usual information concerning the route, dosage, and duration of therapy and the method of monitoring drug effect.

Complications of drug therapy. Complications associated with drug therapy should be described. General complications applicable to all anticoagu-

Table I. Classification for chronic venous insufficiency

<i>Clinical</i>						
<i>Class</i>	<i>Current symptoms</i>	<i>Prior</i>		<i>Anatomic location</i>		<i>Origin</i>
0	Asymptomatic	Same	0	Unknown	0	Unknown
1	Mild	Same	1	Superficial veins	1	Congenital
2	Moderate	Same	2	Perforators	2	Postthrombotic
3	Severe (ulceration)	Same	3	Deep—calf		
			4	Deep—thigh		
			5	Deep—iliofemoral		
			6	Deep—caval		
			7	Combination of 2-5 (any)		

lants include bleeding and drug allergy. Other more agent-specific complications include antibody-induced thrombocytopenia, osteoporosis, and cutaneous necrosis.

Surgical therapy. Venous thrombectomy continues to be performed occasionally for lower extremity DVT. Reports of such procedures should provide a detailed description of the surgical technique and most importantly must include objective patient outcome data regarding patency and valve function obtained at least 6 months postoperatively. Ideally, 2-week postoperative phlebographic data will also be included. In addition to symptoms and phlebographic results, outcome assessment must include vascular laboratory tests, including lower extremity venous refill time. Ambulatory venous pressure and duplex determination of valvular competence may be included but do not eliminate the necessity for venous refill time. The same reporting requirements pertain to venous thrombectomy as to thrombolytic therapy.

Outcome of acute DVT

The time course for the subsidence of local signs, including edema and cyanosis, should be noted if relevant to individual case reports. The presence of recurrent episode(s) of DVT should be specifically noted together with the objective tests used to establish the diagnosis. The subsequent occurrence of postthrombotic syndrome should be noted with attention to the details listed in the later section, "Chronic Venous Insufficiency," if relevant to the report. It is noted that certain vascular laboratory tests may not reliably establish the presence of a new episode of DVT because patients may have permanent vascular laboratory abnormalities after the first episode.

Pulmonary embolism. The occurrence of pulmonary embolism (PE) as a complication of DVT

should be specifically noted, with attention to the details listed in the section, "Pulmonary Embolism" (pages 180-181).

Venous thrombosis prophylaxis

An increasing number of reports describe the outcome of various prophylactic measures for patients defined as being at high risk for DVT, including such groups as postoperative patients and individuals immobilized with associated significant illness. As described in the first section, "Risk Factors," a risk factor index should be calculated for each study patient as well as an average for the study and control groups. In addition, the following should be included in reports on the efficacy of venous thrombosis prophylaxis.

Mechanical methods of prophylaxis. Leg exercises should be described as active or passive and type, frequency, and duration should be specified. For compression stockings, design (whether gradient or not), length, compression measured in torr, and the frequency and duration of use should be specified. For pneumatic leg compression, the number of individual compression chambers and the pressure-time sequence of the pumping pattern, as well as the frequency and duration of treatment should be specified. The type, location, and timing of venous interruption in relation to subsequent or concomitant operations, and whether concomitant anticoagulation is used should be specified. It is noted the term "prophylaxis" should be used only in relation to patients who have not sustained a PE. The technique of device insertion should be described (i.e., operative or percutaneous) and the radiographic confirmation of the localization of the device after insertion should be noted.

Drug prophylaxis. The agents, route of administration, dosage, duration, and method of monitoring drug prophylaxis should be specified. If prophylaxis

laxis is directed toward prevention of postoperative thrombosis, the timing of the initiation of prophylaxis in relation to operation as well as the type and duration of operation should be stated.

CHRONIC VENOUS INSUFFICIENCY

Chronic venous insufficiency (CVI) is defined as an abnormally functioning venous system caused by venous valvular incompetence with or without associated venous outflow obstruction, which may affect the superficial venous system, the deep venous system, or both. The venous dysfunction may result from congenital or acquired processes.

Classification by anatomic region

CVI of the superficial venous system. The most frequently encountered form of CVI is primary varicose veins. Occasionally, isolated incompetence of one or several communicating veins may be encountered. The site of involvement should be specified as described above under the section "Acute Lower Extremity Venous Thrombosis, Clinical Presentation."

CVI of the deep venous system. The author should specify whether CVI has resulted from an acquired or congenital process. In most cases, deep CVI is an acquired disorder, although in occasional patients it may result from congenital venous valvular insufficiency or agenesis, or segmental agenesis of the deep veins. The method of diagnosis of congenital abnormalities must be described. The term "post-thrombotic" may be used if the patient has experienced an objectively documented prior episode of DVT. The term "postphlebotic syndrome" should not be used because this implies the presence of an inflammatory component that is infrequently confirmed. In the absence of a clear documentation of a prior episode of DVT, the condition should be termed CVI without additional suggestion of origin.

Classification by clinical severity (Table I)

Class 0 = asymptomatic.

Class 1 = mild CVI with signs and symptoms including mild to moderate ankle swelling, mild discomfort (e.g., sensation of leg heaviness or painful varicosities), and local or generalized dilatation of subcutaneous veins. In this clinical class, CVI is usually limited to involvement of the superficial veins only.

Class 2 = moderate CVI including hyperpigmentation of the skin in the gaiter area, moderate brawny edema, and subcutaneous fibrosis, which may be either limited in extent or involve the entire malleolar and pretibial area but without ulceration.

There is usually prominent local or regional dilatation of the subcutaneous veins.

Class 3 = severe CVI. Chronic distal leg pain associated with ulcerative or preulcerative skin changes, eczematoid changes, and/or severe edema. This category is usually associated with extensive involvement of the deep venous system with widespread loss of venous valvular function and/or chronic deep vein obstruction.

Physical examination—descriptive terms

Edema. The location and extent of edema should be noted and objectively documented with circumferential limb measurements. Generally, the more proximal the extent of edema, the more severe the underlying CVI.

Venous dilatation. Mild CVI is signified by the occurrence of a submalleolar venous flare. Greater degrees of venous dilatation are apparent by both observation and palpation. They should be specifically stated as involving the greater or lesser saphenous systems, communicating veins, or secondary unnamed intervening venous channels.

Skin pigmentation. The location of pigmentation should be described along with a subjective assessment of severity. The presence or absence of liposclerosis accompanying pigmentary changes should be noted.

Venous ulceration. The location and measurements of any venous ulcer should be described and the presence or absence of granulation tissue noted. The presence of healed venous ulceration manifested by cutaneous scarring should be noted.

Functional assessment of CVI

Vascular laboratory studies are essential in reports dealing with CVI to objectively assess the presence and amount of venous outflow obstruction and the presence and amount of venous reflux in the superficial, communicating, and deep venous systems.

Venous obstruction. Assessment of maximal venous outflow (MVO) by one of various plethysmographic techniques provides objective information on the presence and amount of venous obstruction. Sequential MVO examinations are particularly helpful in following the development of venous collaterals and/or recanalization after DVT. MVO must be related to simultaneously determined venous capacitance. Pressure gradients (e.g., arm/ankle) either at rest or after induced hyperemia may also permit the objective assessment of outflow obstruction.

Venous reflux and calf muscle pump. Directional Doppler examination with proximal compression or Valsalva maneuver is a qualitative test for

assessing valvular competence in both the superficial and deep venous systems. This test provides objective information concerning both the presence and location of valvular incompetence. This technique is highly reliable and accurate when performed by an experienced technologist.

Ambulatory venous pressure. Measurement by superficial venous cannulation of the foot venous pressure at rest in the upright position and the decrease in pressure on walking has historically represented the "gold standard" for the objective assessment of CVI. Normal foot ambulatory venous pressure is less than 40 torr. Normal ambulatory venous pressure should be less than 50% of maximal standing foot venous pressure. Recently, noninvasive estimates of ambulatory venous pressure with photoplethysmography (PPG) have correlated closely with invasive measurements, despite theoretic objections.

Venous refill time. Venous refill time has been used increasingly in recent years in the objective diagnosis of CVI in part because of the ease with which it can be determined noninvasively with PPG. Venous refill time can also be obtained invasively with foot venous cannulation used in conjunction with ambulatory venous pressure. Normal venous refill time is greater than 20 seconds. Severe CVI is generally associated with a venous refill time of less than 5 seconds; moderate CVI with a venous refill time of 5 to 15 seconds; and mild CVI with a venous refill time of 15 to 20 seconds. Normalization of a shortened venous refill time by application of a leg tourniquet compressing superficial veins indicates CVI limited to the superficial venous system. Venous refill time exclusively assesses valvular reflux, whereas ambulatory venous pressure assesses both reflux and calf muscle pump action; thus the two tests do not completely overlap. To date, the clinical states in which one test is preferred over the other have not been clearly defined. It is recommended that all reports of patients with CVI be accompanied by sufficient objective measurements of venous hemodynamics to adequately document CVI.

Anatomic studies of CVI by phlebography and ultrasound

Ascending phlebography defines areas of obstruction, recanalization, and collateral vein formation. Descending phlebography demonstrates competency of venous valves by assessing the magnitude of contrast reflux. Comparisons of different reports of descending phlebography are facilitated by knowledge of the technical details of performance of the pro-

cedure because there is currently no uniformly accepted technique for descending phlebography. Accordingly, reports of descending phlebography should include the details of cannulation; type, volume, and injection rate of contrast medium; tilt angle of the table; and maximal timed descent of the contrast column in the deep venous system.

Duplex examination is a promising noninvasive method that may in the future yield precise information concerning valvular reflux equal or superior to descending phlebography. However, at present there are no uniformly accepted standards for the use of duplex examination in CVI; therefore any reports must include full details of this technique of examination.

Surgical procedures

Superficial system insufficiency. Operation to treat CVI of the superficial venous system consists of ligation and stripping of incompetent greater or lesser saphenous veins and/or their branches or ligation of incompetent communicating veins. Because the valvular competence of the deep veins has an obvious relationship both to the occurrence and recurrence of superficial varicosities, reports of superficial venous ligation and stripping should specifically describe communicating and deep venous valvular competence as assessed by appropriate vascular laboratory tests.

Deep venous obstruction. Various conduits have been used to bypass areas of venous obstruction. Detailed description of type, extent, and configuration of the bypass conduit should be provided. Reports of such procedures in addition to the patients' subjective assessment of benefit should include vascular laboratory MVO measurements obtained preoperatively and at least 6 months postoperatively to objectively assess the surgical outcome (see below).

Deep venous valvular insufficiency. The type of procedure used to correct this defect should be categorized as:

Valvuloplasty: Include a brief technical description of the procedure and the precise location and number of valves repaired.

Venous segmental transposition: Specify site.

Venous segmental transplantation: Specify donor and recipient sites, the length of the transplanted segment, and number of valves contained in the transplanted segment.

Evaluation of operative results: All publications describing patients having surgical repair of deep venous insufficiency or obstruction must include vas-

cular laboratory measurements of lower extremity venous hemodynamics before and after operation to permit objective assessment of results. The tests must include at a minimum venous refill time or ambulatory venous pressure, preferably both. Doppler assessment of valvular competence provides helpful additional information in patients operated on for valvular incompetence, as does MVO in those operated on to correct venous obstruction.

However, neither of these tests replaces the need for ambulatory venous pressure and venous refill time. An author may, at his or her discretion, report the use of new and/or nonstandardized vascular laboratory tests performed in an attempt to document objectively the functional results of deep vein reconstruction, but the report of such tests does not exempt the author from reporting the requisite standardized preoperative and postoperative vascular laboratory tests of venous function. All reports of deep vein repair should report at least 6 months of postoperative vascular laboratory follow-up, and preferably 12-month follow-up since progressive deterioration of initially good surgical results has been reported. All reports must state whether the patient regularly used postoperative elastic compression hosiery. If so, the compression, measured in torr, must be included. Reports should also state whether the patient used intermittent leg elevation during the day. A suggested categorization of clinical outcome is presented in Table II. It is recommended that no clinical outcome grade be assigned until at least 6 months after operation.

UPPER EXTREMITY VENOUS DISEASE

Subclavian-axillary vein thrombosis

Diagnosis. Reports of axillary-subclavian vein thrombosis must use contrast medium or isotope phlebography to objectively establish the diagnosis. This requirement is mandatory because the clinical diagnosis of this condition is imprecise, and functional vascular laboratory tests are not definitive at this time.

Cause. The author should specify the presumed origin of the subclavian-axillary vein thrombosis. Recognized causes include clavicular fracture, either acute or with malunion; central venous cannulation; injection or infusion of hypertonic or irritating solutions; or septic phlebitis. Diagnosis of the latter requires organism identification. In the absence of any of these factors, the thrombosis may be presumed idiopathic. This may or may not result from repetitive venous compression in the region of the thoracic

Table II. Final clinical outcome after operation

+3	Asymptomatic; improved at least one clinical class; improvement of VRT and AVP to normal or at least +5 seconds, and -10 torr, respectively
+2	Moderate improvement; continuing mild symptoms with same clinical and vascular laboratory improvement as in +3
+1	Mild improvement; improvement in either clinical class or vascular laboratory tests, but not both
0	Unchanged clinically or by laboratory tests
-1	Mild worsening; worsening of either clinical outcome by one category or vascular laboratory tests
-2	Significant worsening; both clinical and vascular laboratory worsening
-3	Marked worsening; same as -2 accompanied by either new or worsening ankle claudication

VRT, Venous refill time; AVP; ambulatory venous pressure.

outlet. The term "idiopathic" as used here includes the condition termed "effort syndrome."

Upper extremity postthrombotic syndrome. Description should include the patient's subjective assessment of discomfort either at rest or in relation to specific activities and should also include objective descriptions such as the presence of cyanosis, and the presence and extent of limb swelling documented by circumferential limb measurements compared with the uninvolved limb.

Vascular laboratory. The role of the vascular laboratory has not been established in either the diagnosis of acute upper extremity venous thrombosis or documentation of the postthrombotic syndrome. If vascular laboratory results are reported in addition to phlebography in the diagnosis of acute thrombosis, the author should describe in detail both the performance and results of the tests selected and include results from normal persons, as well as from the contralateral normal upper extremity.

Treatment. The same details of medical treatment should be included as described earlier in the section, "Acute Lower Extremity Venous Thrombosis." The role of operation has not been clearly established either in the treatment of acute upper extremity venous thrombosis or postthrombotic syndrome. Reports of the results of surgical treatment for either of these conditions should include description of postoperative phlebograms clearly visualizing the area of operation. An attempt to assess the efficacy of surgical therapy with only the patient's subjective assessment of benefit may be grossly inaccurate on the basis of the well-described tendency to spontaneous improvement with either of these conditions.

Table III. Classification of pulmonary embolism

Clinical class	Characteristics
0	Asymptomatic PE
1	Symptomatic PE No hemodynamic alterations <40% pulmonary arterial circulatory obstruction
2	Symptomatic PE Minor or no hemodynamic alterations >40% pulmonary arterial circulatory obstruction
3	PE with major hemodynamic alterations and shock regardless of degree of pulmonary arterial circulatory obstruction
4	PE with cardiac arrest regardless of degree of pulmonary arterial circulatory obstruction

Description of surgical results should, whenever possible, include preoperative and postoperative upper extremity vascular laboratory tests, such as MVO, direct pressure measurements, and venous velocity assessment.

PULMONARY EMBOLISM

The author should state the type of pulmonary embolus (PE) being described. The most common is aseptic embolism. Less common but well-recognized PE include septic PE, organism identification required; tumor PE; air PE; fat PE; and foreign body PE, including such items as catheters, heart valves, and caval interruption devices.

Diagnosis

Pulmonary arteriography. This remains the "gold standard" against which all other diagnostic tests must be compared.

Ventilation-perfusion scans (V-Q scans). There is general agreement that high probability V-Q scans are quite accurate and may be used with confidence to establish objectively the diagnosis of PE. A high probability scan requires an embolus sufficiently large to occlude arterial circulation to an entire pulmonary segment and requires that the patient have a normal chest x-ray film. Low probability V-Q scans are missing one or both of these requirements and are inadequate to establish the diagnosis of PE. Pulmonary arteriography is required in the low probability subset. Perfusion lung scanning alone is of unacceptably low specificity to establish the diagnosis. Similarly, although arterial blood gas determinations may be suggestive, they have insufficient sensitivity and specificity to establish a firm diagnosis.

Classification

Massive PE. PE has been classified anatomically and functionally. The term "massive embolism" has traditionally required significant filling defects in two or more lobar arteries, which implies greater than 40% pulmonary circulatory obstruction. The term "submassive embolism" defines a PE with obstruction of less than two lobar arteries. However, these anatomic definitions are of limited usefulness and are less accurate in predicting death than a functional definition based on hemodynamic measurements. The hemodynamic response to acute embolization is a function not only of the size of the embolus but also of coexisting cardiac and pulmonary disease and the magnitude of the neurohumoral responses. Serial hemodynamic measurements essential to the functional definition of PE include blood pressure, pulse, central venous pressure, cardiac output, pulmonary artery pressure, pulmonary capillary wedge pressure, and pulmonary vascular resistance. The presence or absence of cardiac arrest or shock should be described since these are strong predictors of death associated with PE. Unfortunately, the definition of shock is not standardized and must be clearly stated along with the duration of shock. Such a definition should include standard hemodynamic alterations (pulse rate and reductions in blood pressure and cardiac output), systemic responses (based on arterial pH, mixed venous blood gas determinations, oxygen consumption, and reductions in urinary output), and the need for vasopressors and inotropic support. A classification of PE on the basis of clinical, anatomic, and hemodynamic modifiers is seen in Table III.

The term "recurrent PE" may be accurately used only when either a pulmonary arteriogram or high probability V-Q scan documents a new event. No clinical event alone is adequate to permit the objective diagnosis of recurrent PE.

Chronic PE. Use of the term "chronic PE" requires *sequential* documentation of recurrent PE on *multiple* occasions over a period of months by means of either a high probability V-Q scan or multiple pulmonary arteriograms. The term must not be used in the absence of such documentation.

Treatment

The same details of medical treatment should be included as earlier described in the section, "Acute Lower Extremity Venous Thrombosis." The surgical treatment of PE includes both caval interruption as well as open pulmonary artery embolectomy, and percutaneous suction embolectomy. Descriptions of caval interruption should specify whether this was

accomplished by conventional operation or placement of an intraluminal caval filter device. If the latter is used, the author must specify the type of device, route of placement, final location of device, and whether placement was confirmed phlebographically. Reports describing thrombectomy for chronic PE should include postoperative pulmonary function tests as well as pulmonary arteriography with measurement of pulmonary artery pressure because it is well recognized that several patients may display markedly improved postoperative arteriograms without any pulmonary functional improvement.

Establishment of fatal PE at autopsy

Probably lethal PE. Probably lethal PE consists of thrombus or thrombi in the main pulmonary artery trunk and/or bifurcation, a portion of which may be in the right ventricle; thrombi in both right and left pulmonary arteries; thrombi in one or more contralateral lobar arteries.

Possibly lethal PE. The designation of possibly lethal PE requires consideration of both extent of obstruction of the pulmonary arterial system and the patient's underlying cardiopulmonary state. Factors that may aggravate hypoxemia and diminish the capacity of the right side of the heart to accept an increased pressure afterload and might materially affect the ability of the person to survive an acute embolus include the following: thrombus occluding the main right or left pulmonary artery; thrombi in two or more lobar arteries of one lung and in one or more contralateral lobar arteries; combination of thrombi in unilateral or bilateral lobar and/or segmental (and equivalent subsegmental) arteries equal to the above.

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