

Reporting Standards for Endovascular Treatment of Lower Extremity Deep Vein Thrombosis



Suresh Vedantham, MD, Clement J. Grassi, MD, Hector Ferral, MD, Nilesh H. Patel, MD, Patricia E. Thorpe, MD, Vittorio P. Antonacci, MD, Bertrand M. Janne d'Othée, MD, Lawrence V. Hofmann, MD, John F. Cardella, MD, Sanjoy Kundu, MD, Curtis A. Lewis, MD, MBA, Marc S. Schwartzberg, MD, Robert J. Min, MD, and David Sacks, MD, for the Technology Assessment Committee of the Society of Interventional Radiology

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Abbreviations: DVT = deep venous thrombosis, INR = international normalized ratio, IVC = inferior vena cava, PE = pulmonary embolism, PTS = post-thrombotic syndrome, PTT = partial thromboplastin time, QOL = quality of life, SVS = Society for Vascular Surgery, VCSS = Venous Clinical Severity Score, VSDS = Venous Segment Disease Score, VTE = venous thromboembolism

THE feasibility of using endovascular techniques to treat lower extremity deep vein thrombosis (DVT) has been documented in numerous articles within the peer-reviewed radiology literature (1,2). Randomized trials are in progress to evaluate the efficacy of

these therapies, but physicians are currently compelled to base endovascular DVT treatment decisions on published studies of less robust scientific design. Unfortunately, extreme variation in the descriptions of DVT patient populations, endovascular treatment methods, and outcomes assessment confounds accurate comparison of the existing studies and diminishes their relevance to the greater community of physicians who treat DVT. The purpose of this document is to improve the quality and relevance of DVT research published in the radiology literature by recommending basic guidelines for reporting the results of clinical DVT research studies.

CURRENT STATUS OF RESEARCH REPORTING

The current document was produced in a cooperative effort between three Society of Interventional Radiology (SIR) committees: the DVT Research Committee of the SIR Venous Forum, the DVT Standards Committee of the SIR Venous Forum, and the SIR Technology Assessment Committee. To maintain consistency with previous efforts of nonradiology subspecialty organizations to standardize DVT reporting, many terms and definitions

that are widely accepted by the scientific community have been incorporated into this document. Adoption of this common lexicon is expected to enhance the ability of interventional radiologists to effectively communicate the results of endovascular DVT therapies in terms that are meaningful to the many nonradiologists who treat and study DVT.

In 1988, a joint subcommittee of the Society for Vascular Surgery (SVS) and the International Society for Cardiovascular Surgery first published standards for reporting the results of surgical procedures to treat venous disease (3). In 1994, the American Venous Forum introduced the "CEAP" system, which was designed to enable classification of cerebrovascular disease based on its clinical manifestations (C), etiologic factors (E), anatomical distribution of disease (A), and underlying pathophysiologic findings (P). In 1995, the SVS's original reporting standards were revised to incorporate the CEAP system, a "Clinical Score," and a "Disability Score" (4). In 2000, the American Venous Forum's subcommittee on venous outcomes assessment observed that the CEAP classification was a useful descriptive tool but that it had too many static elements to be effective in monitoring

From the Department of Radiology, Mallinckrodt Institute of Radiology, St. Louis, Missouri (S.V.); Department of Radiology, Lahey Clinic Medical Center, Burlington, Massachusetts (C.J.G.); Department of Radiology, Rush University Medical Center, Chicago, Illinois (H.F.); RUSH Presbyterian-St Luke's Medical Center, Chicago, Illinois (N.H.P.); University of Iowa School of Medicine, Iowa City, Iowa (P.E.T.); Charlotte Radiology, Charlotte, North Carolina (V.P.A.); Department of Radiology, Beth Israel Deaconess Medical Center, Boston, Massachusetts (B.M.J.D.O.); Department of Interventional Radiology, Johns Hopkins Hospital, Baltimore, Maryland (L.V.H.); Department of Radiology, University of Colorado Health Sciences Center, Denver, Colorado (J.F.C.); Department of Medical Imaging, Scarborough General Hospital, Richmond Hill, Canada (S.K.); Manuel Maloof Imaging Center, Atlanta, Georgia (C.A.L.); Private Practice, Mt Dora, Florida (M.S.S.); Cornell Medical Imaging, New York, New York (R.J.M.); The Reading Hospital and Medical Center, Reading, Pennsylvania (D.S.). Received September 21, 2005; accepted November 12, 2005. **Address correspondence to S.V., c/o Tricia McClenny, Society of Interventional Radiology, 3975 Fair Ridge Dr, Suite 400 North, Fairfax, VA 22033; E-mail: mcclenny@sirweb.org**

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Table 1
Revised CEAP Classification of Chronic Venous Disease

C	Clinical signs (grade 0-6), supplemented by A for asymptomatic and S for symptomatic presentation
E	Etiologic classification (Congenital, Primary, Secondary)
A	Anatomic distribution (Superficial, Deep, or Perforator, alone or in combination)
P	Pathophysiologic dysfunction (Reflux or Obstruction, alone or in combination)
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"C" (Clinical) classification	
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Class 0	No visible or palpable signs of venous disease
Class 1	Telangiectases or reticular veins
Class 2	Varicose veins
Class 3	Edema
Class 4a	Skin changes including pigmentation or venous eczema
Class 4b	Skin changes including lipodermatosclerosis
Class 5	Healed venous ulceration
Class 6	Active venous ulceration
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"E" (Etiologic) classification	
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Ec (Congenital)	The etiology of the chronic venous disease has been present since birth
Ep (Primary)	Idiopathic chronic venous disease
Es (Secondary)	Chronic venous disease with known etiology (e.g., post-thrombotic)
En	No venous cause identified
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"A" (Anatomic) classification	"P" (Pathophysiologic) classification
Superficial veins (A _S)	Reflux (P _R)
Deep veins (A _D)	Obstruction (P _O)
Perforating veins (A _P)	Both (P _{RO})
No venous location identified (An)	No venous pathophysiology seen (Pn)
Example: A patient with healed ulcerations known to be related to post-thrombotic syndrome, with documented reflux and obstruction would be classified as C ₅ E _S A _D P _{RO} .	

change in disease status with treatment (5). To move beyond disease description to systematic outcomes assessment, the subcommittee recommended adoption of three separate scoring systems with which to categorize the clinical severity (Venous Clinical Severity Score, a substantially improved version of the original "Clinical Score"), anatomical/pathologic severity (Venous Segmental Disease Score, which combines the anatomical and pathologic elements of the CEAP), and disability (Venous Disability Score) of chronic venous disease. In 2004, the CEAP classification system was further refined; the revised version is presented in **Table 1** (6).

Many elements of the population description and outcomes assessment recommendations of the surgical societies have been incorporated into this document and should be easily adopted by interventional radiologists

treating DVT. However, two major modifications have been made to increase their relevance to endovascular DVT therapies. First, standardized terminology for describing endovascular DVT treatment methods is recommended based on the consensus opinion of expert interventional radiologists. Second, discussion of the key DVT outcomes of interest has been modified to recognize the recent development and partial validation of several questionnaire measures to assess post-thrombotic syndrome and quality of life. In arriving at the current recommendations, every effort was made to remain consistent with the existing SIR documents addressing General Principles for Evaluation of New Interventional Technologies and Devices and Reporting Standards for the Treatment of Acute Limb Ischemia with Use of Transluminal Removal of Arterial Thrombus (7,8). In this fashion, the committee members have

striven to create a useful template for clinical DVT research reporting that is relevant to current interventional practice.

POPULATION DESCRIPTION

An accurate population description serves several important purposes: (a) it enables a reader to determine whether a study is relevant to his or her patient population; (b) it helps to delineate which patient subsets are likely to benefit from the intervention being described; and (c) it facilitates meaningful comparison with other studies describing patient cohorts who were treated with the same or different medical, surgical, or interventional therapies. Detailed population description is particularly essential for DVT patient cohorts, since they can exhibit enormous variation in their defining characteristics (9). First and foremost, standardized definitions

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