

Development of a Research Agenda for Endovascular Treatment of Venous Thromboembolism: Proceedings from a Multidisciplinary Consensus Panel

Suresh Vedantham, MD, John H. Rundback, MD, Anthony J. Comerota, MD, David W. Hunter, MD, Mark H. Meissner, MD, Lawrence V. Hofmann, MD, McDonald Horne III, MD, Peter Gloviczki, MD, R. Torrance Andrews, MD, Chieh-Min Fan, MD, Keith M. Hume, MA, Samuel K. Goldhaber, MD, Victor F. Tapson, MD, Mahmood K. Razavi, MD, and Robert J. Min, MD

J Vasc Interv Radiol 2005; 16:1567-1573

Abbreviations: DVT = deep vein thrombosis, NIH = National Institutes of Health, PE = pulmonary embolism, VTE = venous thromboembolism

VENOUS thromboembolism (VTE) is a frequent cause of death, cardiopulmonary morbidity, and late limb disability (1,2). In recent years, minimally invasive endovascular methods have been used to treat deep vein thrombosis (DVT) and pulmonary embolism (PE), the two most common manifestations of VTE (3,4). Although early clinical experiences suggest that these techniques have significant potential to improve patient outcomes, there has been no coordinated effort to determine what research studies are

needed to refine these techniques and scientifically validate their long-term efficacy.

To address these issues, a multidisciplinary meeting of prominent venous disease experts was convened in October 2004 by the Cooperative Alliance for Interventional Radiology Research (CAIRR), the clinical trials network of the Society of Interventional Radiology (SIR) Foundation. The purpose of the meeting was to establish a prioritized research agenda for endovascular VTE interventions that in-

cludes basic science/technology research, pilot clinical studies, and pivotal clinical trials.

MEETING ORGANIZATION

A 14-member VTE Research Consensus Panel was created from a list of leading scientists developed by the SIR DVT Research Committee. The Panel included members from interventional radiology ($n = 8$), vascular surgery ($n = 3$), hematology ($n = 1$), cardiology ($n = 1$), and pulmonary medicine ($n = 1$). Ten members served as primary discussants at the symposium and four members provided their perspective after the meeting's conclusion. Representatives from the Food and Drug Administration, several National Institutes of Health (NIH) agencies, and industry were also present.

Before the meeting, the discussants were given an agenda describing the structure and intent of the workshop. The meeting was structured into four parts per standard SIR Foundation process: (i) introductory presentations; (ii) moderated roundtable panel discussion with comments from industry and governmental representatives; (iii) research topic prioritization; and

From the Mallinckrodt Institute of Radiology (S.V.), Washington University School of Medicine, St. Louis, Missouri; Department of Vascular and Interventional Radiology (J.H.R.), Columbia Presbyterian Medical Center; Department of Radiology (R.J.M.), Weill Medical College of Cornell University, New York, New York; University of Michigan Jobst Vascular Center (A.J.C.), Toledo, Ohio; Department of Radiology (D.W.H.), University of Minnesota, Minneapolis; Division of Vascular Surgery (P.G.), Mayo Clinic College of Medicine, Rochester, Minnesota; School of Medicine (M.H.M.) and Department of Vascular and Interventional Radiology (R.T.A.), University of Washington, Seattle, Washington; Division of Interventional Radiology (L.V.H.), Johns Hopkins Hospital, Baltimore; National Institutes of Health (M.H.), Bethesda, Maryland; Department of Vascular Radiology (C.M.F.), Massachusetts General Hospital; Cardiovascular Division (S.Z.G.), Brigham and Women's Hospital, Boston, Massachusetts; Boston, Massachusetts; Society of In-

terventional Radiology Foundation (K.M.H.), Fairfax, Virginia; Department of Medicine (V.F.T.), Duke University Medical Center, Durham, North Carolina; and St. Joseph Vascular Institute (M.K.R.), Orange, California. Received June 6, 2005; accepted August 18. **Address correspondence to** S.V., Mallinckrodt Institute of Radiology, Department of Radiology, 510 S. Kingshighway Blvd., St. Louis, MO 63110; E-mail: vedanthams@mir.wustl.edu

The Society of Interventional Radiology Foundation received program support for the venous thromboembolism research consensus panel from AngioDynamics, Inc.; Arrow International, Inc.; Bacchus Vascular, Inc.; Bard Peripheral Vascular, Inc.; Bayer Healthcare; Cook, Inc.; Diomed, Inc.; Genentech, Inc.; and Tyco Healthcare.

© SIR, 2005

DOI: 10.1097/01.RVI.0000183868.45154.57

Table 1
Venous Thromboembolism: Clinical Topics (Panelists)

Topic	Score	No. of Panelists	Rank
1. Acute DVT trial: best medical therapy vs Best interventional clot removal method	81	9	1
2. Pharmacomechanical thrombolysis study	29	5	2
3. PE trial: best interventional therapy	23	5	3
4. Study long-term patency of existing stents and new coated venous stents with or without adjuvant therapy	23	5	3
5. Venous stents for chronic venous stasis	22	6	5
6. Public awareness and education	22	6	5
7. Appropriate use of retrievable and nonretrievable IVC filters	22	4	5
8. Stratify results of interventional therapy by extent of clot/venous segment	19	5	8
9. Develop better tools to measure venous obstruction	18	4	9
10. Outpatient ambulatory DVT thrombolysis with daily pulse-spray	17	5	10
11. Direct thrombin inhibitors for DVT	16	4	11
12. Small pilot studies of different DVT treatment combinations	13	3	12
13. Study of residual DVT at filter retrieval	9	3	13
14. Hemodynamic evaluation and stenting of May-Thurner Syndrome	8	2	14
15. Evaluate effect of pneumatic compression with or without anticoagulation on upregulation of endogenous fibrinolysis and treatment outcomes	7	3	15
16. Develop DVT standards via consensus group: physicians and industry	7	1	16
17. Stratify DVT treatment outcomes by hypercoagulability risk assessment	7	1	16
18. Define reference standard with which to compare interventional treatment	7	1	16
19. Heparin dosing during DVT thrombolysis	6	2	19
20. Evaluate need for IVC filters during DVT interventions: study PE incidence	4	2	20
21. Study incidence of pelvic venous obstruction in DVT patients with residual symptoms	3	1	21
22. Pre-hospital hypercoagulability screening	1	1	22
23. Non-invasive testing for proximal venous obstruction: focus on exercise-induced venous hypertension	1	1	22
24. Effect of preoperative venous reflux on risk of post-operative DVT	1	1	22
25. Treatment of lymphedema	0	0	25
26. Validate the usefulness of surrogate outcome measures of success	0	0	25
27. Economic/cost analysis of DVT treatments including mechanical thrombectomy and stents	0	0	25
28. Comparison of surgical thrombectomy vs thrombolysis vs anticoagulation	0	0	25
29. Effect of complete vs partial clot lysis upon clinical outcomes	0	0	25

(iv) preliminary clinical research protocol development (5).

DATA COLLECTION

The panelists' comments were compiled into two lists of proposed VTE research topics, one for clinical research and the other for basic science/technology research. A separate list of organizational suggestions was also compiled. Each panel member and audience attendee was asked to select and prioritize 11 topics from each composite list with a scoring system used in a previous SIR Foundation Research Consensus Panel (5).

DATA ANALYSIS

The scores assigned by the expert panelists were summed to yield a total priority score for each topic. Topics with substantially overlapping content

as judged by the Panel Chairman were merged into broader aggregate designations to avoid underestimation of related responses, and the aggregate rank score for each topic was then recalculated.

The feasibility and design of a pivotal trial designed to address the single highest-priority clinical research topic were discussed in detail. The final recommendations were refined after consultation with Panel members who did not attend the meeting and review of the prioritization rankings and informal feedback obtained from the governmental and industry representatives.

RESULTS: RANK ORDER PRIORITIZATION OF PARTICIPANT RESPONSES

A total of 51 clinical research topics and 24 basic science/technology re-

search topics were initially proposed. After aggregate grouping, 29 clinical research topics and 16 basic science research topics were obtained. The results of the prioritization voting on the aggregate clinical VTE research topics are presented in **Table 1** (expert panelists) and **Table 2** (governmental and industry representatives). The highest total score was 81 points for "acute DVT trial: best medical therapy versus best interventional clot removal method." Notably, this topic was the highest rated topic by every individual member of the expert panel and was also scored as the highest rated topic by the governmental and industry representatives. The next three clinical topic selections by the expert panelists, in order, were "pharmacomechanical thrombolysis study" (29 points), "pulmonary embolism trial: best interventional therapy" (23 points), and "study of long-term pa-

Download English Version:

<https://daneshyari.com/en/article/9391290>

Download Persian Version:

<https://daneshyari.com/article/9391290>

[Daneshyari.com](https://daneshyari.com)