

Treatment of varicose veins, international consensus on which major complications to discuss with the patient: A Delphi study

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Abstract

Objective: To reach consensus on which complications of varicose vein treatments physicians consider major or minor, in order to standardize the informed consent procedure and improve shared decision-making.

Methods: Using the e-Delphi method, expert physicians from 10 countries were asked to rate complications as “major” or “minor” on a 5-point Likert scale. Reference articles from a Cochrane review on varicose veins were used to compose the list of complications.

Results: Participating experts reached consensus on 12 major complications: allergic reaction, cellulitis requiring intravenous antibiotics/intensive care, wound infection requiring debridement, hemorrhage requiring blood transfusion/surgical intervention, pulmonary embolism, skin necrosis requiring surgery, arteriovenous fistula requiring repair, deep venous thrombosis, lymphocele, thermal injury, transient ischemic attack/stroke, and permanent discoloration.

Conclusion: An international consensus was reached about what physicians consider to be major complications of varicose vein treatments. This consensus may assist in standardizing the information physicians discuss with patients prior to varicose vein treatment.

Keywords

Varicose veins, complications, major, consensus, Delphi, shared decision-making, informed consent

Introduction

The possible complications discussed by physicians with patients prior to varicose vein (VV) treatment vary.^{1,2} The “major” and most frequently occurring complications are usually discussed. However, no uniformity exists on which specific major complications should be discussed.

Understanding and agreeing upon which major complications to discuss with patients would harmonize how physicians inform their patients and obtain informed consent. This would also help physicians to engage patients in shared decision-making, if multiple similarly effective treatment options are available. However, for effective shared decision-making to take place, it is crucial that patients are aware of the possible major complications to be able to adequately balance the benefits and harms of the available treatment options.

In a joint venture the American Venous Forum and the Society of Interventional Radiology developed

reporting standards to harmonize and standardize the reporting of postintervention complications.³ These reporting standards facilitate the comparison of results between studies and improve the overall quality of clinical research on venous disease. However, this document was not designed to specify those specific major complications that should be discussed with patients in the consulting room.

We therefore set out to reach consensus on which specific complications following VV treatment are major and which are minor using the expert opinions

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of VV physicians throughout Europe and North America.

Methods

Delphi method

The Delphi method is a widely recognized iterative process designed to achieve consensus from a group of experts using a series of questionnaires interspersed with feedback. Electronically distributed questionnaires are predesigned and completed by experts. Subsequent questionnaires are adapted based on the results of the previous version. The process stops when consensus is reached.⁴

Experts

With the permission of the organizers of the 2015 VEITH symposium and via the Dutch Society for Vascular Surgery, we invited European and North American vascular surgeons, dermatologists, and phlebologists to participate in this electronic Delphi study.

Listing of complications

The list of possible complications was composed by presenting both 30-day and long-term complications of sclerotherapy, foam sclerotherapy, endovascular procedures, and open surgery.^{5–17} We extracted all complications from reference articles in the Cochrane systematic review on VV treatment of Nesbitt et al.¹⁸ Since the different treatment options for VV have many possible complications in common, these complications were all included in one questionnaire. The first round started with a total of 20 complications.

Treatment complications can lead to mild, moderate, or severe sequelae. Therefore, all complications were described extensively, based on the three-tiered severity scoring system from reporting standards for other vascular diseases.^{19–21} For example, the complication “arteriovenous fistula” is divided into a “mild” level arteriovenous fistula if no additional intervention is required, a “moderate” level if endovascular repair is required, and a “severe” level if surgical repair is required. If the complication or its severity was not stated in the reporting standards, we used the Clavien–Dindo classification²² together with information from the reference articles or daily practice. A few complications had only two levels of severity, for example discoloration that resolves after six weeks and permanent discoloration. To avoid ranking bias when composing the surveys, the complications were presented in alphabetical order.

Composing the surveys

As is shown in Figure 1, the differing levels of complication severity were introduced in a stepwise manner to avoid extensive surveys containing all 20 complications, each with up to three levels of severity.

The first Delphi round started by presenting the moderate level of severity for complications. If the physicians rated this moderate level as a minor complication, the assumption was made that the corresponding mild level would also be deemed minor. In the next round the experts were asked to rate the severe level of this complication. Similarly, if the experts rated a moderate complication as major, the severe level was also deemed major. The experts were then asked to rate the mild level of the same complication in the next round.

For complications with only two levels of severity, the choice whether to start the first Delphi round with the mild or the severe level was made randomly. When consensus was reached on one level of severity, the same assumptions as mentioned in the previous paragraph were made. For instance, if a severe level was deemed to be a minor complication, the mild level was also assumed to be minor as well and vice versa.

If consensus was not reached in the first round, the physicians were asked to rate the same complication again in the next round. In subsequent rounds, each complication was now presented accompanied by the percentages of agreement obtained from the previous round. This allowed physicians to adjust their own rating based on the ratings of others.

Study conduct

SurveyMonkey (San Mateo, California, USA), an online survey tool, was used to develop and distribute the surveys. The complications presented in the survey were rated by the physicians using a 5-point Likert scale, ranging from 1 (definitely minor) to 5 (definitely major). If at least 80% of physicians rated a complication with a Likert score of 1 or 2, this complication was considered to be minor. Likewise, if 80% of the physicians rated a complication with Likert score 4 or 5, this complication was considered to be major.

During the first round, the physicians were able to propose any additional complications they considered to be missing from the survey. These complications were then included in the second round. In each round, physicians were given at least two weeks to respond to the survey.

Four Delphi rounds were planned as this was considered sufficient for reaching consensus. However, after fourth round we added a fifth round to ask physicians to rate the remaining complications that had not been presented in previous rounds due to the stepwise manner of introducing the complications.

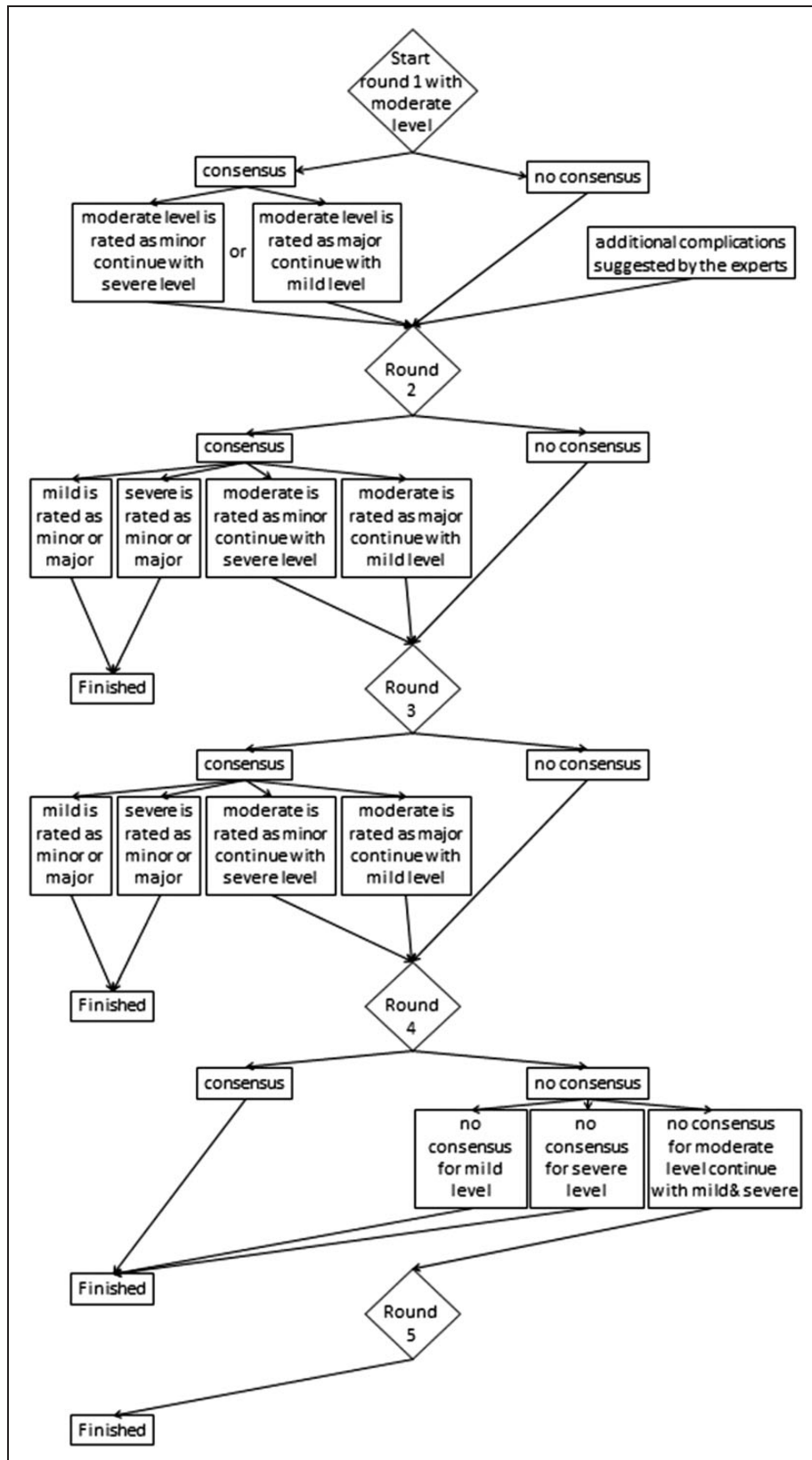


Figure 1. Flowchart to introduce different severity levels of complications into the five DISCOVAR Delphi rounds.

Data analysis

The internal consistency of the first Delphi round was calculated using Cronbach's alpha using IBM SPSS Statistics version 23 (Armonk, New York, USA). A Cronbach's alpha outcome of 0.7 or higher is considered to be acceptable and an outcome of 0.9 or higher is considered excellent.²³

Results

For this Delphi study we invited 43 vascular surgeons, five dermatologists, and one phlebologist to participate. Eleven vascular surgeons and one phlebologist accepted our invitation and participated in the first round (response rate of 24%). The physicians performed a median number of 300 (range 200–1500) VV interventions annually. Physicians from the first Delphi round were affiliated to medical centers in the United States of America, Austria, the United

Kingdom, and the Netherlands. Six vascular surgeons and one phlebologist participated in the final round (14% response rate).

In the first round, physicians proposed the following additional complications: contact allergy, arteriovenous fistula, transient ischemic attack or stroke, and incomplete obliteration. The Cronbach's alpha score was 0.93.

Table 1 provides the list of the 12 major and 12 minor complications of VV treatment on which the physicians reached consensus. Online Appendix A shows the complete list of complications with the level of consensus achieved. The physicians did not reach consensus on some complications. For instance, no consensus was reached on complications such as cellulitis, hyperpigmentation still present after 12 months, superficial wound infection requiring oral antibiotics, and posttreatment pain requiring analgesics for two weeks.

Table 1. List of complications on which consensus was reached for varicose vein treatment.

Major	1	Allergic reaction requiring treatment to be aborted and medication to be started or to treatment being aborted and ventilator support as a result of medication
	2	Cellulitis requiring hospital admission for treatment with IV antibiotics or IV antibiotics and ICU support due to hemodynamic instability
	3	Deep wound infection requiring surgical debridement
	4	Hemorrhage requiring one blood transfusion, blood transfusion and limited surgical or endovascular interventions or massive transfusion and extensive surgical intervention
	5	Pulmonary embolism requiring anticoagulant therapy or surgical therapy due to hemodynamic instability
	6	Skin necrosis requiring surgical debridement or split skin graft
	7	Arteriovenous fistula formation requiring endovascular repair or surgical repair
	8	Deep venous thrombosis requiring long-term anticoagulant therapy or lytic therapy
	9	Lymphocele requiring drainage or lymphorrhea with permanent debilitating edema or continuous lymphorrhea
	10	First-degree thermal injury requiring no additional treatment, second-degree thermal injury requiring a topical agent, or third-degree thermal injury requiring surgical intervention
	11	Transient ischemic attack resolved within 24 h or stroke resulting in mild or temporary cognitive function impairment or stroke with permanent disability and inability to live independently
	12	Permanent discoloration
Minor	1	Discoloration that resolves after six weeks
	2	Ecchymosis that limits the patient to wearing posttreatment compression stockings
	3	Erythema self-limiting after two weeks
	4	Posttreatment pain requiring no additional treatment
	5	Superficial thrombophlebitis requiring analgesics for two weeks or no additional therapy
	6	Telangiectatic matting requiring additional sclerotherapy or endovenous therapy or no additional therapy
	7	Contact allergy to plaster requiring use of a different plaster
	8	Incomplete obliteration requiring reintervention or no additional intervention
	9	Migraine including migraine aura, requiring triptan therapy after sclerotherapy
	10	Hyperpigmentation resolved within 12 months
	11	Paresthesia resolved within 12 months
	12	Posttreatment pruritus causing skin rash due to scratching

ICU: intensive care unit; IV: intravenous.

Discussion

Our Delphi study shows that physicians reached consensus on 12 major and 12 minor complications of VV treatment. The consensus on these complications may assist physicians when informing patients about the associated potential risks of the VV treatments for which the patient is eligible.

To decide which complications should be discussed with patients prior to treatment remains a difficult but important topic. On the one hand, physicians want their patients to be fully informed about their possible treatment options. On the other hand, physicians do not want to frighten or overwhelm patients by presenting every potential complication.²⁴ For example, most VV physicians will not discuss the risk of stroke with permanent disability after foam sclerotherapy due to an air embolism in patients with a patent foramen ovale.²⁵ Nevertheless, many patients do want more information than is given by their physicians.²⁶

Legislation on informed consent in the United Kingdom requires physicians to discuss the risks a reasonable person in the patient's position would deem of significance or the risks deemed of significance by this particular patient.²⁷ In the Netherlands, the Royal Dutch Medical Association (KNMG) provides information on informed consent, which is also based on court rulings. The KNMG states that complications occurring in more than 1% of patients must be discussed, in addition to those major complications that occur less often.²⁸ Unfortunately, both the UK and Dutch laws and professional societies do not provide detailed information about the type of major or significant complications physicians need to discuss. Also for minor complications, perhaps the arbitrary cutoff point of 1% should be lower for VV treatment, since it is often performed for non-limb-threatening symptoms or cosmetic reasons.

The consensus reached in our study appears to provide an appropriate group of major complications to discuss with patients. However, this is currently only based on what physicians deem to be major complications for discussion with the patient. Future studies should analyze if patients agree that these are the complications they want to be informed about. Combining the physician's view and the patient's view may help to close the physician-patient information gap²⁹ and could empower VV patients to engage in shared decision-making. This seems particularly relevant for VV patients because of the existence of several treatment options, including no treatment (at least initially). All these options have their merits and disadvantages and can be weighed against the patients' burden of disease. Thus, information should be provided about complications that might influence a reasonable patient's view on a treatment.³⁰ The consensus list of major

complications from our Delphi study may assist VV physicians on deciding which complications to discuss with their patients.

The strengths of this study are first of all that the participating physicians were experienced and originated from four different countries practicing Western medicine. This suggests that the results of our study are valid for a wide range of Western countries. Second, the items in our first survey round had a high Cronbach's alpha score. This indicates that the questions asked belonged to a single construct, which is likely since all items were about possible complications after VV treatment. Third, the list of complications was quite comprehensive, since few additional complications were added based on the suggestions of the physicians.

One of the limitations of this study may first be the limited number of physicians that participated in our Delphi study and the withdrawal of five out of 12 experts after the first round. However, the literature suggests that the more participants, the lower the possibility of reaching consensus. Panel sizes of 5–30 participants are recommended.⁴ Hence, we believe our panel size was sufficient throughout the Delphi rounds. Second, none of the invited dermatologists participated in our study. Thus, unfortunately, no insight was gained into the expert opinion of dermatologists with regard to which complications from VV treatment they would deem minor or major. Perhaps, this absence of participating dermatologists may have led to an underestimation of the severity of cosmetic complications. Third, only physicians practicing Western medicine were invited. It is unclear whether involving participants from non-Western countries would have altered the consensus reached here.

In conclusion, this Delphi study rendered international consensus about which complications of VV treatment are considered minor and which major. This consensus may help to harmonize the information that physicians discuss with their patients prior to VV treatment.

Collaborators in the DISCOVAR study in alphabetical order

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Ethical approval

Ethical approval was not applicable. This article is a Delphi study in which only the expert opinion of vascular surgeons was used.


Guarantor

DTU.

Contributorship

SMLM: study design, data collection, data analysis, writing. FES: study design, data collection, writing. DAL: study design, data collection, data analysis, writing. RB: study design, data collection, data analysis, writing. DTU: study design, data collection, data analysis, writing. All authors reviewed and edited the manuscript and approved the final version of the manuscript.

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References

- Knops AM, Ubbink DT, Legemate DA, et al. Information communicated with patients in decision making about their abdominal aortic aneurysm. *Eur J Vasc Endovasc Surg* 2010; 39: 708–713.
- McManus PL and Wheatley KE. Consent and complications: risk disclosure varies widely between individual surgeons. *Ann R Coll Surg* 2003; 85: 79–82.
- Kundu S, Lurie F, Millward SF, et al. Recommended reporting standards for endovenous ablation for the treatment of venous insufficiency: joint statement of the American Venous Forum and the Society of Interventional Radiology. *J Vasc Interv Radiol* 2007; 18: 1073–1080.
- Clayton MJ. Delphi: a technique to harness expert opinion for critical decision-making tasks in education. *Educ Psychol* 1997; 17: 373–386.
- Biemans AA, Kockaert M, Akkersdijk GP, et al. Comparing endovenous laser ablation, foam sclerotherapy, and conventional surgery for great saphenous varicose veins. *J Vasc Surg* 2013; 58: 727–734 e721.
- Carradice D, Mekako AI, Mazari FA, et al. Randomized clinical trial of endovenous laser ablation compared with conventional surgery for great saphenous varicose veins. *Br J Surg* 2011; 98: 501–510.
- Darwood RJ, Theivacumar N, Dellagrammaticas D, et al. Randomized clinical trial comparing endovenous laser ablation with surgery for the treatment of primary great saphenous varicose veins. *Br J Surg* 2008; 95: 294–301.
- Helmy ElKaffas K, ElKashef O and ElBaz W. Great saphenous vein radiofrequency ablation versus standard stripping in the management of primary varicose veins – a randomized clinical trial. *Angiology* 2011; 62: 49–54.
- Lurie F, Creton D, Eklof B, et al. Prospective randomized study of endovenous radiofrequency obliteration (closure procedure) versus ligation and stripping in a selected patient population (EVOLVE Study). *J Vasc Surg* 2003; 38: 207–214.
- Pronk P, Gauw SA, Mooij MC, et al. Randomised controlled trial comparing sapheno-femoral ligation and stripping of the great saphenous vein with endovenous laser ablation (980 nm) using local tumescent anaesthesia: one year results. *Eur J Vasc Endovasc Surg* 2010; 40: 649–656.
- Rasmussen LH, Bjoern L, Lawaetz M, et al. Randomized trial comparing endovenous laser ablation of the great saphenous vein with high ligation and stripping in patients with varicose veins: short-term results. *J Vasc Surg* 2007; 46: 308–315.
- Rasmussen LH, Lawaetz M, Bjoern L, et al. Randomized clinical trial comparing endovenous laser ablation, radiofrequency ablation, foam sclerotherapy and surgical stripping for great saphenous varicose veins. *Br J Surg* 2011; 98: 1079–1087.
- Rass K, Frings N, Glowacki P, et al. Comparable effectiveness of endovenous laser ablation and high ligation with stripping of the great saphenous vein: two-year results of a randomized clinical trial (RELACS study). *Arch Dermatol* 2012; 148: 49–58.
- Rautio T, Ohinmaa A, Perala J, et al. Endovenous obliteration versus conventional stripping operation in the treatment of primary varicose veins: a randomized controlled trial with comparison of the costs. *J Vasc Surg* 2002; 35: 958–965.
- Rigby KA, Palfreyman SJ, Beverley C, et al. Surgery versus sclerotherapy for the treatment of varicose veins. *Cochrane Database Syst Rev* 2004; CD004980.
- Shadid N, Ceulen R, Nelemans P, et al. Randomized clinical trial of ultrasound-guided foam sclerotherapy versus surgery for the incompetent great saphenous vein. *Br J Surg* 2012; 99: 1062–1070.
- Subramonia S and Lees T. Randomized clinical trial of radiofrequency ablation or conventional high ligation and stripping for great saphenous varicose veins. *Br J Surg* 2010; 97: 328–336.
- Nesbitt C, Bedenis R, Bhattacharya V, et al. Endovenous ablation (radiofrequency and laser) and foam

- sclerotherapy versus open surgery for great saphenous vein varices. *Cochrane Database Syst Rev* 2014; CD005624.
19. Chaikof EL, Blankensteijn JD, Harris PL, et al. Reporting standards for endovascular aortic aneurysm repair. *J Vasc Surg* 2002; 35: 1048–1060.
 20. Stoner MC, Calligaro KD, Chaer RA, et al. Reporting standards of the Society for Vascular Surgery for endovascular treatment of chronic lower extremity peripheral artery disease: executive summary. *J Vasc Surg* 2016; 64: 227–228.
 21. Timaran CH, McKinsey JF, Schneider PA, et al. Reporting standards for carotid interventions from the Society for Vascular Surgery. *J Vasc Surg* 2011; 53: 1679–1695.
 22. Dindo D, Demartines N and Clavien PA. Classification of surgical complications: a new proposal with evaluation in a cohort of 6336 patients and results of a survey. *Ann Surg* 2004; 240: 205–213.
 23. George D and Mallery P. *SPSS for Windows step by step: a simple guide and reference. 11.0 update*. Boston, MA: Allyn and Bacon, 2003.
 24. Anderson OA and Wearne IM. Informed consent for elective surgery – what is best practice? *J R Soc Med* 2007; 100: 97–100.
 25. Delaney MC, Bowe CT and Higgins GL. Acute stroke from air embolism after leg sclerotherapy. *West J Emerg Med* 2010; 11: 397.
 26. Santema TB, Stoffer EA, Kunneman M, et al. What are the decision-making preferences of patients in vascular surgery? A mixed-methods study. *BMJ Open* 2017; 7: e013272.
 27. Sokol DK. Update on the UK law on consent. *BMJ* 2015; 350: h1481.
 28. Legemaate J. Informed consent, <https://www.knmg.nl/advies-richtlijnen/knmg-publicaties/informed-consent.htm> (2001, accessed 16 November 2017).
 29. Masso Guijarro P, Aranaz Andres JM, Mira JJ, et al. Adverse events in hospitals: the patient's point of view. *Qual Saf Health Care* 2010; 19: 144–147.
 30. Page AE. Safety in surgery: the role of shared decision-making. *Patient Saf Surg* 2015; 9: 24.