

Who Determines Which Procedure Is Best?

How key industry leaders are removing device-manufacturer influence on patient procedures.

BY PETER GLOVICZKI, MD

Decisions on how to best treat an ailment have traditionally been made by the doctor and the patient. The patient's preference is often largely influenced by the personal experience of the physician and by the trust the patient has developed in the physician during consultations and preprocedure evaluations.

Evidence-based medicine has added another dimension to the process of decision making.¹⁻³ The impact of scientific evidence on the efficacy of a procedure has been recognized by the medical community; evidence-based guidelines have been developed, continuously updated, and published. These guidelines have also been adopted by medical societies and scientific boards. Depending on the risks and burdens of a particular procedure to the patient versus the expected benefits, different grading systems have been recommended.

The system used most frequently has been published by Guyatt et al,⁴ and includes two grades of recommendations: Grade 1 (strong) recommendations are reserved for procedures in which the benefits clearly outweigh risks and burden, or vice versa; Grade 2 (weak) recommendations are suggested for procedures in which the benefits are closely balanced with the risks and burden. The levels of scientific evidence of efficacy are also important, and the quality of evidence can be high (A), medium (B), low or very low (C).

Important updates of guidelines on which procedures to use (for

instance, regarding the prevention and treatment of acute deep venous thrombosis) have been developed by the American College of Chest Physicians.⁵ Guidelines based on evidence for management of chronic venous diseases have also been published in journals^{6,7} or in the recent 3rd edition of the *Handbook of Venous Disorders, Guidelines of the American Venous Forum*.⁸

In 2009, it is expected that deciding which procedure is best for the patient will be based on a combination of three factors: the scientific evidence of the efficacy of the procedure, the clinical experience of the interventionist, and the preference of the patient.¹⁻³

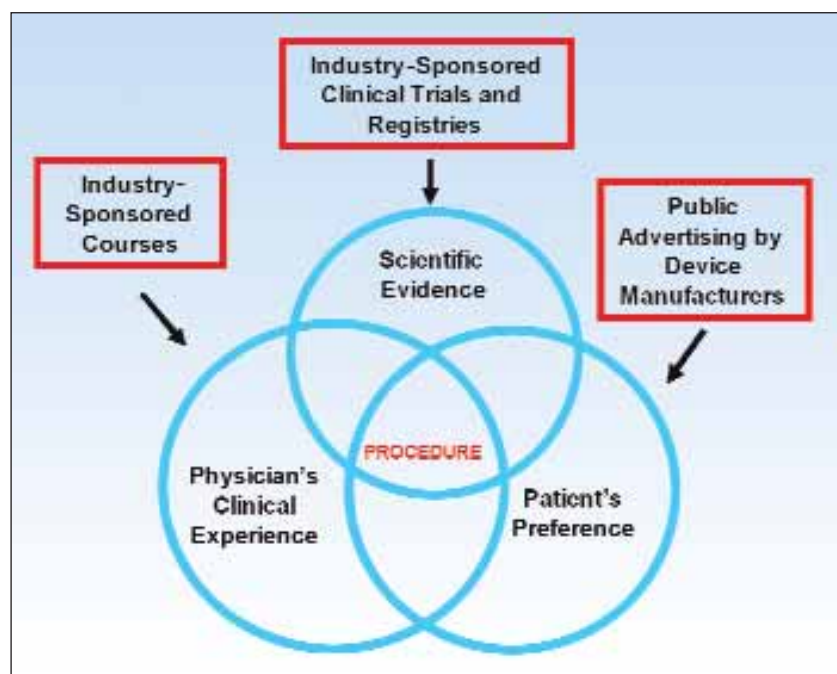


Figure 1. The influence of medical industry on selection of the best procedure for the patient.

So, what is the role of industry, particularly of the medical device industry, in this decision-making process? For the superficial observer, it appears that it is not much; industry is not even listed among those who make the decisions. Still, one does not have to be close to the fire to discover that industry has become a strong determinant of which medical procedures are performed today (Figure 1). This is true for every area of endovascular interventions, and even more so in the field of venous disease; industry exerts profound influence on patients and doctors, and on some of the published scientific evidence.

“ . . . the choice on how to best treat patients should be based on solid and high-quality scientific evidence, the physician’s experience, and the patient’s preference.”

Patients have become savvy in the 21st century. Mass media and the Internet are, for the most part, responsible for this. Search online for “veins” or “varicose veins” and the available information from both medical and nonmedical sources is legion. More importantly, device manufacturers, who have tools to treat venous disease, discuss the condition on their Web sites in detail and include current treatment options with emphasis on the benefits of their selected procedure. Patient testimonials are presented—they are positive without exception and often provide commentaries on patients like the one whose “swelling disappeared by the time she got to her car.” Industry Web sites always offer a list of physicians who are available to use their tools. The Web sites also present insurance information and the immediate opportunity to buy stock in the company.

Patients can be persuaded to select a treatment option based on their Internet research, as well as by their treating physician. Patients frequently arrive at the physician’s office and request thermal ablation of their saphenous vein (presenting the physician with horrendous pictures of legs after surgical stripping and high ligation) and commonly inquire about the type of laser they want to be used or ask for the latest generation of radiofrequency catheter.

Physicians have also been greatly influenced by medical industry in their decisions of which procedure they use for their patients. Industry-sponsored courses for endovascular specialists have been the norm and frequently the only way to become expert in minimally invasive endovascular procedures. Physicians and trainees

have been routinely sponsored by individual companies, who organized the training courses (at times requested by the Food and Drug Administration), to become credentialed to use new technology. It was not until recently that corporate representatives and leaders of the Society for Vascular Surgery have come together to discuss ways to offer society-sponsored courses combining multiple medical companies to decrease the industry bias to the interventionists and allow physicians to learn multiple techniques and try different devices to treat the same disease. This meeting was prompted by the recent proposal of the Accreditation Council for Continuing Medical Education (ACCME) to eliminate commercial bias of CME activities and by the report of the American Association of Medical Colleges (AAMC) task force on industry funding of medical education. The AAMC task force recognized the need for and benefits of physicians working together with the medical industry to improve health care but requested that the relationship between the two parties remain principled, transparent, and capable of sustaining intense public scrutiny. They also urged all academic medical centers to adopt policies that better manage and, when necessary, prohibit academic-industry interactions that can create conflicts of interest and undermine standards of professionalism. Key industry leaders as well as major academic institutions immediately expressed support of the AAMC plan.

The Physician Payments Sunshine Act was recently introduced in the United States Senate; it would require annual transparency reports from the medical industry, including payments to individual physicians. Several companies, including Medtronic, Inc., (Minneapolis, MN), already announced on their Web sites that they will voluntarily disclose payments made to US physicians. It is evident that the medical industry, the major vascular societies, and leading academic institutions are committed to implementing multiple actions to change current industry influence on practicing physicians as well as on trainees. The effect of industry on which procedure a physician selects for the individual patient will clearly diminish in the future.

Industry has also had an influence on some of the published scientific data that support evidence of efficacy of certain procedures. Admittedly, with low or very low quality of evidence, industry-sponsored registries have frequently been the only large-volume databases that provided useful information on short- and long-term efficacy of treatment. It is not uncommon that interventionists participating in industry-sponsored clinical studies also participated in the company-sponsored speaker’s bureau or received grant or research support from the company. Occasionally, the inventor of the

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device was the principal investigator of the clinical trial. While peer-reviewed journals and CME activities required authors to declare all conflicts of interest when working with companies, industry-sponsored clinical trials and publications have contributed to recent attempts at regulating physician-industry relationships.

It is likely that in the future, high-quality scientific evidence to support a vascular or endovascular procedure will be based on multicenter, prospective, randomized studies sponsored by the National Institutes of Health/National Heart Lung and Blood Institute, vascular societies, or vascular foundations, funded in part by unrestricted grants from multiple medical companies.

The medical industry has been a tremendous source of success for physicians and patients alike. Progress in manufacturing medical devices has been remarkable in the past decades; for this, medical companies deserve our admiration. These companies, together with great physician innovators of our time—such as Drs. Thomas Fogarty, Juan Parodi, Julio Palmaz, and Robert Min, among others—have been largely responsible for the revolution that has taken place in endovascular interventions. However, the choice on how to best treat patients should be based on solid and high-quality scientific evidence, the physician's experience, and the patient's preference.¹⁻⁴ The medical device industry should not be a part of this crucial decision. ■

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- Haynes RB, Devereaux PJ, Guyatt GH. Physicians' and patients' choices in evidence based practice. *BMJ*. 2002;324:1350.
- Gloviczki P. Do we need evidence-based medicine in the field of venous diseases? *Perspect Vasc Surg Endovasc Ther*. 2004;16:129-133.
- Meissner MH. "I enjoyed your talk, but . . .": Evidence-based medicine and the Scientific Foundation of the American Venous Forum. Presidential Address. *J Vasc Surg*. 2009;49:244-248.
- Guyatt G, Gutterman D, Baumann MH, et al. Grading strength of recommendations and quality of evidence in clinical practice guidelines: report from an American College of Chest Physicians task force. *Chest*. 2006;129:174-81.
- Hirsh J, Guyatt G, Albers GW, et al. Antithrombotic and thrombolytic therapy: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines (8th Edition). *Chest*. 2008;133(6 Suppl):110S-112S.
- Partsch H, Flour M, Coleridge Smith P. Indications for compression therapy in venous and lymphatic disease. Consensus based on experimental data and scientific evidence. *Int Angiol*. 2008;27:193-219.
- Nicolaidis AN, Allegra C, Bergan J, et al. Management of chronic venous disorders of the lower limbs: guidelines according to scientific evidence. *Int Angiol*. 2008;27:1-59.
- Gloviczki P. *Handbook of Venous Disorders. Guidelines of the American Venous Forum*. 3rd ed. London, England: Hodder Arnold; 2009.