Editor's Choice – Management of Lower Extremity Venous Outflow Obstruction: Results of an International Delphi Consensus

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WHAT THIS PAPER ADDS

The treatment of lower extremity venous outflow obstruction has evolved rapidly; however, the pace of growth has occurred with a paucity of available evidence to support treatment. This has been compounded by difficulty in running larger randomised controlled trials. This study is a large international expert consensus that identifies clear areas of agreement and disagreement to support future research and writing of guidelines in this field. Areas where consensus is lacking will benefit from particular focus for evidence generation.

Objective: The endovascular treatment of venous obstruction has expanded significantly in recent years. Best practices for optimal patient outcomes are not well established and the evidence base is poor. The purpose of this study was to obtain consensus on management criteria for patients with lower extremity venous outflow obstruction.

Methods: The study was conducted as a two round Delphi consensus. Statements addressed imaging, symptoms and other baseline measures, differential diagnosis, treatment algorithm, indications for stenting, inflow and outflow assessment, successful procedural outcomes, post-procedure therapies and stent surveillance, and clinical success factors. Statements were prepared by six expert physicians (round 1, 40 statements) and an expanded panel of 24 physicians (round 2, 80 statements) and sent to a pre-identified group of venous experts who met qualifying criteria. A 9 point Likert scale was used and consensus was defined as $\geq$ 70% of respondents rating a statement between 7 and 9 (agreement) or between 1 and 3 (disagreement). Round 1 results were used to guide rewording and splitting compound statements for greater clarity in round 2.

Results: In round 1, 75 of 110 (68%) experts responded, and 91 of 121 (75%) experts responded in round 2. Round 1 achieved consensus in 32/40 (80%) statements. Consensus was not reached in the treatment algorithm section. Round 2 achieved consensus in 50/80 (62.5%). Statements reaching consensus were imaging (2/3, 66%), symptoms and other baseline measures (12/24, 50%), differential diagnosis (2/8, 25%), treatment algorithm (10/17, 59%), indications for stenting (10/10, 100%), inflow and outflow assessment (2/2, 100%), procedural outcomes (2/2, 100%), post-procedure therapies and stent surveillance, (5/7, 71%), and clinical success factors (5/7, 71%).

Conclusion: This study demonstrated that considerable consensus was achieved between venous experts on the optimal management of lower extremity venous outflow obstruction. There were multiple domains where consensus is lacking, highlighting important areas for further investigation and research.

Keywords: Delphi technique, Endovascular procedures, Post-thrombotic syndrome, Veins, Venous stent, Venous obstruction
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INTRODUCTION

Endovenous treatment for patients with venous outflow obstruction has seen an enormous increase in popularity in recent years, driven not only by a greater understanding of the disease process, but also by the introduction of new devices.[1,2] While this expansion of technology has the potential to improve treatment options available to clinicians, it has also focused attention on the lack of evidence to support treatments.

The lack of available evidence was highlighted in the recently published European Society for Vascular Surgery Guidelines for the treatment of both acute and chronic venous disease.[3,4] These publications, though providing recommendations for treatment, highlighted the lack of high quality evidence. The potential dangers of a rapidly expanding therapy were clearly shown by the recent device recall affecting two of the dedicated venous stents that have recently been launched and are likely to become more apparent as more devices to treat lower extremity venous outflow obstruction become available.[5]

The objective of this study was to achieve a robust Delphi consensus on different management criteria for venous outflow obstruction using an international multispecialty expert panel. An additional goal was to identify areas where consensus was lacking, in order to focus future clinical research efforts.

MATERIALS AND METHODS

Delphi procedure

The Delphi method is a structured communication technique developed as a systematic, interactive forecasting method. It relies on experts answering questionnaires in two or more rounds. The experts are encouraged to revise their earlier answers considering the replies of other members of the panel. During this process it is anticipated that the range of answers will decrease and the group will converge towards a correct or consensus answer.

This study consisted of a two round Delphi consensus process. The first round of questions was generated by an expert panel of six international multispecialty experts with recognised expertise in the management of venous outflow obstruction. This group participated in a series of semi-structured discussions covering the entire spectrum of deep venous pathophysiology, diagnosis, clinical assessment, investigations, indications for treatment, technical details of procedures, and post-intervention follow up. Based on these discussions, areas of particular importance or controversy (and therefore variation in practice) were identified and a series of 40 statements was drafted covering the identified topics (Supplementary Table S1). The statements were divided into nine categories to allow thematic grouping: imaging (5), clinical symptoms and other baseline measures (6), differential diagnosis (2), treatment (10), indications for stenting (8), inflow and outflow assessment (2), successful procedural outcomes (1), post-procedure therapies and stent surveillance (4), and clinical success factors (2).

To indicate the level of agreement (or disagreement) with each statement, survey participants were asked to rate each statement on a 9 point scale, with a rating of 1 indicating strong disagreement with the statement and 9 indicating strong agreement. Consensus was defined as $\geq$ 70% of received responses scoring between 7 and 9 (indicating agreement or acceptance of the statement) or between 1 and 3 (indicating disagreement or rejection of the statement).

Expert panel

International multispecialty experts were identified from lists of venous network contacts from the study authors. Potential experts were required to complete a pre-questionnaire survey to confirm their standing in the field (based on clinical experience of treating venous outflow obstruction and participation in clinical studies and publications) (Supplementary Table S3). Using this process, 110 international multispecialty experts were selected. The experts represented multiple specialities and a broad geographic distribution (Tables 1 and 2). Selected experts were asked to complete round 1 of the Delphi consensus process using an online web based platform. Invitations to participate in round 1 were sent in October 2019, with reminder emails sent to non-responders.

Revision of statements

Round 1 results (with free text comments) were reviewed by the authors. In order to create the revised statements, working groups were created, each consisting of two study authors and five or six venous experts (selected from the participants) with 22 experts in total forming these groups. Each working group was allocated a quota of statements from round 1 to review and decide whether consensus had been adequately reached and no further statements were needed for a particular topic, or whether further statements should be formulated for inclusion in the second round of the Delphi process to achieve further clarity. Many of the statements that did not reach consensus in round 1 were amended, primarily to clarify ambiguous statements. In addition, the working groups created additional questions to be more specific and delineate areas of controversy that may have been overgeneralised in the statements from round 1. Even in the case of a statement reaching clear consensus, the working groups were given the freedom to create new statements with a similar theme, if they felt that the new statement would highlight an important or controversial area to achieve greater clarity. This flexibility was important given the evolution of best practices for treating venous obstruction.

Once the working groups had completed the review process and created new statements (by simplification or division into multiple consensus statements), round 2 of the Delphi process included 80 statements (Supplementary Table S2). The same thematic grouping was followed: imaging (3), clinical symptoms and baseline measures (24), differential diagnosis (8), treatment (17), indications for

Table 1. Identified subspecialty of experts completing the consensus questionnaire

Speciality	Round 1 respondents	Round 2 respondents
Vascular surgeon	38 (50.7)	48 (52.7)
Interventional radiologist	26 (34.7)	30 (33.0)
Interventional cardiologist	6 (8.0)	8 (8.8)
Other	5 (6.7)	5 (5.4)
Total	75 (100)	91 (100)

Data are presented as *n* (%).

Table 2. Region of practice of experts completing questionnaire

Region for practice	Round 1 respondents	Round 2 respondents
North and South America	49 (65.3)	67 (73.6)
Europe, Middle East, Africa	13 (17.3)	17 18.7)
Asia Pacific	6 (8.0)	7 (7.7)
Total	75 (100)	91 (100)

Data are presented as *n* (%).

stenting (10), inflow/outflow assessment (2), successful procedural outcomes (2), post-procedural care and follow up (7), and successful clinical outcomes (7).

Invitations to round 2 were sent to the original 110 experts plus a further 11 experts identified through the same process who were asked to review each of the revised statements and rate each using the same nine point score, with the same definitions for consensus. Invitations for the second round were sent in October 2020, with reminders sent to non-responders. The survey was closed on November 13, 2020.

RESULTS

The first round of the Delphi consensus received 75/110 (68%) complete responses from the identified expert panel and are summarised in Tables 3 and 4 with comments received in Supplementary Tables S4 and S5. Consensus was achieved in eight of nine categories on all questions (imaging 5/5, 100%; clinical symptoms 5/5, 100%; differential diagnosis 1/1, 100%; treatment algorithm 3/10, 30%; indications for stenting 8/8, 100%; inflow/outflow assessment 2/2, 100%; successful outcomes 3/3, 100%; post-procedure follow up 4/4, 100%.

The results of the second round of the Delphi with expanded questions received 91/121 (75%) responses from the identified expert panel and are summarised in Tables 5—7 with comments received in Supplementary Tables S4 and S5. In this round consensus was only achieved in 50/80 (62.5%) of statements. Consensus was reached on every statement in three categories: indications for stenting 10/10 (100%), inflow and outflow assessment 2/2 (100%), and procedural outcomes 2/2 (100%). In the other six categories consensus was achieved in imaging 2/3 (66%), clinical symptoms and other baseline measures 12/24 (50%), differential diagnosis 2/8 (25%), treatment algorithm 10/17 (59%), and post-procedural care 5/7 (74%).

For patients with non-thrombotic iliac vein lesions (NIVLs), the experts agreed that patients should only have an intervention if their symptoms significantly affect quality of life, fail conservative therapy, and have a greater than 60% reduction in cross sectional area on intravascular ultrasound (IVUS) or diameter on multiplanar venography. For patients with deep vein thrombosis (DVT), the experts strongly agreed that culprit lesions identified post-thrombus removal should be stented. For patients with post-thrombotic syndrome (PTS), the experts agreed that treatment should be clinically driven based on symptom severity and expected improvement.

Statements in the treatment algorithm category achieved the poorest consensus. In round 1, consensus was not reached on statements regarding the threshold for stenting post-thrombotic disease, bilateral disease, concomitant superficial, and deep disease, as well as the need for thrombophilia testing. In round 2, statements did not reach consensus regarding the threshold for stenting acute disease, post-thrombotic disease, residual thrombus, and relining thrombosed stents as well as the need for thrombophilia testing.

DISCUSSION

This study has demonstrated that despite the lack of high quality evidence guiding the treatment of lower extremity deep venous outflow disease, consensus was achieved for most statements in round 1 and round 2 of this Delphi process. However, many aspects of diagnosis and treatment are still subject to individual variation and an unprecedented element of medical device inertia despite a lack of high quality evidence. This variability was confirmed by the lack of consensus in multiple facets of treatment identified by this Delphi process. This study represents the most widespread survey of experts to date and provides an important benchmark of consensus that highlights areas where further research is needed to clarify treatment for patients with venous disease. Importantly, the clear lack of consensus in many areas highlights the fact that significant efforts are needed to improve the current level of evidence.

Broad and consistent consensus was achieved through both rounds in the categories for (1) pre-operative assessment, (2) indication for treatment, (3) inflow and outflow assessment, and (4) procedural outcomes. Much of this consensus is probably related to the prospective study design and subsequent approval of four venous stents.[1,2] However, given the focused nature of clinical trials for medical devices, areas of scientific ambiguity are often excluded to optimise for a positive clinical trial. The panel did achieve consensus in assessment of clinical symptoms and baseline

Table 3. Round 1 Delphi consensus statements results for imaging, symptoms, baseline measures, and differential diagnosis

Statements	Agree *	Disagree †	Consensus ‡
Q1. DUS is the primary non-invasive imaging modality because it is inexpensive and widely available. In the hands of a trained operator, anatomic variations, size, vessel patency, reflux, and other abnormalities of the lower legs can be visualised.	93	3	Yes
Q2. CTV is a secondary non-invasive imaging modality providing good visualisation of the status of the disease in the pelvic and leg veins as well as the ability to visualise other structures but is more expensive than DUS and exposes the patient to radiation and does not visualise flow.	83	1	Yes
Q3. MRV is also a secondary non-invasive imaging modality that allows greater visualisation of detail inside the vein lumen than CTV, does not expose the patient to radiation, but is the most expensive and requires dedicated post-image processing.	77	3	Yes
Q4. Contrast venography is the primary invasive imaging modality used to visualise the extent of obstructive disease and is able to visualise flow in the inflow vessels, target vessels, outflow vessels, and collateral vessels.	76	9	Yes
Q5. IVUS is an additional invasive imaging modality that has been shown to have greater sensitivity and specificity than venogram in detecting the presence of a lesion, lesion shape, and lesion length and allows for cross sectional area measurements pre- and post stenting but is not always available and may increase cost.	92	4	Yes
Q6. A complete physical examination is important for looking at the legs and pelvis for swelling (oedema), skin changes/telangiectasia, collaterals, and other abnormalities that may indicate reflux or obstruction. Patients should be asked about heaviness, pain, and changes in activity level (i.e., venous claudication).	100	0	Yes
Q7. In patients with oedema, measurements should be taken at consistent points using anatomic landmarks and should include the ankle, calf, and thigh.	72	3	Yes
Q8. While venous ulcers are more often associated with superficial reflux, they can occur with deep obstructive disease, and accurate size measurements and tissue characterisation should be recorded	88	3	Yes
Q9. Lymphoedema occurs when chronic venous hypertension overloads the lymphatic system and may or may not improve with stenting depending upon whether the lymph system has been permanently damaged.	72	8	Yes
Q10. For non-clinical trial patients, baseline clinical measures should include a CEAP score, functional status or VDS, VCSS, oedema circumferences, and ulcer area (if present). If you disagree, please comment on which measures should be used.	80	3	Yes
Q11. For clinical trial/registry patients, baseline clinical measures should include a CEAP score, VCSS, VDS, Villalta, and a patient QOL score such as CIVIQ or VEINES-QOL/SYM along with oedema circumferences, and ulcer area (if present). If you disagree, please comment on which measures should be used.	88	4	Yes
Q12. Venous disease is often multifactorial and patients presenting with symptoms such as obesity, diabetes, and sleep apnoea may have a variety of medical conditions that mimic venous obstructive disease and therefore requires a thorough patient history and clinical exam including a review of all medications.	93	0	Yes
Q13. *A differential diagnosis of venous obstructive disease should rule out the following (please select all that apply)*			
Check for good pulses to rule out arterial disease.	95		Yes
Skin changes such as hyperpigmentation can be related to diabetes or erythema.	88		Yes
Bilateral oedema may be caused by non-vascular conditions.	100		Yes
Leg swelling can be caused by right heart disease and some oral medications (oral hypoglycaemics and dihydro beta blockers).	100		Yes
Look to distinguish between lipoedema *vs.* lymphoedema. If lymphoedema, look for venous sources overloading the lymphatic system versus primary lymphatic disease.	93		Yes
Q14. It is important to understand the functioning of the patient's entire lower body venous system before a treatment plan can be established including pelvic, deep, and superficial veins.	88	0	Yes
Q15. If patients present with both superficial and deep disease, treat the superficial disease first because it is less invasive, less expensive, and may improve deep system flow. If symptoms persist, then treat the deep disease.	32	27	No
Q16. Patients with NIVLs who are symptomatic have been shown to have high patency rates patency and symptom improvement; however, there is no evidence supporting that these patients should be treated from a cost *vs.* QOL perspective.	56	19	No
Q17. In patients with acute, acute on chronic, or subacute iliofemoral thrombosis who are intervened upon, patients with an identifiable culprit lesion should be stented to prevent recurrence.	92	1	Yes
Q18. Residual thrombus is not considered a culprit lesion and therefore is not an indication for stenting.	32	36	No

Table 3-*continued*

Statements	Agree *	Disagree †	Consensus ‡
Q19. The threshold for stenting venous lesions is symptomatic patients who have either a greater than 50% reduction in cross sectional area as measured by IVUS or a greater than 50% reduction in luminal diameter as measured on venogram.	47	16	No

Data are presented as %. DUS = duplex ultrasound; CTV = computed tomography venogram; MRV = magnetic resonance venography; IVUS = intravascular ultrasound; VCSS = Venous Clinical Severity Score; VDS = Venous Disability Score; CEAP = Clinical, Etiological, Anatomical, Pathophysiological; QOL = quality of life; NIVL = non-thrombotic iliac vein lesion.
* Likert codes 7 through 9.
† Likert codes 1 through 3.
‡ Greater than or equal to 70% agree (codes 7–9).

assessments and identified that many of the assessment tools are still not robust enough. This is reflected in the lack of consistency in outcomes measures published in the literature which makes it difficult to compare studies.[6] The need for improved outcome measures has long been a criticism of the limited randomised trials that exist in the field.[7]

For statements related to procedural intervention, consensus was most difficult to achieve reflecting the inconsistent approach to these patients as well as the paucity of evidence to guide treatment. Through the second round, the study also identified that as patient complexity increases, the consensus decreases. The role of deep venous disease in driving venous pathology remains a controversial area.[8] For example, experts could not agree on whether to treat deep or superficial venous disease first in the presence of both pathologies and on post-intervention anti-coagulation strategies.[9–11]

The expert panel in this study comprised a large, international and multispecialty group of venous experts. While this could be considered a strength, it could also have contributed to some of the lack of consensus as intrinsic differences between healthcare systems, treatment pathways, equipment availability, and reimbursement models may have led to different interpretations of statements. Also, this study deviated from the traditional Delphi methodology where initial statements undergo iterative revision over several rounds to try and achieve consensus. In this study, working groups were given the flexibility to completely rewrite or change statements in the second round, to improve clarity, and clinical value. It could be argued that the round 1 statements were too general, confusing, or addressed multiple topics in a single statement. Nevertheless, the statements in both rounds where consensus was achieved provide an excellent framework to design clinical pathways for the evaluation and treatment of patients with venous outflow obstruction.

It was interesting that the lack of consensus was most common in statements relating to treatment. This demonstrates a clear need to focus further research studies on the treatment algorithm itself and clinical outcomes (including health economic outcomes) to help ensure that treatments become more robust.

The consensus on indications for stenting provides important guidelines for achieving immediate and long term technical success when treating deep vein occlusive disease. Consistent application of stenting indications will facilitate further research on patient selection, procedure outcomes and post-operative care, for example, and avoid the confounding variable of different technical approaches that cloud conclusions in these areas.

The study has several implications for collection of baseline measures, treatment algorithms for patients with NIVLs, DVT, and PTS, as well as technical aspects for stent placement. Regarding baseline measures for patients not participating in clinical trials, the experts agreed on three primary measures of CEAP C classification (Clinical, Etiological, Anatomical, Pathophysiological), Venous Clinical Severity Scores, and ulcer area if applicable should be tracked at baseline and post-operatively. This finding highlights the need to streamline clinical measures that burden staff and patients but lack a patient reported quality of life measure. This aspect is important to both patients and payers and is an area of treatment clearly identified as requiring further research.

Regarding treatment algorithms for patients with NIVLs, DVT, and PTS, the recommendations demonstrate the need for clinical expertise and judgement to avoid over-treating patients, which is necessary to ensure appropriate intervention. A technical consideration that contrasts with the treatment of peripheral arterial disease (PAD) is that patients with deep venous obstruction should be stented from a widely patent inflow vein to a widely patent outflow vein. This statement is supported by the understanding that thrombosis is the primary mechanism of failure in patients with iliofemoral vein stents. Patency failures are primarily due to poor inflow and outflow leading to thrombosis, and not intimal hyperplasia as seen in patients with PAD.

CONCLUSION

This study has demonstrated that while there are several areas where venous experts agree on the assessment and management of lower extremity venous outflow obstruction, there are multiple domains where consensus was not achieved. This underlines that treating venous disease

Table 4. Round 1 Delphi consensus statements results for treatment algorithm, indications for stenting, inflow assessment, successful procedural outcomes, post-procedure care, and successful clinical outcomes

Statements	Agree *	Disagree †	Consensus ‡
Q20. Testing for thrombophilia may inform the need for long term anticoagulation.	55	10	No
Q21. Patients with bilateral disease or vena cava involvement are at greater risk of recurrence and should be treated more aggressively including post-stenting therapy.	69	8	No
Q22. In cases of possible re-intervention, the decision to re-intervene should be based upon patient symptoms and should begin with prolonged in stent venoplasty to treat in stent narrowing and use IVUS if available to look for missed lesions. Additional stenting is appropriate to cover missed lesions.	92	1	Yes
Q23. In patients with lymphoedema, lymphatic system assessments should not routinely be done because they do not change patient management.	43	28	No
Q24. Venous stenting should be clinically driven and not based on image findings as venous compressive lesions occur naturally in a high percentage of the population, most of whom do not need to be stented. Before intervening with stent placement, it is important to rule out other potential causes of patient symptoms.	96	3	Yes
Q25. Venoplasty alone is not successful in treating de novo lesions of the iliofemoral veins due to the high degree of type I collagen causing elastic recoil. Venous stents are required in this area.	87	4	Yes
Q26. Stenting should be performed from healthy vein to healthy vein or more importantly from good inflow to good outflow.	97	0	Yes
Q27. Most iliac vein lesions require stenting proximally past the iliac confluence 5–10 mm into the IVC. However, stenting too far into the IVC can jail the contralateral iliac vein causing thrombosis.	88	4	Yes
Q28. Stenting should generally not occur below the lesser trochanter which usually signifies the confluence of the femoral and profunda veins.	90	4	Yes
Q29. Stenting of the femoral vein has had poor results and is strongly discouraged.	74	7	Yes
Q30. Before stent placement, pre-dilatation of the scarred vein is recommended and should be done either sequentially or directly up to the reference vessel diameter. A balloon can generate orders of magnitude of more force than a stent and is the primary force to open the lesion.	83	3	Yes
Q31. Post-stent dilatation is also recommended to ensure proper stent expansion and good wall apposition. Post-stent dilatation should match the size of the reference vessel or the stent diameter.	96	1	Yes
Q32. Achieving good inflow and outflow is an important predictor of successful clinical outcomes, and a venogram is the preferred method of assessing flow through primary veins and collaterals before and after interventions.	87	4	Yes
Q33. IVUS can effectively show stent lumen, shape (cross sectional area), residual thrombus, and can characterise to some degree the nature of the lesion but does not visualise flow.	92	1	Yes
Q34. Successful procedural outcomes are determined primarily by improvements in flow that are visualised by axial inflow, brisk flow through the target lesion(s), brisk outflow into the proximal veins, and a reduction in collateral flow if present prior to the procedure. There are no specific definitions of contrast washout and brisk flow and therefore requires clinical judgment.	92	1	Yes
Q35. Interventions cause a temporary hypercoagulable state requiring peri-procedural anticoagulation. While there are no specific agreed upon guidelines, it is advised to use LMWH (Lovenox) immediately after the procedure for 2–4 weeks due to its anti-inflammatory effects and bridge to an oral anticoagulant such as Warfarin or a DOAC.	71	7	Yes
Q36. The use of antiplatelet therapy such as Plavix or aspirin should be considered although there is no evidence to support it.	81	5	Yes
Q37. Compression stockings can be used to pull over the access site to provide light pressure after the procedure and can be helpful in the reduction of oedema.	74	0	Yes
Q38. Because stent thrombosis is usually an early complication, patients should be seen within 2-4 weeks after the procedure, and at 3 mo, 6 mo, 12 mo, and annually thereafter.	92	0	Yes
Q39. Successful clinical outcomes are a reduction of symptoms, resumption of normal activities, and freedom from re-intervention.	99	0	Yes
Q40. Patient outcomes are related to how acutely symptoms presented and were treated, patient compliance with anticoagulation and compression, and resumption of activity levels. Exercise is an important component in achieving good clinical outcomes.	88	0	Yes

Data are presented as %. IVUS = intravascular ultrasound; IVC = inferior vena cava; LMWH = low molecular weight heparin; DOAC = direct oral anticoagulant.

* Likert codes 7 through 9.

† Likert codes 1 through 3.

‡ Greater than or equal to 70% agree (codes 7–9).

Table 5. Round 2 Delphi consensus statements results for imaging, symptoms, baseline measures, and differential diagnosis

Statements	Agree *	Disagree †	Consensus ‡
Q1. All patients with clinically significant venous disease should undergo DUS of the superficial and deep venous systems as the first imaging modality.	96	1	Yes
Q2. In patients with suspected venous outflow obstruction, cross sectional imaging (CTV or MRV) should be performed prior to invasive imaging or procedures.	64	9	No
Q3. Assuming availability, IVUS guidance should be considered for venous stenting procedures enabling accurate identification of lesion length, stent landing zones, and accurate stent expansion.	91	3	Yes
Q4. In addition to superficial and deep duplex ultrasound assessment, specific iliac outflow imaging should be performed in the following three clinical scenarios: patient presents with a new venous ulcer (2 mo) and has no history of DVT and no signs or symptoms of post-thrombotic disease.	52	21	No
Q5. In addition to superficial and deep duplex ultrasound assessment, specific iliac outflow imaging should be performed in the following three clinical scenarios: patient presents with a new venous ulcer (2 mo) and a history of DVT or signs or symptoms of post-thrombotic disease.	81	4	Yes
Q6. In addition to superficial and deep duplex ultrasound assessment, specific iliac outflow imaging should be performed in the following three clinical scenarios: patient presents with discordant clinical signs and symptoms compared with the duplex ultrasound image findings.	86	2	Yes
Q7. Phlebolymphoedema is multifactorial and it is difficult to predict if swelling will improve with stenting.	81	1	Yes
For clinical trial and registry patients, the following baseline assessments should be performed routinely to measure clinical outcomes			
Q8. CEAP C classification	83	3	Yes
Q9. CEAP full classification	44	17	No
Q10. VCSS	92	0	Yes
Q11. VDS	56	5	No
Q12. Villalta	76	5	Yes
Q13. Validated disease specific QOL	91	0	Yes
Q14. Validated generic QOL	44	3	No
Q15. Oedema circumferences	71	2	Yes
Q16. Ulcer area	89	0	Yes
Q17. Maximum walking distance	54	10	No
For non-clinical trial/registry patients, the following baseline clinical assessments should be performed routinely to measure clinical outcomes			
Q18. CEAP C classification	84	2	Yes
Q19. CEAP full classification	31	28	No
Q20. VCSS	78	3	Yes
Q21. VDS	24	17	No
Q22. Villalta	60	11	No
Q23. Validated disease specific QOL	51	8	No
Q24. Validated generic QOL	18	23	No
Q25. Oedema circumferences	60	10	No
Q26. Ulcer area	82	1	Yes
Q27. Maximum walking distance	38	16	No
For patients with bilateral symptoms, venous outflow obstruction should not be treated until the following conditions have been assessed and optimised			
Q28. Medications	71	5	Yes
Q29. Obesity	48	11	No
Q30. Cardiac disease	76	2	Yes
Q31. Renal or liver failure	68	4	No
Q32. Sleep apnoea	45	11	No
Q33. Lipoedema	42	12	No
Q34. Lymphoedema	45	14	No
Q35. Hypoproteinaemia	59	4	No

Data are presented as %. DUS = duplex ultrasound; CTV = computed tomography venography; MRV = magnetic resonance venography; DVT = deep vein thrombosis; CEAP = Clinical, Etiological, Anatomical, Pathophysiological; VCSS = Venous Clinical Severity Score; QOL = quality of life; VDS = Venous Disability Score.

* Likert codes 7 through 9.

† Likert codes 1 through 3.

‡ Greater than or equal to 70 agree (codes 7–9).

Table 6. Round 2 Delphi consensus statements results for treatment algorithm, and indications for stenting

Statements	Agree *	Disagree †	Consensus ‡
Q36. It is important to understand the presence and degree of proximal vein obstruction, superficial reflux, and deep reflux before a treatment plan is established.	91	3	Yes
Q37. For patients with CEAP C3 or higher disease presenting with both superficial reflux and deep vein obstruction, treatment should be tailored to the severity of symptoms and the severity of the superficial *vs.* deep venous disease.	90	1	Yes
Q38. If a patient presents with post-thrombotic obstruction and superficial reflux, then treat the post-thrombotic obstruction first.	70	9	Yes
Q39. If a patient presents with a non-thrombotic obstruction and superficial reflux with a large calibre vein, then treat the superficial disease first.	59	19	No
Q40. If a patient presents with a non-thrombotic obstruction and moderate superficial reflux with small calibre veins, then treat the deep obstruction first.	62	11	No
Q41. Patients with NIVL should only have an intervention if their symptoms significantly affect quality of life, fail conservative therapy, and have a greater than 60% reduction in cross sectional area on IVUS or diameter on multiplanar venography.	85	7	Yes
Q42. Patients with CEAP C1 or C2 disease should not be treated with venous stenting.	70	8	Yes
Q43. In patients who have had acute thrombus removal and a culprit lesion is identified, stenting is recommended to prevent recurrence.	94	0	Yes
Q44. Residual acute thrombus is not an indication for stenting.	45	16	No
Q45. The threshold for stenting symptomatic post-thrombotic lesions is a greater than 50% reduction in cross sectional area on IVUS or diameter on multiplanar venography.	65	8	No
Q46. In post-thrombotic patients, treatment should be clinically driven based upon symptom severity and expected improvement.	98	1	Yes
Q47. Testing for heritable thrombophilia is discouraged because it does not change the course of treatment.	33	34	No
Q48. Testing for antiphospholipid antibodies is recommended routinely because it may alter the choice of anticoagulation.	47	15	No
Q49. Although definitive evidence is lacking, patients with symptomatic bilateral disease or vena cava involvement are at greater risk of recurrence and more invasive treatments including stenting should be considered.	72	2	Yes
Q50. In symptomatic patients or patients with progressive impending in stent failure, re-intervention for stent stenosis should be considered.	93	0	Yes
Q51. Re-intervention treatments to consider are in stent venoplasty and stent extension (caudal or cephalad) to treat missed lesions.	94	0	Yes
Q52. Relining of stents is discouraged except for evidence of mechanical stent failure.	47	18	No
Q53. Venous stenting should be clinically driven and not based solely on image findings as iliofemoral venous compressive lesions occur naturally in a high percentage of the asymptomatic population, and not all need to be stented.	92	2	Yes
Q54. Before intervening in patients with lower extremity or pelvic chronic venous insufficiency symptoms, it is important to rule out other potential causes of the patient's presentation other than outflow obstruction.	92	0	Yes
Q55. Venoplasty alone is rarely sufficient to treat iliac and common femoral obstructive lesions, therefore venous stenting is required to treat these types of lesions.	89	1	Yes
Q56. Venous stenting should be performed from widely patent inflow vein to widely patent outflow vein. Note: Historical literature has referred to stenting healthy to healthy vein. However, present literature refers to good inflow to good outflow which more accurately reflects current scientific understanding.	97	1	Yes
Q57. Proper cranial landing of a venous stent treating an iliac vein stenosis to the IVC confluence should generally be past the confluence into the IVC but not covering the contralateral iliac vein and may vary based upon lesion location and stent design.	90	1	Yes
Q58. Venous stents should generally not be placed below the confluence of the femoral and profunda veins.	79	3	Yes
Q59. Stent placement in the femoral veins is currently strongly discouraged due to a lack of supporting data.	78	5	Yes
Q60. When necessary to improve venous inflow, femoral–popliteal venoplasty can be performed.	76	8	Yes
Q61. Before stent placement, pre-dilatation of the scarred post-thrombotic vein is recommended and should be done either sequentially or directly up to the reference vessel/stent target diameter.	85	0	Yes
Q62. Post-stent dilatation to the reference vessel or the stent diameter is recommended to ensure proper stent expansion and good wall apposition.	90	2	Yes

Data are presented as %. CEAP = Clinical, Etiological, Anatomical, Pathophysiological; NIVL = non-thrombotic iliac vein lesion; IVUS = intravascular ultrasound; IVC = inferior vena cava.

* Likert codes 7 through 9.

† Likert codes 1 through 3.

‡ Greater than or equal to 70 agree (codes 7–9).

Table 7. Round 2 Delphi consensus statements results for inflow assessment, procedural outcomes, post-procedure care, and clinical outcomes

Statements	Agree *	Disagree †	Consensus ‡
Q63. Procedural outcome after venous stenting should be evaluated with IVUS and venogram, with specific attention to assessing lumen gain, flow adequacy, appropriate stent location/apposition, and adequate lesion coverage.	91	1	Yes
Q64. Post-stent placement, IVUS can be useful for the evaluation of stent lumen (cross sectional area), shape, residual disease/thrombus, stent/vein wall apposition, and stent overlap when multiple stents are used.	97	1	Yes
Q65. Successful post-intervention venogram findings should include improvement in flow that is visualised by axial inflow, brisk flow through the target lesion(s), brisk outflow into the proximal veins, and resolution or significant reduction in collateral flow if visualised prior to the intervention.	95	0	Yes
Q66. There are no specific definitions of contrast washout and brisk flow and therefore, technical success as viewed by imaging requires clinical judgment and experience.	86	2	Yes
Q67. For non-thrombotic patients, there is no evidence to support the routine use of anticoagulation in this population.	58	10	No
Q68. For acute and post-thrombotic patients, anticoagulation therapy should be prescribed.	97	1	Yes
Q69. If Coumadin is chosen as the final A/C therapy, LMWH should be used as a bridge until therapeutic levels of A/C are reached.	96	1	Yes
Q70. If a DOAC is chosen as the final A/C therapy, LMWH should be considered as an initial therapy for 2–4 weeks after the procedure.	55	17	No
Q71. Compression stockings should be used post-intervention in patients with persistent oedema.	92	0	Yes
Q72. Because stent thrombosis can be an early complication, patients should be assessed within 2–4 weeks after the procedure.	90	2	Yes
Q73. Patients should enter an ongoing surveillance protocol and be seen if they develop new or recurrent symptoms.	99	0	Yes
Q74. Treatment success should be primarily defined by patient reported outcomes rather than technical outcomes.	75	3	Yes
Patient compliance with the following factors is very important for good patient outcomes			
Q75. Anticoagulation	97	1	Yes
Q76. Antiplatelet (aspirin or Plavix)	57	11	No
Q77. Compression	58	4	No
Q78. Physical activity	79	1	Yes
Q79. Weight loss	73	1	Yes
Q80. Clinical surveillance	90	0	Yes

Data are presented as %. IVIS = intravascular ultrasound; LMWH = low molecular weight heparin; A/C = anticoagulation.
* Likert codes 7 through 9.
† Likert codes 1 through 3.
‡ Greater than or equal to 70 agree (codes 7–9).

remains a controversial area and requires focused and coordinated research efforts across specialties to answer several unresolved clinical questions. The Delphi consensus has identified those areas in which these efforts should be focused.

CONFLICT OF INTEREST

S.B.: Consultant for Cook Medical, BSCI, Medtronic, Gore, Phillips, Vesper, Veryan, Surmodics, BD. M.G.: Consultant for Cook Medical, Medtronic, Gore. R.D.G.: Consultant for Cook Medical, Philips/Volcano, Bentley, BD/Straub. P.G.: Consultant for Cook, Medtronic, Philips, Bard/BD, Boston Scientific. M.S.: Consultant for Gore & Associates, Cook Medical, Boston Scientific Corporation, Inari Medical, and Medtronic; Speaker Bureau for Bristol/Pfizer Alliance and Astra Zeneca; Board Member for Contego Medical. L.V.H.: Consultant for Cook Medical, BSX, Medtronic, and Becton Dickenson; Co-founder Grand Rounds, Inc.

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APPENDIX A. SUPPLEMENTARY DATA

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ejvs.2023.09.044.

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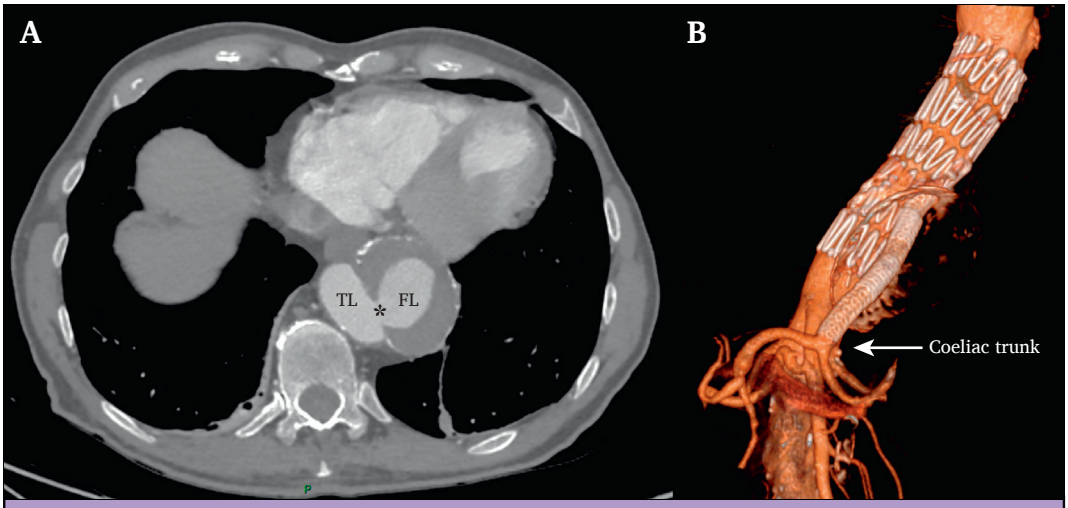
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COUP D'OEIL

Treatment of a Chronic Type B Aortic Dissection With a Single Branched Custom Made Device

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An 81 year old male who underwent an aortohepatic bypass to treat hepatic malperfusion 15 years ago due to an acute type B aortic dissection was referred. (A) Pre-operative computed tomography angiography (CTA) showed a 7 cm aneurysm with a true (TL) and large false (FL). The FL supplied the coeliac trunk. The previous bypass was occluded. A custom made single branched stent graft 42-34-131 mm (Cook Medical, Bloomington, IN, USA) was deployed in front of the residual entry tear (asterisk). (B) Three Advanta V12 10 × 59 mm stents (Atrium Medical, Hudson, NH, USA) were deployed in the coeliac trunk. The aneurysm was excluded as shown on the CTA at one month.

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