

ANELISE RODRIGUES BEZERRA DOS SANTOS

**Pigmentação após escleroterapia com espuma ou Cryo-
Laser Cryo-Escleroterapia para veias reticulares dos
membros inferiores: um ensaio randomizado intrapaciente.**

Tese apresentada ao Curso de Pós-Graduação da Faculdade de Ciências Médicas da Santa Casa de São Paulo para obtenção do título de Mestra em Ciências da Saúde.

SÃO PAULO

2025

ANELISE RODRIGUES BEZERRA DOS SANTOS

**Pigmentação após escleroterapia com espuma ou Cryo-
Laser Cryo-Escleroterapia para veias reticulares dos
membros inferiores: um ensaio randomizado intrapaciente.**

Tese apresentada ao Curso de Pós-Graduação
da Faculdade de Ciências Médicas da Santa
Casa de São Paulo para obtenção do título de
Mestra em Ciências da Saúde.

Área de Concentração: Ciências da Saúde

Orientador: Prof. Dr. Eduardo Ramacciotti

Co-orientadora: Profa. Dra. Walkiria Hueb
Bernardi

SÃO PAULO

2025

FICHA CATALOGRÁFICA
Preparada pela Biblioteca Central da
Faculdade de Ciências Médicas da Santa Casa de São Paulo

Santos, Anelise Rodrigues Bezerra dos
Pigmentação após escleroterapia com espuma ou Cryo-Laser
Cryo-Escleroterapia para veias reticulares dos membros inferiores: um
ensaio randomizado intrapaciente./ Anelise Rodrigues Bezerra dos Santos.
São Paulo, 2025.

Dissertação de Mestrado. Faculdade de Ciências Médicas da
Santa Casa de São Paulo – Curso de Pós-Graduação em Ciências da
Saúde.

Área de Concentração: Ciências da Saúde
Orientador: Eduardo Ramacciotti
Co-orientadora: Walkiria Hueb Bernardi

1. Varizes 2. Pigmentação 3. Lasers 4. Escleroterapia

BC-FCMSCSP/52-25

DEDICATÓRIA

Aos meus pais e avós, de sangue e de coração, por forjarem a pessoa que sou hoje.

Aos meus irmãos, que também são parte de mim.

Ao meu marido, pelo companheirismo, compreensão e apoio constantes.

Aos meus filhos, fonte diária de inspiração e minha maior razão para seguir em frente.

AGRADECIMENTOS

À Faculdade de Ciências Médicas da Santa Casa de São Paulo e à Irmandade da Santa Casa de Misericórdia de São Paulo, pela oportunidade de realização deste Mestrado.

À CAPES, pela taxa concedida durante a realização desta tese.

Ao Conselho do Programa de Pós-Graduação em Ciências da Saúde, pelo apoio e ajuda durante o curso

Ao meu orientador dr Eduardo Ramacciotti pelos ensinamentos, amizade e compreensão

Ao dr Henrique Jorge Guedes Neto por me incentivar a entrar no mundo acadêmico

Ao dr Kasuo Miyake, com quem aprendi a técnica CLaCS

À dra Juliana Puggina por abraçar minhas idéias e me ajudar a superar cada obstáculo no caminho

Aos drs Walkiria Hueb, Fabricio Santiago, Rodrigo Kikuchi e Samantha Neves pela disponibilidade em me orientar sempre que precisei

À dra Camila Magalhães, por não me deixar desistir no meio do caminho

À Viviane Santana por todo auxílio, cuidado e orientação

Aos meus pacientes, sem os quais nada disso teria sido possível

CITAÇÃO

*Para ser grande, sê inteiro
Nada teu exagera ou exclui
Sê todo em cada coisa
Põe quanto és no mínimo que fazes
Assim, em cada lago a lua toda brilha
Porque alta vive*

Fernando Pessoa

ABREVIATURAS E SÍMBOLOS

DVC	Doença Venosa Crônica
CEAP.	do inglês " <i>Clinical, Etiological, Anatomical, and Pathophysiological</i> " - aspectos Clínicos, Etiológicos Anatômicos e Fisiopatológicos,
Laser Nd:YAG	Laser de granada de ítrio e alumínio dopada com neodímio
CLaCS	<i>Cryo-Laser Cryo-Sclerotherapy</i>
HPE	Hiperpigmentação pós-escleroterapia
HPI	Hiperpigmentação pós inflamatória
ANA-scale	Escala análoga numérica estética
ΔE	Diferença de tonalidade entre 2 superfícies, mensuradas através de colorimetria

SUMÁRIO

1- INTRODUÇÃO.....	01
1.1 – Doença Venosa Crônica e Veias Reticulares.....	02
1.2 – Escleroterapia.....	03
1.3 – Uso do Laser e Técnica CLaCS.....	05
1.4 – Hiperpigmentação Pós Escleroterapia (HPE).....	06
2- OBJETIVO.....	08
2.1 – Objetivo Primário.....	09
2.2 – Objetivo Co-Primário.....	09
2.3 – Objetivo Secundário.....	09
3- CASUÍSTICA E MÉTODOS.....	10
3.1 – Desenho do Estudo.....	11
3.2 – Participante.....	11
3.3 – Randomização e alocação.....	12
3.4 – Intervenções.....	12
3.5 – Desfechos.....	14
3.5,1 – Desfecho Primário.....	14
3.5,2 – Desfecho Co-primário.....	15
3.5,3 – Desfecho Secundário.....	16
3.6 – Cálculo do Tamanho Amostral.....	17
3.7 – Análises Estatísticas.....	17
4- RESULTADOS.....	19
4.1 – Supplementary table (online only) Kappa and inter-evaluator concordance Analysis.....	30
4.2 – Supplementary Figure (online only), Different levels of pigmentation according to ΔE	30
5- CONSIDERAÇÕES FINAIS.....	31
6- REFERÊNCIAS BIBLIOGRÁFICAS.....	36
7- ANEXOS.....	41
<i>Anexo 1 – Aprovação do Comitê de Ética e Pesquisa.....</i>	<i>42</i>
<i>Anexo 2 – Termo de Consentimento Livre e Esclarecido.....</i>	<i>48</i>
<i>Anexo 3 – Termo de Consentimento Para Acervo de Dados.....</i>	<i>53</i>
<i>Anexo 4 – Termo de Consentimento Para Uso de Imagem.....</i>	<i>55</i>
<i>Anexo 5 – Normas para Publicação da Revista.....</i>	<i>57</i>

1.1. Doença Venosa Crônica e Veias Reticulares

A Doença Venosa Crônica (DVC) compreende um amplo espectro de alterações estruturais e funcionais no sistema venoso dos membros inferiores, com manifestações clínicas que vão desde telangiectasias e veias reticulares até úlceras venosas. A classificação CEAP (do inglês “Clinical, Etiological, Anatomical, and Pathophysiological” - aspectos Clínicos, Etiológicos Anatômicos e Fisiopatológicos), atualizada em 2020, padroniza a descrição dessas manifestações, e define como C1 a presença de telangiectasias ou veias reticulares. (fig 1 – classificação ceap)

CEAP Classification System and Reporting Standard Revision 2020		
C (Clinical Manifestations), E (Etiology), A (Anatomic Distribution), P (Pathophysiology)		
	C0	No visible or palpable signs of venous disease
	C1	Telangiectasias or reticular veins
	C2	Varicose veins
	C2r	Recurrent varicose veins
	C3	Edema
	C4	Changes in skin and subcutaneous tissue secondary to chronic venous disease
	C4a	Pigmentation or eczema
	C4b	Lipodermatosclerosis or atrophie blanche
	C4c	Corona phlebectatica
	C5	Healed
	C6	Active venous ulcer
	C6r	Recurrent active venous ulcer



Journal of
Vascular Surgery
Venous and Lymphatic Disorders

Lurie et al. *J Vasc Surg Venous Lymphat Disord*, May 2020

Copyright © 2020 by the Society for Vascular Surgery®



@JVascSurg



@TheJVascSurg

Nesse contexto, as veias reticulares são definidas como vasos subdérmicos azulados, de 1 a 3 mm de diâmetro, frequentemente associados às telangiectasias que alimentam, formando redes superficiais visíveis e esteticamente incômodas.^(1, 2) e tem incidência estimada em 25% de acordo com uma revisão sistemática recente.⁽³⁾

O impacto psicossocial da DVC não deve ser subestimado. A literatura destaca que a busca por procedimentos para tratamento de varizes é motivada não apenas por sintomas, mas também por fatores emocionais, sociais e profissionais. A presença dessas veias pode limitar a escolha de roupas, atividades de lazer e até influenciar a vida profissional de indivíduos que lidam com o público ou cuja imagem corporal é relevante para sua atuação profissional. São, portanto, uma causa comum de incômodo estético e constrangimento, e motivação para buscar tratamento médico.⁽⁴⁻

⁶⁾ Um estudo de 2022 cita que em questionário de qualidade de vida, a DVC CEAP C0–4 representa uma causa de ansiedade e medo do futuro, especialmente em pacientes mais jovens; no mesmo questionário, dos pacientes entre C0 e C1, 11% relatam alto impacto psicológico e 39% um alto impacto estético da DVC em sua qualidade de vida.⁽⁷⁾

Embora em muitos casos dos pacientes classificados como C1 o objetivo principal do tratamento dessas veias seja a melhora estética, intervenções eficazes, como a escleroterapia e o uso de lasers, também podem aliviar sintomas locais, melhorar a hemodinâmica venosa, prevenir a progressão da doença e, consequentemente, melhorar a qualidade de vida.⁽⁸⁾

1.2. Escleroterapia

A escleroterapia é a técnica de escolha para o tratamento de veias reticulares e telangiectasias dos membros inferiores.^(1, 9) Essa abordagem consiste na injeção de uma substância esclerosante, que atua lesionando o endotélio venoso, promovendo fibrose e, posteriormente, a reabsorção do vaso tratado. Diversos esclerosantes podem ser utilizados para essa finalidade, com diferentes mecanismos de ação

(detergentes, como polidocanol ou osmóticos, como glicose hipertônica) e a escolha de qual utilizar depende de fatores como a natureza das veias a serem tratadas, a preferência do médico e a resposta do paciente ao tratamento. O procedimento é minimamente invasivo e pode oferecer resultados significativos, o que o torna uma escolha popular entre os pacientes.

Duas formas principais de escleroterapia são utilizadas na prática clínica: a escleroterapia líquida e a escleroterapia com espuma. Embora os consensos europeu e americano sugiram uso de ambas escleroterapia líquida ou em espuma (resultante da mistura do esclerosante com gás - ar ambiente ou dióxido de carbono) para veias reticulares^(1, 9), um documento recente da União Internacional de Flebologia afirma que a escleroterapia líquida é recomendada apenas para telangiectasias e escleroterapia com espuma para todos os outros tipos de veias. As concentrações variam de acordo com tipo, diâmetro e espessura da parede do vaso a ser tratado – no caso de veias reticulares, recomenda-se utilização de espuma com polidocanol ou STS em concentração de até 0,5%.⁽¹⁰⁾

A espuma injetada atua como êmbolo dentro da veia, empurrando o sangue, consequentemente diminuindo a diluição do esclerosante intraluminal e aumentando o contato do mesmo com a parede da veia, aumentando o efeito esclerosante comparado com o mesmo volume na forma líquida.⁽¹¹⁾ No entanto, apesar de sua eficácia, a escleroterapia com espuma apresenta limitações. Há risco de eventos adversos como sintomas neurológicos, dor no trajeto venoso, reações inflamatórias, formação de microtrombos e hiperpigmentação. Além disso, o volume total de espuma que pode ser utilizado em uma única sessão é limitado, o que pode restringir a extensão da área tratada. ⁽¹¹⁻¹⁴⁾

1.3. Uso do Laser e Técnica CLaCS

A eficácia dos lasers em medicina é baseada na fototermólise seletiva. O laser de granada de ítrio e alumínio dopada com neodímio (Nd:YAG) com comprimento de onda de 1064nm possibilita uma penetração mais profunda do feixe do laser ao mesmo tempo em que foca na hemoglobina como cromóforo alvo nas lesões vasculares, permitindo assim a lesão térmica das veias reticulares com relativa preservação dos tecidos adjacentes. As complicações reportadas, tais como bolhas, crostas e pequenas úlceras, foram amplamente atribuídas às altas energias necessárias para um o tratamento efetivo, especialmente na ausência de mecanismos de resfriamento da epiderme.^(15, 16) A associação de mecanismos de resfriamento da epiderme aumentou a tolerabilidade e a segurança do laser, reduzindo riscos de queimaduras, bolhas e desconforto durante o procedimento, permitindo a aplicação de fluências mais altas com menor incidência de complicações.^(17, 18)

O uso combinado de laser com escleroterapia passou a ser explorado como forma de potencializar os efeitos de ambas as terapias. A técnica CLaCS (Cryo-Laser Cryo-Sclerotherapy), desenvolvida no Brasil, associa a aplicação de laser Nd:YAG 1064nm de pulso longo à escleroterapia líquida com glicose 75%, realizada em sequência, sob resfriamento epidérmico contínuo e com o auxílio de dispositivos de realidade aumentada.^(19, 20)

Com relatos iniciais de boa tolerância e menor ocorrência de hiperpigmentação, inclusive em pacientes com pele mais pigmentada, a técnica passou a ser utilizada na prática clínica como alternativa para o tratamento estético das veias reticulares.

1.4. Hiperpigmentação Pós Escleroterapia (HPE)

A hiperpigmentação pós-escleroterapia é uma complicação frequente e uma preocupação entre os pacientes que buscam tratamento por razões cosméticas. A literatura relata taxas de incidência variando entre 2% e 67,9% dependendo dos fatores descritos e da metodologia de avaliação⁽¹⁴⁾. Embora a maioria dos casos tenda à resolução espontânea em semanas ou meses, alguns podem se tornar permanentes, especialmente quando associados a inflamação intensa ou deposição profunda de pigmento. ^(14, 21, 22)

A HPE uma condição multifatorial, causada por mecanismos interligados que resultam na pigmentação cutânea subsequente. O principal mecanismo descrito é o extravasamento de hemácias após a lesão endotelial induzida pelo esclerosante. Os macrófagos fagocitam e degradam a hemoglobina extracelular, e o ferro fica armazenado na forma de hemossiderina, um pigmento marrom-dourado que se deposita na derme e no subcutâneo.^(21, 23, 24) Esse depósito pode se tornar visível na pele como manchas acastanhadas. Em alguns casos também pode haver deposição de melanina, como resultado do estado inflamatório perivascular que estimula os melanócitos a produzirem e liberarem mais melanina (melanogênese), especialmente em pacientes de pele mais pigmentada (hiperpigmentação pós inflamatória – HPI). ⁽²⁴⁾

A persistência de microtrombos nos vasos tratados também desempenha papel relevante no surgimento de HPE. Coágulos que não são reabsorvidos ou drenados mantêm o sangue estagnado por mais tempo, favorecendo o depósito de pigmentos e prolongando o processo inflamatório local. ⁽²³⁾

Outros fatores de risco para HPE incluem veias epifasciais, concentrações mais altas de esclerosante, níveis altos de ferritina sérica e fototipo cutâneo mais alto ⁽¹⁴⁾

(IV a VI), conforme definido pela escala de Fitzpatrick (essa classificação avalia a resposta da pele à exposição solar, sendo os tipos mais altos mais propensos à pigmentação pós-inflamatória devido à maior atividade melanocítica).⁽²⁵⁾

Em casos nos quais a veia não é ocluída, a presença visual do vaso pode ser erroneamente interpretada como pigmentação residual gerando o “sombreamento venoso”, onde a própria veia permanece visível sob a pele, podendo ser confundida com pigmentação verdadeira. Nesses casos, a dermatoscopia pode ser uma ferramenta útil, permitindo a diferenciação entre pigmento cutâneo real e veias residuais ainda permeáveis. Essa distinção é fundamental para orientar condutas, evitar tratamentos desnecessários e manejar adequadamente a expectativa do paciente.^(26, 27)

Embora seja considerada uma complicação menor, a HPE é uma preocupação significativa para pacientes que buscam melhorias estéticas, e a possibilidade de desenvolver essa alteração pode ser causa de desistência do tratamento.⁽²⁸⁾

2. OBJETIVO

2.1 Objetivo Primário

Analisar a incidência HPE 60 dias após sessão única de CLaCS e escleroterapia com espuma de polidocanol, através de avaliação fotográfica.

2.2 Objetivo Co-primário

Analisar a incidência HPE 60 dias após sessão única de CLaCS e escleroterapia com espuma de polidocanol, através de medida objetiva com colorimetria.

2.3 Objetivos Secundários

Avaliar:

- o desaparecimento da veia tratada, através de ultrassom em modo B;
- a intensidade da pigmentação pós-tratamento através da colorimetria;
- o volume de esclerosante utilizado para tratamento dos vasos;
- a intensidade da dor utilizando escala análoga visual ;
- a satisfação do paciente após o procedimento utilizando a escala análoga numérica estética (ANA-scale);
- Incidência de eventos adversos menores: cicatrizes, tosse, tromboflebite superficial, matting telangiectático, alergias, lipotímia, migrânea, escotomas, necessidade de microtrombectomia. Incidência de eventos adversos maiores: dor torácica, anormalidades neurológicas transitórias, punção arterial inadvertida, necrose tecidual, trombose venosa profunda, embolia pulmonar;

3.1. Desenho do Estudo

Este foi um ensaio clínico de segurança, prospectivo, aberto, randomizado, com controle ativo e delineamento intrapaciente, conduzido em um único centro médico.

O estudo foi registrado na Plataforma Brasileira de Registros de Ensaios Clínicos (ReBEC – RBR-88mcd4c) e na International Clinical Trials Registry Platform (UTN U1111-1265-8900), e foi realizado de acordo com as diretrizes CONSORT para ensaios clínicos randomizados, com extensão para estudos do tipo intrapaciente⁽²⁹⁾, além dos princípios éticos da Declaração de Helsinque. O protocolo foi aprovado pelo Comitê de Ética do Hospital Leforte (parecer nº 4.532.514), e todos os participantes assinaram o termo de consentimento livre e esclarecido antes de qualquer procedimento. Os dados foram coletados e gerenciados utilizando a plataforma REDCap® (versão 11.1.29), hospedada na Universidade de Yale.

3.2. Participantes

Os critérios de inclusão contemplaram pacientes com mais de 18 anos, portadores de veias reticulares nos membros inferiores (com ou sem telangiectasias), com distribuição semelhante nos dois membros (as lesões a serem tratadas deveriam ter aproximadamente o mesmo comprimento e localização em ambos os lados)^(29, 30), e com diâmetro interno das veias de até 2,2 mm, medido por ultrassonografia em modo B, com o paciente em posição ortostática.

Os critérios de exclusão incluíram histórico de reações alérgicas locais ou sistêmicas ao polidocanol; gestação, puerpério e lactação; uso de medicamentos

tópicos ou sistêmicos potencialmente causadores de hiperpigmentação cutânea (ex.: isotretinoína, minociclina); presença de lesões cutâneas locais ou infecção; e insuficiência de veias pélvicas, perforantes ou safenas (magna e/ou parva) associadas à área tratada.

Após triagem, os pacientes elegíveis assinaram o termo de consentimento e foram submetidos à avaliação clínica por cirurgião vascular capacitado. As características basais, incluindo dados demográficos, comorbidades, satisfação estética e achados clínicos foram coletadas no dia do tratamento, antes da randomização, por meio da plataforma RedCap®.

3.3. Randomização e alocação

Para garantir a comparação intrapaciente, cada participante recebeu ambos os tratamentos, sendo um para cada membro inferior. A randomização foi realizada com base nos membros, e não nos pacientes. Antes do tratamento, o membro inferior direito foi randomizado para receber CLaCS ou escleroterapia com espuma de polidocanol, utilizando o sistema eletrônico RedCap®.

3.4. Intervenções

Após a randomização e a documentação fotográfica inicial, os tratamentos foram realizados.

O membro designado para receber a técnica CLaCS foi sempre tratado primeiro, seguido da escleroterapia com espuma de polidocanol 0,5% no membro contralateral. Essa ordem foi escolhida com base em evidências que sugerem menor

risco de complicações sistêmicas com o CLaCS, além do potencial documentado de reações sistêmicas com a escleroterapia com espuma.

A distância entre os locais de tratamento e a ausência de efeitos cruzados permitiram a realização sequencial dos procedimentos.⁽²⁹⁻³¹⁾ Para garantir isonomia, cada técnica foi atribuída a um investigador principal com experiência específica, sendo este profissional o responsável por realizar o procedimento em todos os membros alocados para aquela técnica.

A técnica CLaCS consistiu na aplicação de laser Nd:YAG transdérmico de pulso longo, 1064 nm (Harmony™, Alma Lasers, Tel-Aviv, Israel), sobre a veia reticular, com resfriamento cutâneo (Freddo™, Fabinject, Taubaté, Brasil) e orientação por realidade aumentada (Vein Viewer™, Christie Medical, Memphis, EUA).^(32, 33) Os parâmetros do laser incluíram spot de 6 mm, duração do pulso de 15 milissegundos e fluência ajustada conforme o fototipo de Fitzpatrick^(25, 34) (70 J/cm² até fototipo IV e 50 J/cm² para fototipo V). Em seguida, injetou-se dextrose a 75% (Victa Lab, São Paulo, Brasil) nas mesmas veias, com uso contínuo de resfriamento e visualização direta com realidade aumentada.

Vinte minutos após o CLaCS e a coleta de dados, foi realizada a escleroterapia com espuma de polidocanol no membro contralateral. A espuma foi preparada pelo método de Tessari⁽³⁵⁾, misturando-se polidocanol a 0,5% (Victa Lab, São Paulo, Brasil) com ar ambiente, na proporção 1:3. A aplicação foi realizada com atenção às limitações técnicas, sobretudo quanto ao volume máximo por sessão.^(1, 11, 36)

Em ambos os membros, foram aplicadas bolas de algodão fixadas com fita adesiva nos locais de punção, compressão excêntrica com rolo de algodão dental sobre o trajeto venoso tratado, e meias de compressão graduada (24–30 mmHg). Os pacientes foram orientados a remover a compressão excêntrica e as meias após 24

horas e agendados para retornos em 7, 30 e 60 dias para avaliações clínicas, documentação fotográfica e avaliação estética com escala analógica numérica (ANAScale).⁽³⁷⁾

3.5. Desfechos

3.5.1 Desfecho primário

O desfecho primário foi a incidência de hiperpigmentação cutânea 60 dias após uma única sessão de tratamento, avaliada por análise fotográfica comparativa antes e depois do procedimento, realizada por três avaliadores cegos e independentes (cirurgiões vasculares com ampla experiência em flebologia).

Todos os avaliadores receberam imagens em alta definição dos membros inferiores dos pacientes atribuídos a eles, incluindo uma imagem anterior ao tratamento com marcação branca da veia tratada, para identificação exata da área. Em seguida, foram convidados a responder à pergunta: “Você acredita que há pigmentação pós-tratamento nas áreas tratadas deste membro? Sim ou não?”, conforme seu próprio julgamento técnico. A resposta escolhida pela maioria dos avaliadores foi considerada para a análise estatística.

3.5.2 Desfecho co-primário

Foi a diferença de tonalidade da pele (ΔE) entre a área tratada e a pele adjacente, mensurada por colorimetria digital. Esta metodologia já foi previamente validada e permite medições precisas de variações na cor da pele.^(38, 39)

O valor de ΔE deriva das diferenças no espaço de cor Lab* da Comissão Internacional de Iluminação (CIELAB), que representa a cor com base em três parâmetros: luminosidade (L^*), cromaticidade vermelho-verde (a^*) e cromaticidade amarelo-azul (b^*). Esses parâmetros possibilitam a identificação única de cada cor visível, sendo amplamente utilizados para descrição objetiva da cor da pele em contextos clínicos e científicos.^(40, 41)

A interpretação da escala ΔE é a seguinte:

- $\Delta E < 1$: diferença imperceptível (sem pigmentação);
- $1 \leq \Delta E < 2$: diferença percebida apenas por observadores experientes (leve);
- $2 \leq \Delta E < 3,5$: diferença também perceptível por observadores inexperientes (discreta);
- $3,5 \leq \Delta E < 5$: diferença perceptível (moderada);
- $\Delta E \geq 5$: impressão de que se tratam de cores diferentes (intensa).

No presente estudo, valores de $\Delta E \geq 1$ foram considerados positivos para pigmentação, embora somente valores acima de 2 tenham sido considerados de impacto clínico (perceptíveis mesmo por observadores inexperientes).

3.5.3 Desfecho secundário

A intensidade da descoloração cutânea foi determinada com base nos valores de ΔE (quanto maior o ΔE , maior a alteração de cor). A taxa de redução do diâmetro da veia tratada foi calculada pela comparação entre os valores de base e os do 60º dia, com ultrassonografia em modo B, utilizando transdutor linear de 20 MHz e paciente em posição ortostática.

Outras variáveis avaliadas incluíram:

- Volume de esclerosante utilizado;
- Número de punções venosas;
- Ocorrência de equimoses, microtrombos e necessidade de microtrombectomia;
- Eventos adversos menores: cicatrizes, tosse, trombose venosa superficial; matting, reações alérgicas, síncope, enxaqueca e escotomas;
- Eventos adversos maiores: dor torácica, alterações neurológicas, punção arterial inadvertida, necrose tecidual, trombose venosa profunda e embolia pulmonar;
- Intensidade da dor (avaliada por escala analógica visual após cada sessão);
- Satisfação estética do paciente antes e 60 dias após o procedimento, para cada membro tratado, avaliada com a escala analógica numérica estética (ANA-scale).⁽³⁷⁾

3.6. Cálculo do tamanho amostral

Considerando um desfecho dicotômico (pigmentação: sim/não), poder estatístico de 80%, nível de significância de 5% ($\alpha = 0,05$), e uma taxa média de hiperpigmentação de 31,6% após escleroterapia com espuma de polidocanol³⁴ e zero com CLaCS^(13, 20, 42, 43), estimou-se o tamanho amostral necessário em 20 pacientes (40 membros). Considerando uma taxa de perda de 15%, a inclusão mínima recomendada foi de 24 pacientes (48 membros).

Devido à complexidade do cálculo amostral em estudos intrapaciente ⁽²⁹⁾, optou-se por um cálculo baseado em modelo paralelo (não pareado), que tende a superestimar o tamanho amostral necessário. Apesar de ser uma escolha conservadora, foi adotada para evitar subdimensionamento da amostra.

3.7. Análise Estatística

As análises foram realizadas com o software R (versão 4.2.2). Estatísticas descritivas incluíram frequências absolutas e relativas para variáveis categóricas, e medidas de tendência central (média e mediana) e dispersão (desvio padrão, valores mínimo e máximo) para variáveis contínuas.

Para comparações entre os dois tratamentos (CLaCS e espuma) em dados contínuos pareados que não apresentaram distribuição normal, utilizou-se o teste de Wilcoxon pareado (unilateral). Para variáveis categóricas pareadas, foi aplicado o teste de McNemar em sua forma unilateral, com teste binomial aplicado aos pares discordantes, para avaliar a direção dos efeitos.

O nível de significância foi estabelecido em 5% ($p < 0,05$). A concordância entre os avaliadores foi medida por meio do coeficiente kappa e análise de concordância bruta.



Pigmentation after foam or cryo-laser cryo-sclerotherapy for lower limb reticular veins: A within-patient randomized trial

Anelise Rodrigues, MD,^{a,b} Juliana Puggina, MD, PhD,^c Viviane Santana da Silva, BSc,^d Camilla Moreira Ribeiro, PhD,^d Fabrício Rodrigues Santiago, MD, PhD,^e Samantha Neves, MD, PhD,^b Gabriel Henrique Simoni, MS,^f Maria Fernanda Portugal, MD, PhD,^g and Eduardo Ramacciotti, MD, PhD,^{b,d,h} Cuiabá, MT, São Paulo, SP, Goiânia, GO, and Várzea Grande, MT, Brazil; and Maywood, IL

ABSTRACT

Objective: Skin hyperpigmentation is a common complication after leg vein sclerotherapy and a primary concern for patients with cosmetic complaints. The aim of this study was to determine if cryo-laser cryo-sclerotherapy technique (CLaCS) presents a lower incidence and intensity pigmentation after procedure compared with 0.5% polidocanol foam sclerotherapy. 60 days after a single treatment of reticular veins.

Methods: This was an open-label, prospective, within-patient, randomized, active controlled, safety trial with blind evaluators. Interventions took place from August through September 2021, with a 2-month follow-up. Interventions were performed in a private clinic. Eligible patients were volunteers over 18 years old, with aesthetic discomfort related to bilateral lower limb reticular veins, similar length and distribution, with veins' internal diameter up to 2.2 mm in B-mode ultrasound. Patients underwent consecutive CLaCS treatment in one limb and 0.5% polidocanol foam in the contralateral limb on the same day. The primary outcome was the presence of post-procedure pigmentation in treated areas 60 days after a single treatment, determined through photo evaluation and objective measurement of skin color dissimilarity between the treated area and the adjacent skin, using a precision colorimeter. Patients' aesthetic satisfaction improvement, vein diameter reduction, and minor/major adverse events were also assessed.

Results: Twenty-three women (46 limbs) were treated, and two were lost to follow-up. No significant statistical difference in the number of limbs that developed posttreatment pigmentation was found for both photo (7 CLaCS vs 5 foam; $P = .8906$) and colorimetric (9 CLaCS vs 13 foam; $P = .1445$) evaluations. The CLaCS group had significantly lower intensity of pigmentation in colorimetry (mean ΔE of 1.30 for CLaCS vs 1.44 for foam; $P = .02735$). No significant difference in veins' diameter reduction was found. Both groups presented substantial improvement in patients' satisfaction with their leg appearance.

Conclusions: Although no statistical difference was found regarding the number of limbs that developed hyperchromia after treatment of the reticular veins, CLaCS resulted in a lower intensity of skin color dissimilarity, less microthrombi formation and drainage, less bruising and lower volume of sclerosant needed, without difference in diameter reduction rates, compared with polidocanol foam sclerotherapy. No major adverse events were reported. (J Vasc Surg Venous Lymphat Disord 2025;13:102285.)

Keywords: CLaCS; Laser; Pigmentation; Reticular veins; Sclerotherapy

From the Clínica Dra. Anelise Rodrigues, Cuiabá^a; the Vascular Surgery, Irmandade da Santa Casa de Misericórdia de São Paulo,^b the Instituto Circular,^c the Science Valley Research Institute,^d São Paulo, Brazil; the Vascular Surgery, Universidade Federal de Goiás, Goiânia^e; the Centro Universitário de Várzea Grande, Várzea Grande^f; the Vascular Surgery, Hospital Israelita Albert Einstein, São Paulo^g; and the Hemostasis & Thrombosis Research Laboratories, Loyola University Medical Center, Maywood.^h

Trial Registration ReBEC: RBR-88mcd4c <https://ensaiosclinicos.gov.br/rg/RBR-88mcd4c> UIN U1111-1265-8900.

Additional material for this article may be found online at www.jvsvenous.org. Correspondence: Anelise Rodrigues, MD, Av Andre Antonio Maggi, 487, Ste 1904 - Centro Político Administrativo, Cuiabá, MT 78.049-080, Brazil (e-mail: contato@draanelise.med.br).

The editors and reviewers of this article have no relevant financial relationships to disclose per the Journal policy that requires reviewers to decline review of any manuscript for which they may have a conflict of interest.

2213-333X

© 2025 THE AUTHOR(S). Published by ELSEVIER INC. on behalf of the Society for Vascular Surgery. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

<https://doi.org/10.1016/j.jvsv.2025.102285>

Chronic venous disease is highly prevalent worldwide. Among its clinical manifestations, telangiectasias and reticular veins are frequent concerns, particularly in aesthetic practice. The management of reticular veins in the lower limbs has gained increasing relevance, especially among patients presenting with isolated cosmetic complaints, classified as C1 asymptomatic under the CEAP system.^{1,2}

Liquid and foam sclerotherapy may be successfully used to treat reticular veins, with sclerosant concentrations determined by vessel type, diameter, and wall thickness.³⁻⁸ A well-documented complication associated with its use is post-sclerotherapy hyperpigmentation (PSH), especially for patients with Fitzpatrick IV to VI.^{9,10} Although considered a minor adverse event, PSH can significantly affect patients' quality of life and often undermines overall satisfaction and potentially deters them from the procedure.¹¹

The adjunctive use of laser has been shown to enhance the efficacy of sclerotherapy. The cryo-laser cryo-sclerotherapy (CLaCS) technique, which combines a 1064-nm Nd:YAG transdermal laser with liquid sclerotherapy using 75% dextrose, is performed under skin cooling and visual guidance with illumination devices and has been previously described.¹²⁻¹⁶

This study investigates the potential of the CLaCS technique to reduce the incidence of post-sclerotherapy pigmentation, given the consistently low rates reported in the literature.

METHODS

Study design. This was an open, prospective, randomized, with active control, within-patient safety trial conducted at a single medical center.

The trial was registered on the Brazilian Registry of Clinical Trials (RBR-88mcd4c) and International Clinical Trials Registry Platform (UTN U1111-1265-8900), performed following the Consolidated Standards of Reporting Trials (CONSORT) guideline for randomized clinical studies with extension for within-person trials¹⁷ and the ethical principles of the Declaration of Helsinki. The local ethical committee approved the study protocol (Hospital Leforte Ethical committee 4.532.514), and all participants provided written informed consent before any procedure. Study data were collected and managed using REDCap (version 11.1.29) electronic data capture tools hosted at Yale University.

Participants. Eligibility criteria included patients over 18 years old, who signed informed consent, with lower limb reticular varicosities (with or without telangiectasias), with similar distribution in both legs (lesions to be treated had to be approximately of the same length and be located at the same part of the leg),^{17,18} veins with internal diameter measuring up to 2.2 mm in B-mode ultrasound, standing position, considering the largest diameter along the segment to be treated. No contraindications for any of the procedures studied could be present.

Exclusion criteria were personal history of any local/systemic allergic reaction to polidocanol injection; pregnancy, puerperium, and breastfeeding; use of topical/systemic drugs that might induce skin hyperpigmentation (eg, isotretinoin, minocycline); local tissue damage or infection; and insufficiency of pelvic, perforator, or saphenous (great/small) veins connected to the studied area.

On the treatment day, after screening, patients signed informed consent and underwent standard clinical evaluations by a trained vascular surgeon. Before randomization, data on baseline characteristics, including demographics, comorbidities, aesthetic satisfaction, and clinical findings, were collected using the RedCap software.

ARTICLE HIGHLIGHTS

- **Type of Research:** Single-center, open, prospective, within-person, randomized, with active control, safety study
- **Findings:** Despite comparison in the number of limbs that developed pigmentation in patients who underwent consecutive cryo-laser cryo-sclerotherapy (CLaCS) treatment in one limb and polidocanol foam in the contralateral limb showed no significant statistical difference, the CLaCS group demonstrated a significantly lower intensity of pigmentation in colorimetry, less microthrombi formation/drainage, less bruising and lower volume of injected sclerosant, with no significant difference in veins' diameter reduction rate.
- **Take Home Message:** The CLaCS procedure can be a safe and effective alternative for treating reticular veins, with less intense postprocedural hyperpigmentation.

Randomization and allocation. To ensure within-patient comparison, each participant received both treatments, one for each lower limb, with randomization performed based on limbs rather than patients. Prior to treatment, each participant had their right lower limb randomly assigned to either CLaCS or polidocanol foam sclerotherapy, via the RedCap electronic system.

Interventions. After randomization and photographic documentation, treatments were performed.

The limb assigned to the CLaCS technique was always treated first, followed by 0.5% polidocanol foam sclerotherapy on the contralateral limb. This sequence was adopted based on evidence suggesting lower risk of systemic complications for CLaCS and documented potential of systemic reactions to foam sclerotherapy.

The distance between treatment sites and the absence of carry-across effects allowed us to perform the sequential treatments.¹⁷⁻¹⁹ To ensure equipoise, each technique was assigned to a different leading investigator based on their expertise, and this investigator performed the given technique for all the limbs randomized to it.

The CLaCS technique involved applying a 1064-nm long-pulse Nd:YAG transdermal laser (Harmony, Alma Lasers) along the reticular vein, with a skin cooling device (Freddo, Fabinject) and augmented-reality guidance (Vein Viewer, Christie Medical).^{20,21} Laser emission settings were a 6-mm spot size, 15-millisecond pulse duration, and energy adjusted according to Fitzpatrick Phototype Scale^{22,23} (70 J/cm² for Fitzpatrick up to IV and 50 J/cm² for Fitzpatrick V). Liquid 75% dextrose (Vicia Lab) was then injected intravenously into the same vessels under skin cooling and augmented-reality guidance.²⁴



Fig 1. Example of before and after pictures sent to blind evaluators.

Twenty minutes after the CLaCS procedure and data collection, polidocanol foam sclerotherapy was performed in the contralateral limb. The foam was obtained using the Tessari method,²⁵ mixing 0.5% polidocanol (Vista Lab) and ambient air in a 1:3 ratio. It was injected intravenously into the affected area, observing the technique's limitations, especially the maximum volume per session.²⁶⁻²⁸

On both limbs, cotton balls held by adhesive tape were applied to puncture sites to stop bleeding, eccentric compression with a dental cotton roll was applied to the vessel site, and 24- to 30-mmHg compression stockings were placed.

Patients were instructed to remove eccentric compression and stockings after 24 hours and scheduled for follow-up visits after 7, 30, and 60 days for clinical evaluation, photographic documentation, and assessment of cosmetic satisfaction with an aesthetic numeric analog scale (ANA-scale).²⁹

Outcome measures. The primary outcome was the incidence of post-procedure skin hyperpigmentation 60 days after a single treatment session, evaluated through before-and-after photo documentation analysis by three independent and blind observers (vascular surgeons highly experienced in phlebology).

All the evaluators received access to high-definition before and after pictures of the patient's legs that were designated for them, together with a before picture with a white tracing of the treated vessel, to identify exactly the treated areas (Fig 1). Then they were invited to answer the question "Do you think there is post treatment pigmentation in the treated areas of this limb, yes or no?" for each limb, according to their own expertise. The answer chosen by most of the evaluators was considered for data analysis.

The co-primary outcome was the skin tone dissimilarity (expressed as ΔE) at treated and adjacent areas measured with digital colorimetry. This method was previously described and allows precise measures of skin color differences.^{30,31}

The ΔE value derives from the differences in the International Commission on Illumination $L^*a^*b^*$ (CIELAB) color space, which provides a systematic way to represent color differences based on three parameters: lightness (L^*), red-green chromaticity (a^*), and yellow-blue chromaticity (b^*). Measured CIELAB color space parameters enable the unique identification of every color that may be visually distinguished, and their use is proposed for the unambiguous communication of skin color information for clinical or scientific purposes.^{32,33}

This metric provides a structured approach to quantifying color differences, with specific intervals indicating varying levels of perceptibility that may be translated into different intensities of pigmentation.

- $0 < \Delta E < 1$: difference is unnoticeable (no pigmentation).
- $1 < \Delta E < 2$: difference is only noticed by experienced observer (mild).
- $2 < \Delta E < 3.5$: difference is also noticed by inexperienced observer (light).
- $3.5 < \Delta E < 5$: difference is noticeable (moderate).
- $5 < \Delta E$: gives the impression that these are two different colors (intense)

Patients were submitted to colorimetric analysis, ΔE being the skin color difference between the treated and the adjacent areas. For study purposes, a ΔE of 1 or higher was considered positive, even though only ΔE over 2 was considered to have a clinical impact (also noticed by inexperienced observers).

Secondary outcomes. The intensity of color dissimilarity at treated sites was calculated based on ΔE values (higher ΔE reflects more intense color difference). The treated vessel's internal diameter reduction rate was calculated using baseline and D60 measurements of the largest diameter on the treated vein, on B-mode ultrasound using a 20-MHz probe with a standing patient.

Other variables collected were sclerosant agent volume and the number of vein punctures; occurrence of

Table 1. Demographic and baseline characteristics of participants

Variables	Population
Sex (female)	23 (100)
Age, years	44.04 (8.28)
Hypertension	2 (8.7)
Diabetes	1 (4.3)
Thrombophilia	1 (4.3)
Gestations	1.91 (1.20)
Vein location	
Popliteal fossa	12
Lateral thigh	10
Posterior thigh	1
Fitzpatrick ^a	
III	8 (34.7)
IV	13 (56.5)
V	2 (8.7)
Data are presented as number (%) or mean (standard deviation).	
^a Fitzpatrick: Fitzpatrick skin type classification.	

post-treatment ecchymosis, microthrombi and need of micro thrombectomy (all microthrombi were drained); minor adverse events such as scarring, cough, superficial venous thrombosis, telangiectatic matting, allergies, fainting, migraine, and scotomas; major adverse events rate such as chest pain, neurologic abnormalities, inadvertent arterial puncture, tissue necrosis, deep vein thrombosis, and pulmonary embolism; pain intensity measured using a pain visual analog scale after each treatment session; and patient's cosmetic satisfaction before and 60 days after procedure, for each treated limb, using the ANA scale.

Sample size calculation. Considering a dichotomous endpoint (pigmentation yes/no), an 80% power at an alpha level of .05, and mean reported hyperpigmentation rate after the treatment of varicose veins as 31.6% for polidocanol foam³⁴ and zero for CLaCS,^{13,16} a sample size of twenty patients (forty limbs) was calculated. Assuming a drop-out rate of 15%, a minimum of twenty-four patients (forty-eight limbs) should be initially included.

Due to the complexities of within-patient trials sample size calculations, including estimating a correlation coefficient,¹⁷ the sample size was calculated considering parallel unpaired binary outcomes, which is known to require a higher sample than that needed for paired inpatient data. Although a conservative approach, it was chosen to ensure the sample size was not underestimated.

Statistical methods. Statistical analyses were performed using R software (version 4.2.2). Descriptive

statistics included absolute and relative frequencies for categorical variables, and measures of central tendency (mean and median), and dispersion (standard deviation, minimum and maximum values) for continuous variables.

For categorical paired outcomes, the McNemar test was applied in its unilateral form, using a one-tailed binomial test on discordant pairs to assess the directionality of the effects.

For the intragroup comparisons between the two treatment modalities (CLaCS and foam), the paired Wilcoxon signed-rank test was applied for continuous variables that did not meet parametric assumptions, using a one-tailed approach.

The significance level was set at 5% ($P < .05$).

Interrater reliability among evaluators was calculated using kappa concordance and gross agreement tests.

RESULTS

Participant flow

From August through September 2021, 39 volunteers filled in an online pre-screening form and were invited to an on-site clinical assessment for eligibility. Twenty-six volunteers attended this clinical screening. Two patients were excluded for not meeting the study criteria. Twenty-four patients were randomized; one withdrew informed consent.

A total of 23 volunteer women, with mean age of 44.04 years (standard deviation [SD], 8.28 years) and Fitzpatrick skin types III (30.4%), IV (60.9%), and V (8.7%) were submitted to both treatments according to randomization allocation. Demographic characteristics are described in Table 1. Two patients were lost to follow-up, and 21 patients completed the study. Forty-six limbs were assessed for baseline data and D7 secondary outcomes. Forty-two limbs were assessed for D60 primary and secondary outcomes, as shown in the CONSORT flowchart (Fig 2).

Outcomes and estimation

Systemic outcomes were assessed per patient, and local outcomes were assessed per limb.

Main outcomes

There were no significant differences in the number of limbs presenting with hyperpigmentation between the groups in both photo (7 CLaCS vs 5 foam; $P = .8906$) and colorimetric (9 CLaCS vs 13 foam; $P = .1445$) evaluations.

Secondary outcomes. In the colorimetric evaluation, CLaCS had significantly lower mean ΔE values, suggesting a lower intensity of pigmentation, since higher ΔE reflects more intense color difference, with mean ΔE of 1.3 (SD, 1.88) for CLaCS vs 1.44 (SD, 1.00) for foam ($P = .02735$). For patients with Fitzpatrick skin types

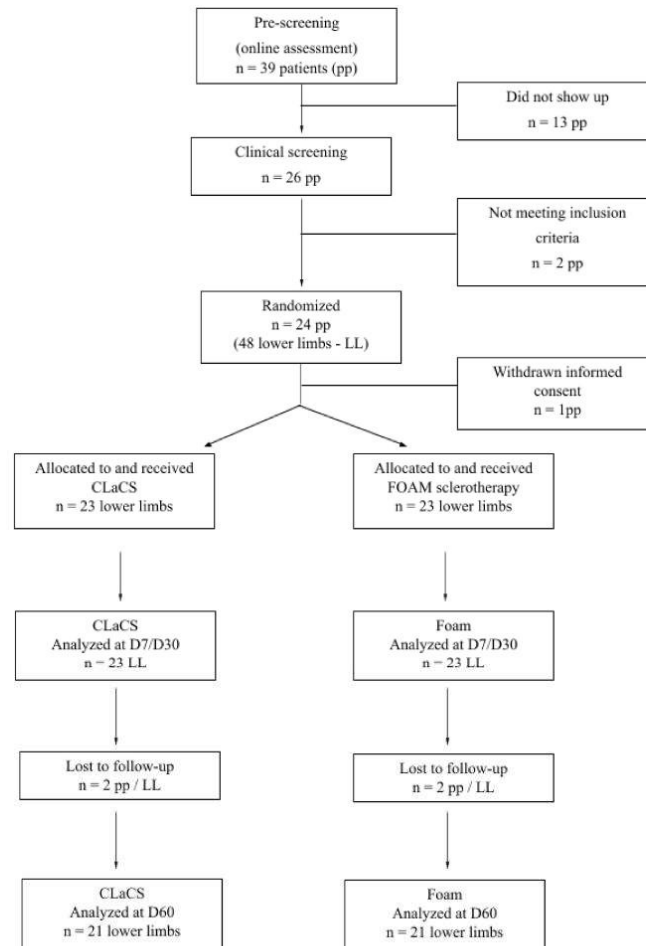


Fig 2. Consolidated Standards of Reporting Trials (CONSORT) flowchart. CLaCS, Cryo-laser cryo-sclerotherapy; D, days; LL, lower limbs; pp, people.

III and IV, this difference is more noticeable, with mean ΔE of 0.91 (SD, 0.61) for CLaCS vs 1.48 (SD, 1.00) for foam ($P = .006$).

No statistical difference was found between treatments in the treated vessel internal diameter reduction rate, measured on B mode ultrasound, using a 20-MHz linear probe, with patients in orthostatic position.

The volume of injected sclerosants was significantly lower in the CLaCS group compared with the foam group (median 0.3 vs 2.0 mL; $P < .0001$), whereas the number of punctures for sclerosant injections showed no statistical difference.

The legs treated with polidocanol foam showed a significantly higher incidence of microthrombi formation and consequent need for drainage in the foam group (9 vs 3; $P = .035$, being 2 bilateral, 7 only for foam limb and 1 only for CLaCS limb).

Also, limbs treated with CLaCS presented with less bruising on day 7 when compared with limbs treated with foam (3 vs 9; $P = .0156$). Of those, three presented bruising bilaterally and six only for foam-treated limbs.

Other minor adverse events:

- Two bilateral topic reactions and redness (one related to the tape used for blood-stopping and one related to the stocking silicon).

Table II. Efficacy and safety results for cryo-laser cryo-sclerotherapy (CLaCS) and foam

Outcomes	No. ^a	CLaCS	Foam	Bilat	P value ^b
Pigmentation on photo	21	7 (33.3)	5 (23.8)	3	.8906
Colorimetry $\Delta E >1$	21	9 (42.8)	13 (61.9)	7	.1445
Colorimetry $\Delta E >2$	21	3 (14.2)	7 (33.3)	2	.1094
Colorimetry $\Delta E >2$ FP III/IV	20	2 (10)	7 (35)	2	.0312
Bruising D7	23	3 (13)	9 (39.1)	3	.0156
Micro thrombi/drainage	23	3 (13)	9 (39.1)	2	.0351
Matting	21	0	1 (4.7)	0	1
Scarring	21	1 (4.7)	0	0	1
Redness/topic reaction	23	2 (8.6)	2 (8.6)	2	1

Bilat. Patients that presented the outcome in both lower limbs; *FP*, Fitzpatrick skin type classification. Data are presented as number (%).

^aNo. varies due to participant loss to follow-up.

^bP value calculated using McNemar test.

- One matting (foam limb).
- One blistering and scarring at the compression site (CLaCS limb), resulting in a dark scar. This was the only limb in the study that presented an intense pigmentation (ΔE of 9.1).

No major adverse events, such as chest pain, neurologic abnormalities, inadvertent arterial puncture, deep vein thrombosis, or pulmonary embolism, were observed.

Patients did not report high pain levels for either procedure. On a scale of 0 to 10, the mean pain value for the CLaCS limb was 2.72 (SD, 1.49) vs 1.85 (SD, 1.16) for foam limb, with a $P = .9901$.

Detailed statistic data on efficacy and safety outcomes for CLaCS and foam are described in [Tables II](#) (categorical) and [III](#) (continuous).

Statistical analysis of the ANA scale demonstrated a significant improvement in patient satisfaction regarding leg appearance perception pre- and post-procedure for both methods. Changes in appearance showed no statistically significant differences between interventions ([Table IV](#))

DISCUSSION

PSH is a common complication and a major concern for patients seeking leg aesthetical improvement. It presents as an abnormal deposit of melanin and/or

Table III. Efficacy and safety results for cryo-laser cryo-sclerotherapy (CLaCS) and foam

Variable	Group	No. ^a	Mean	SD	Min	Median	Max	P value ^b
ΔE intensity	CLaCS	21	1.3	1.88	0.12	0.8	9.1	.02735
	Foam	21	1.44	1	0	1.1	3.4	
ΔE intensity FP III/IV	CLaCS	20	0.91	0.61	0.12	0.75	2.2	.006
	Foam	20	1.48	1.01	0	1.11	3.4	
Reduction rate, %	CLaCS	21	62.34	25.65	10	62.5	100	.3475
	Foam	21	68.45	26.68	20	63.64	100	
Sclerosant volume	CLaCS	23	0.5	0.6	0.1	0.3	3	<.0001
	Foam	23	1.85	0.73	0.5	2	3	
Vein punctures	CLaCS	23	4.52	1.75	1	4	10	.9966
	Foam	23	3.13	1.42	2	3	6	
Pain score, cm	CLaCS	23	2.72	1.48	0.2	2.3	6.5	.9885
	Foam	23	1.85	1.14	0.5	1.75	5	

FP, Fitzpatrick skin type classification; *Max*, maximum value; *Min*, minimum value.

^aNo. varies due to participant loss to follow-up.

^bP value calculated using Wilcoxon statistical test for comparisons between the Foam and CLaCS groups.

Table IV. Patient cosmetic satisfaction: aesthetic numeric analog (ANA) scale

Intervention	Mean	SD	95% CI		Min	Median	Max	P ^b
			Inferior	Superior				
Foam								.526
ANA Pre	4.62	2.31	3.63	5.61	1.00	5.00	9.00	
ANA Post	9.14	0.91	8.79	9.50	7.00	9.00	10.00	
	<.001 ^a							
CLaCS								
ANA Pre	4.48	2.31	3.48	5.47	1.00	5.00	8.00	
ANA Post	9.48	0.68	9.12	9.83	8.00	10.00	10.00	
	<.001 ^a							

ANA pre-post, ANA scale values before intervention and on day 60; CI, confidence interval; CLaCS, Cryo-laser and cryo-sclerotherapy; Foam, 0.5% polidocanol sclerosing foam; Min, minimum value; Max, maximum value; SD, standard deviation.

^aWilcoxon.

^bOne-way analysis of variance for repeated measures.

hemosiderin, primarily due to a perivascular inflammatory status (post-inflammatory hyperpigmentation [PIH]). This inflammation is mainly caused by vessel rupture and blood extravasation, sclerosing agent's action on the vein and surrounding tissues, and/or persistence of blood clots inside the vein lumen. As the formation of microthrombi is a well-known cause of inflammation and subsequent PIH, a greater formation of microthrombi in the foam group may have contributed to the observed difference in pigmentation intensity between the procedures.

When the veins are not entirely shut, the shadow of the vein may be visible and mistaken for pigmentation. Dermoscopy may be used to differentiate pigmentation from persistent veins.^{2,35,36}

The combination of transdermal LASER and sclerotherapy for reticular veins has emerged as a promising, minimally invasive treatment option and is also present in the latest European guidelines.²⁸ Recent studies indicate that CLaCS is associated with a favorable safety profile and practical outcomes, with no major complications reported. Combining thermal and chemical treatments, while using reduced laser energy and sclerosant volume, may promote varicose vein obliteration while preserving surrounding tissues, which is crucial for minimizing complications.^{12,37,38} This might be linked to a lower inflammatory response associated with CLaCS, thus explaining the diminished post-procedure intensity of pigmentation when compared with foam treatment in the same patient.

The within-patient design was chosen to minimize bias related to patients' personal pigmentation tendencies, ensuring equitable outcome comparisons. This design is particularly useful for stable conditions with localized, short-term effects, enhancing study sensitivity to detect treatment differences with fewer subjects than

traditional randomized controlled trials, allowing direct intra-individual treatment comparison and minimizing variability due to individual differences.^{17,18} In other words, this allowed us to observe if pigmentation was linked only to procedure and/or also patients' matters. In fact, seven of the nine patients with $\Delta E > 1$ in the CLaCS group showed pigmentation in the contralateral limb. Also, two of the three patients that presented $\Delta E > 2$ in the CLaCS group had more intense pigmentation in the contralateral limb.

Our study population consisted of individuals with higher Fitzpatrick skin types (III: 30.4%, IV: 60.9%, V: 8.7%), which are known to be linked to a higher risk of pigmentation after sclerotherapy.^{10,22} This likely reflects the predominant population in the city the study was conducted. Additionally, lesion locations in lateral thigh (43.5%) and popliteal fossa (52.2%) further increased hyperpigmentation risk.

It is also interesting to reinforce the fact that the results in this trial were measured after one single session and at an early moment (60 days); besides that, most of the positive results were mild/light pigmentation (Supplementary Fig, online only). This, along with all the other matters described, might have contributed to a higher incidence of pigmented limbs in this series.

As CLaCS and foam methods are performed differently, it was not possible to conceal them from patients or doctors/investigators. However, evaluators were blinded and unaware of which treatment was applied to the limb they evaluated in the before and after pictures. They also had no access to contralateral limb images.

Even though the blinded evaluators were experienced vein specialists, and the results of their responses matched the colorimetry conclusions (the alternative with the majority answers for either "yes" or "no" was considered), the inter-evaluators' kappa calculation

showed no significant statistical concordance, with gross agreement rates ranging from 52.4% to 70% (Supplementary Table, online only). On photo evaluation, a 100% concordance among the evaluators was found only for 13 of 30 limbs (44%) in the non-pigmented group, and three of 12 (25%) in the pigmented group. This highlights the personal and subjective nature of photographic evaluation, and enhances the importance of objective measuring tools, such as colorimetry, as a way of mitigating doubts, especially when patient complaints arise.

A crucial element of aesthetic treatment is not just the objectively positive outcome but also the level of patient satisfaction. Successful cosmetic procedures can enhance psychological well-being and social status, ultimately improving quality of life.^{39,40}

In the patient-reported outcome, the ANA scale²⁹ analysis showed a significant improvement in satisfaction with leg appearance pre- and post-procedure for both treatments. However, it is worth noting that all treated patients in this study were volunteers who received the treatments free of charge, which may have contributed to a higher degree of satisfaction for either treatment. In private practice, patients seem to be more likely to express dissatisfaction with the results.

The ANA scale was chosen to assess satisfaction with cosmetic results separately, per limb, in the same patient. As standard quality of life questionnaires are related to patients' overall conditions, they were not applicable for this matter.^{17,41-43}

It is important to reinforce that, despite no statistically significant difference being observed when considering the entire study population, when analyzing only patients with Fitzpatrick skin phototypes III and IV—who are known to be prone to post-inflammatory hyperpigmentation—a statistically significant difference was found in the number of pigmented limbs (Table II). In addition, there was a significant difference in the overall intensity of pigmentation, which was more pronounced following foam sclerotherapy compared with CLaCS.

In conclusion, for patients who are intrinsically more likely to develop PIH and/or who have higher aesthetic expectations, CLaCS may represent a more suitable option to minimize post-treatment pigmentation, offering a favorable profile regarding hyperpigmentation intensity in the first 60 days post-treatment of reticular veins, in addition to a lower volume of sclerosant injection and less microthrombi formation, when compared with polidocanol foam sclerotherapy, markedly in patients with Fitzpatrick skin types III and IV, without compromising treatment effectiveness.

As for treatment session duration for a comparable extent of lesions, the difference in time from patient admission to discharge between the two interventions is minimal.

Because the initial cost of setting up a treatment suite equipped with laser devices represents a significant investment, CLaCS procedure tends to be predominantly offered in private clinics. In these settings, we suggest individualized treatment planning, incorporating all therapeutic options considered most beneficial for a given patient, with cost to the patient based on clinical complexity and physician expertise, rather than only on the specific technique used.

Clinical implications. Identifying patients at higher risk for pigmentation and tailoring treatment approaches can enhance outcomes. As this study showed that CLaCS may lead to less intense hyperpigmentation in the first 60 days post-treatment without compromising efficacy, for patients known to be more prone to pigmentation, it may be a suitable alternative for such cases.

The reduced need for sclerosant volume in the CLaCS procedure might allow for treating larger areas in one session, especially when the sclerosant used is limited to a safe per-session volume, thus reducing the number of visits needed for treatment completion, particularly in patients with extensive lesions.

Furthermore, the lower incidence of thrombus formation with the CLaCS technique may decrease the risk of PIH and the need for early returns for clot drainage, while also reducing patients' discomfort, given that all patients who underwent microthrombi drainage have spontaneously reported this as the most uncomfortable part of the treatment.

Limitations. This study's limitations include the small sample size, limited Fitzpatrick variety, lesion location in areas prone to pigmentation, and lack of blinding, which may introduce bias. The short follow-up period also limits our ability to assess long-term outcomes.

Despite these limitations, some highlights of the study are the prospective within-patient analysis, one designated expert investigator to apply each of the techniques, and the first-time use of objective colorimetry analysis for hyperpigmentation post-varicose vein treatment. Furthermore, the Fitzpatrick limitation ended up providing us with important data on patients that are known for a higher risk of developing pigmentation.

Future studies should explore the long-term outcomes and safety profiles of CLaCS in diverse populations with larger, varied samples to validate these findings and examine the long-term effects of both treatments on pigmentation and patient satisfaction. Further research into the mechanisms underlying individual variability in pigmentation response could also enhance treatment personalization.

CONCLUSIONS

Although this study showed no statistical difference in the number of limbs that developed PSH after

treatment of reticular veins with either CLaCS or polidocanol foam sclerotherapy, the CLaCS procedure resulted in lower intensity of skin color dissimilarity compared with polidocanol foam sclerotherapy, in addition to a lower sclerosant volume usage and less microthrombi formation, without loss in efficacy. It can be a safe alternative for treating reticular veins in patients prone to pigmentation.

The authors would like to thank Venosan Brasil, who donated the compression stockings for all the treated patients and GE Brasil, who provided the high-frequency linear probe for vein diameter measurements. The authors also thank Leticia Murata for before and after photo organization; blind evaluators Suzanna Sanches, Rodrigo Kikuchi, Ben-Hur Parente, and Felipe Mamprim; Andressa Kutschenko and Stela Verzinhasse for statistical analysis; and Dr Alvaro Orrego for proof-reading the manuscript. The authors also thank Dr Kasuo Miyake for consulting on CLaCS technique. Finally, the authors would like to thank the Science Valley Research Institute for logistical support for the study.

AUTHOR CONTRIBUTIONS

Conception and design: AR, JP, CR, ER
Analysis and interpretation: AR, JP, CR, FS, SN, GS, MP, ER
Data collection: AR, JP, VS
Writing the article: AR, JP, SN, ER
Critical revision of the article: AR, JP, VS, CR, FS, SN, GS, MP, ER
Final approval of the article: AR, JP, VS, CR, FS, SN, GS, MP, ER
Statistical analysis: Not applicable
Obtained funding: Not applicable
Overall responsibility: AR

FUNDING

This was a self-funded study with modest support from the Science Valley Research Institute.

DISCLOSURES

E.R. reports grants and consulting fees from Bayer and Pfizer; research grants from Bayer, Althalia, Pfizer, Novartis, Bios, and the Brazilian Ministry of Science and Technology; and personal fees from Aché Pharma, EMS, Novartis, and Daiichi-Sankyo, outside the submitted work. J.P. reports grants and consulting fees from Sigvaris, Supera, Merz, Urgo Medical, Essity, and Servier.

REFERENCES

- Lurie F, Passman M, Meisner M, et al. The 2020 update of the CEAP classification system and reporting standards. *J Vasc Surg Venous Lymphat Disord*. 2020;8:342–352. <https://doi.org/10.1016/j.jvsv.2019.12.075>
- Nakano LC, Cacione DC, Baptista-Silva JC, Flumignan RL. Treatment for telangiectasias and reticular veins. *Cochrane Database Syst Rev*. 2021;10:CD012723. <https://doi.org/10.1002/14651858.CD012723.pub2>
- Weiss RA, Goldman MP. Advances in sclerotherapy. *Dermatol Clin*. 1995;13:431–445.
- Rabe E, Schliephake D, Otto J, Breu FX, Pannier F. Sclerotherapy of telangiectases and reticular veins: a double-blind, randomized, comparative clinical trial of polidocanol, sodium tetradecyl sulphate and isotonic saline (EASI study). *Phlebology*. 2010;25:124–131. <https://doi.org/10.1258/phleb.2009.009043>
- Bertanha M, Jaldin RG, Moura R, et al. Sclerotherapy for reticular veins in the lower limbs: a triple-blind randomized clinical trial. *JAMA Dermatol*. 2017;153:1249–1255. <https://doi.org/10.1001/jama-dermatol.2017.3426>
- Gloviczki P, Lawrence PF, Wasan SM, et al. The 2023 Society for Vascular Surgery, American Venous Forum, and American Vein and Lymphatic Society clinical practice guidelines for the management of varicose veins of the lower extremities. Part II: Endorsed by the Society of Interventional Radiology and the Society for Vascular Medicine. *J Vasc Surg Venous Lymphat Disord*. 2024;12:101670. <https://doi.org/10.1016/j.jvsv.2023.08.011>
- Tan M, Moreno HB, Bechter-Hugl B, et al. Sclerotherapy: indications and safety volumes. *Phlebology*. 2024;39:135–138. <https://doi.org/10.1177/02683555231211092>
- Palm MD, Guiha I, Coldman MP. Foam sclerotherapy for reticular veins and nontruncal varicose veins of the legs. *Dermatol Surg*. 2010;36(Suppl 2):1026–1033. <https://doi.org/10.1111/j.1524-4725.2010.01496.x>
- Goldman MP, Kaplan RP, Duffy DM. Postsclerotherapy hyperpigmentation: a histologic evaluation. *J Dermatol Surg Oncol*. 1987;13:547–550. <https://doi.org/10.1111/j.1524-4725.1987.tb00940.x>
- Bossart S, Daneluzzi C, Cazzaniga S, et al. Skin hyperpigmentation after sclerotherapy with polidocanol: a systematic review. *J Eur Acad Dermatol Venereol*. 2023;37:274–283. <https://doi.org/10.1111/jdv.18639>
- Honigman RJ, Phillips KA, Castle DJ. A review of psychosocial outcomes for patients seeking cosmetic surgery. *Plast Reconstr Surg*. 2004;113:1229–1237. <https://doi.org/10.1097/01.prs.0000110214.88868.ca>
- Miyake K, Grill MH, Feitoza HSN. Case report: Novel leg vein treatment CLaCS guided by augmented reality 11 years follow-up. *J Cosmet Dermatol*. 2023;22(Suppl 2):16–20. <https://doi.org/10.1111/jocd.15832>
- Miyake RK, Chi YW, Franklin IJ, Giansini S. State of the art on cryo-laser cryo-sclerotherapy in lower limb venous aesthetic treatment. *J Vasc Surg Venous Lymphat Disord*. 2020;8:893–895. <https://doi.org/10.1016/j.jvsv.2020.01.003>
- Fonseca MM, Mocelin FJ, Grill MH, et al. Nd:YAG laser combined with injection sclerotherapy in the treatment of reticular veins and telangiectasias (CLaCS method): a triple-blind randomized clinical trial comparing two sclerosing agents associated with same laser patterns. *Phlebology*. 2023;38:165–171. <https://doi.org/10.1177/02683555231153533>
- Nasser MM, Ghoneim BM, Eldaly W, Elmahdy H. A comparative study between cryo-laser cryo-sclerotherapy and sclerotherapy in the treatment of telangiectasia and reticular veins: a randomized controlled trial. *J Vasc Surg Venous Lymphat Disord*. 2024;12:101874. <https://doi.org/10.1016/j.jvsv.2024.101874>
- Miyake RK, Fidelis R, Duarte FH. New leg veins air-cooled treatment using 1064 nm laser combined with sclerotherapy: technique description and one-year follow-up. *Lasers Med Sci*. 2003;18:145–149. Joint International Laser Conference – abstracts. *Lasers in Medical Science* 2003;18(1):S1–S67. DOI: 10.1007/s10103-003-0277-3.
- Pandis N, Chung B, Scherer RW, Elbourne D, Altman DG. CONSORT 2010 statement: extension checklist for reporting within-person randomized trials. *BMJ*. 2017;357:j2835. <https://doi.org/10.1136/bmj.j2835>
- Bull RH, Clements D, Collarte AJ, Harding KC. The impact of a new intervention for venous leg ulcers: a within-patient controlled trial. *Int Wound J*. 2023;20:2260–2268. <https://doi.org/10.1111/wj.14107>
- Wang F, Schilsky RL, Page D, et al. Development and validation of a natural language processing tool to generate the CONSORT reporting checklist for randomized clinical trials. *JAMA Netw Open*. 2020;3:e2014661. <https://doi.org/10.1001/jamanetworkopen.2020.14661>
- Kunishige JH, Goldberg LH, Friedman PM. Laser therapy for leg veins. *Clin Dermatol*. 2007;25:454–461. <https://doi.org/10.1016/j.clindermatol.2007.05.008>

21. Kauvar AN, Khrom T. Laser treatment of leg veins. *Semin Cutan Med Surg.* 2005;24:184–192. <https://doi.org/10.1016/j.sder.2005.10.003>
22. Fitzpatrick TB. The validity and practicality of sun-reactive skin types I through VI. *Arch Dermatol.* 1988;124:869–871. <https://doi.org/10.1001/archderm.124.6.869>
23. Spencer JM, Amonette R. Tanning beds and skin cancer: artificial sun + old sol = real risk. *Clin Dermatol.* 1998;16:487–501. [https://doi.org/10.1016/S0738-081X\(98\)00022-4](https://doi.org/10.1016/S0738-081X(98)00022-4)
24. Miyake RK, Zeman HD, Duarte FH, et al. Vein imaging: a new method of near-infrared imaging, where a processed image is projected onto the skin for the enhancement of vein treatment. *Dermatol Surg.* 2006;32:1031–1038. <https://doi.org/10.1111/j.1524-4725.2006.32226.x>
25. Tessari L, Cavezzi A, Frullini A. Preliminary experience with a new sclerosing foam in the treatment of varicose veins. *Dermatol Surg.* 2001;27:58–60.
26. Frullini A, Cavezzi A. Sclerosing foam in the treatment of varicose veins and telangiectasias: history and analysis of safety and complications. *Dermatol Surg.* 2002;28:11–15. <https://doi.org/10.1046/j.1524-4725.2002.01182.x>
27. Stucker M, Kobus S, Altmeyer P, Reich-Schupke S. Review of published information on foam sclerotherapy. *Dermatol Surg.* 2010;36(Suppl 2):983–992. <https://doi.org/10.1111/j.1524-4725.2009.01406.x>
28. De Maeseneer MG, Kakkos SK, Aherne T, et al. Editor's choice - European Society for Vascular Surgery (ESVS) 2022 clinical practice guidelines on the management of chronic venous disease of the lower limbs. *Eur J Vasc Endovasc Surg.* 2022;63:184–267. <https://doi.org/10.1016/j.ejvs.2021.12.024> [published correction appears in *Eur J Vasc Endovasc Surg.* 2022 Aug-Sep;64:284–285. doi: 10.1016/j.ejvs.2022.05.044.]
29. Funk W, Podmelle F, Guiol C, Metelmann HR. Aesthetic satisfaction scoring - Introducing an aesthetic numeric analogue scale (ANAScale). *J Craniomaxillofac Surg.* 2012;40:439–442. <https://doi.org/10.1016/j.jcms.2011.07.018>
30. Ly BCK, Dyer EB, Feig JL, Chien AL, Del Bino S. Research techniques made simple: cutaneous colorimetry: a reliable technique for objective skin color measurement. *J Invest Dermatol.* 2020;140:3–12. e1. <https://doi.org/10.1016/j.jid.2019.11.003>
31. Huikeshoven M, Koster PH, de Borgie CA, Beek JF, van Gemert MJ, van der Horst CM. Reddarkening of port-wine stains 10 years after pulsed-dye-laser treatment. *N Engl J Med.* 2007;356:1235–1240. <https://doi.org/10.1056/NEJMoa064329>
32. Weatherall IL, Coombs BD. Skin color measurements in terms of CIELAB color space values. *J Invest Dermatol.* 1992;99:468–473. <https://doi.org/10.1111/1523-1747.ep12616156>
33. Shriver MD, Parra EJ. Comparison of narrow-band reflectance spectroscopy and tristimulus colorimetry for measurements of skin and hair color in persons of different biological ancestry. *Am J Phys Anthropol.* 2000;112:17–27. [https://doi.org/10.1002/\(SICI\)1096-8644\(200005\)112:1<17::AID-AJPA3>3.0.CO;2-D](https://doi.org/10.1002/(SICI)1096-8644(200005)112:1<17::AID-AJPA3>3.0.CO;2-D)
34. Jia X, Mowatt G, Burr JM, Cassar K, Cook J, Fraser C. Systematic review of foam sclerotherapy for varicose veins. *Br J Surg.* 2007;94:925–936. <https://doi.org/10.1002/bjs.5891>
35. Gonzalez Ochoa AJ, Carrillo J, Manriquez D, Manrique F, Vazquez AN. Reducing hyperpigmentation after sclerotherapy: a randomized clinical trial. *J Vasc Surg Venous Lymphat Disord.* 2021;9:154–162. <https://doi.org/10.1016/j.jvsv.2020.06.019>
36. CK DAS, Caffaro RA, Castelli Junior V, et al. The impact of dermatoscopy on the pretreatment assessment of lower limbs telangiectasias: a prospective study. *Int Angiol.* 2022;41:413–419. <https://doi.org/10.23736/S0392-9590.22.04909-4>
37. Moreno-Moraga J, Smarandache A, Pascu ML, Royo J, Trelles MA. 1064 nm Nd:YAC long pulse laser after polidocanol microfoam injection dramatically improves the result of leg vein treatment: a randomized controlled trial on 517 legs with a three-year follow-up. *Phlebology.* 2014;29:658–666. <https://doi.org/10.1177/0268355513502786>
38. Meesters AA, Pitassi LH, Campos V, Wolkenstorfer A, Dierckx CC. Transcutaneous laser treatment of leg veins. *Lasers Med Sci.* 2014;29:481–492. <https://doi.org/10.1007/s10103-013-1483-2>
39. Darvall KA, Bate GR, Sam RC, Adam DJ, Silverman SH, Bradbury AW. Patients' expectations before and satisfaction after ultrasound guided foam sclerotherapy for varicose veins. *Eur J Vasc Endovasc Surg.* 2009;38:642–647. <https://doi.org/10.1016/j.ejvs.2009.07.014>
40. Jafferany M, Salimi S, Mkhoyan R, Kalashnikova N, Sadoughifar R, Jorgaql E. Psychological aspects of aesthetic and cosmetic surgery: clinical and therapeutic implications. *Dermatol Ther.* 2020;33:e13727. <https://doi.org/10.1111/dth.13727>
41. Silva A, Sousa TP, Guimaraes RA, et al. Validation of the patient-reported experiences and outcomes of safety in primary care compact form Brazil. *PLoS One.* 2024;19:e0305414. <https://doi.org/10.1371/journal.pone.0305414>
42. Ricci-Cabello I, Avery AJ, Reeves D, Kadam UT, Valderas JM. Measuring patient safety in primary care: the development and validation of the "patient reported experiences and outcomes of safety in primary care" (PREOS-PC). *Ann Fam Med.* 2016;14:253–261. <https://doi.org/10.1370/afm.1935>
43. Mounce LTA, Salema NE, Gangannagaripalli J, et al. Development of 2 short patient-report questionnaires of patient safety in primary care. *J Patient Saf.* 2022;18:161–170. <https://doi.org/10.1097/PTS.0000000000000880>

Submitted Apr 23, 2025; accepted Jun 27, 2025.

Additional material for this article may be found online at www.jvsvenous.org.

4.1 - Supplementary table 1. Kappa and inter-evaluator concordance analysis.

Evaluators	Kappa	P	Gross Agreement (%)
RLL evaluators 1 x 2	0,14	0,517	66,70
RLL evaluators 1 x 3	0,021	0,92	57,10
RLL evaluators 2 x 3	-0,061	0,776	52,40
LLL evaluators 1 x 2	0,175	0,423	60,00
LLL evaluators 1 x 3	0,341	0,128	70,00
LLL evaluators 2 x 3	0,175	0,423	60,00

Abbreviations: RLL – Right Lower Limb LLL – Left Lower Limb Kappa – Cohen's Kappa coefficient, measuring inter-reviewer agreement beyond chance. P – P-value, indicating statistical significance of the agreement. Agreement – Percentage of exact matches between reviewers.

Kappa values indicate the level of agreement beyond chance. Values close to zero suggest poor agreement, while values above 0.60 indicate moderate to strong agreement.

b Negative Kappa values (e.g., -0.061) indicate disagreement below the chance level.

4.2 - Supplement Fig. (online only), Different levels of pigmentation according to ΔE



5. CONSIDERAÇÕES FINAIS

Considerações finais

Este estudo comparou diretamente duas técnicas para o tratamento de veias reticulares, inserindo-se no contexto atual de busca por intervenções menos invasivas, com perfil de segurança favorável e bons resultados estéticos.

O desenho intrapaciente adotado contribuiu para uma avaliação mais precisa das técnicas, reduzindo a influência de fatores individuais que podem impactar diretamente os desfechos estéticos — como fototipo cutâneo, espessura da pele, tendência inflamatória, perfil vascular e resposta cicatricial. Nesse desenho, cada participante recebeu ambos os tratamentos: um em cada membro inferior, em regiões com veias reticulares de distribuição, diâmetro e profundidade semelhantes, permitindo comparação direta entre as técnicas e reduzindo o número de participantes necessários para atingir poder estatístico adequado⁽²⁹⁾.

O modelo adotado também permitiu avaliação mais precisa de efeitos adversos, como hiperpigmentação, dor ou resposta inflamatória, já que cada paciente atua como seu próprio controle.

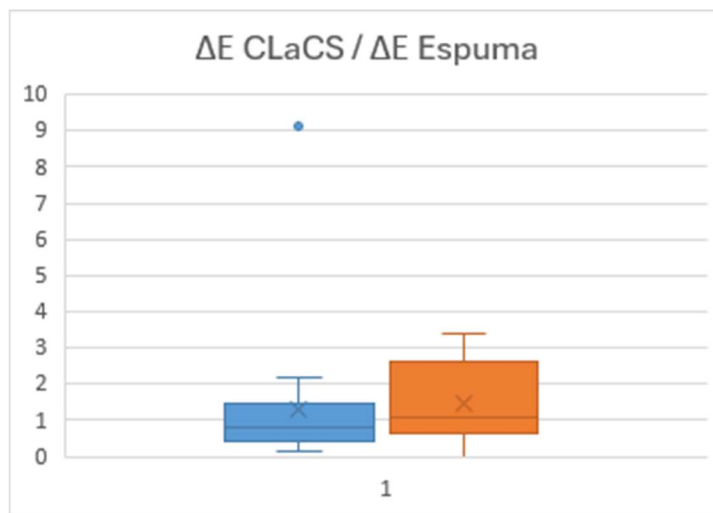
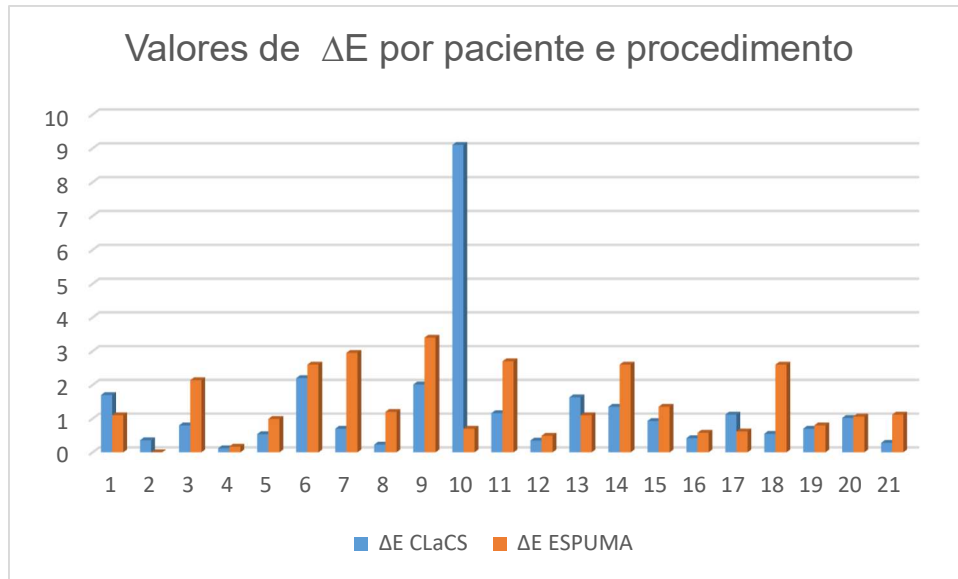
O tratamento das veias reticulares, as quais estão frequentemente conectadas a telangiectasias, tem um papel central na prática da flebologia moderna. Com a crescente valorização da estética corporal e da medicina minimamente invasiva, há uma demanda progressiva por intervenções eficazes, seguras e com recuperação rápida. Nesse cenário, é fundamental entender as opções terapêuticas disponíveis, suas limitações e os avanços tecnológicos que vêm sendo incorporados, na tentativa de otimizar os resultados e minimizar complicações.

A disparidade de opiniões entre os avaliadores cegos demonstra que a percepção do que é considerado pigmentação varia de acordo com a vivência pessoal e opinião de cada profissional, e reforça a necessidade crescente de inclusão de medidas mais refinadas e padronizadas na avaliação de resultados cosméticos, como

por exemplo através da colorimetria digital, especialmente em áreas onde a subjetividade pode mascarar diferenças clinicamente relevantes.

A tabela e os gráficos a seguir ilustram os resultados das medidas de diferença de tonalidade de pele entre as áreas tratadas e adjacentes, obtidos através da colorimetria digital (ΔE), por paciente e procedimento. Em negrito na tabela, os resultados considerados clinicamente relevantes (ΔE maior que 2).

ID .	ΔE CLaCS	ΔE ESPUMA
#9	1,7	1,1
#11	0,36	0
#17	0,8	2,14
#18	0,12	0,17
#21	0,54	0,99
#22	2,2	2,6
#23	0,7	2,95
#24	0,23	1,2
#25	2,01	3,4
#28	9,1	0,7
#29	1,16	2,7
#35	0,35	0,49
#37	1,63	1,1
#38	1,35	2,6
#40	0,93	1,35
#41	0,42	0,58
#43	1,12	0,62
#44	0,55	2,6
#46	0,7	0,8
#47	1,02	1,06
#49	0,28	1,12



É importante destacar que, apesar de a hiperpigmentação pós-escleroterapia geralmente apresentar caráter transitório, com tendência à regressão espontânea ao longo do tempo, esse aspecto natural da evolução clínica nem sempre é suficiente para atender às expectativas do público que busca tratamento estético. Pacientes com queixa predominantemente cosmética valorizam resultados rápidos e visíveis, e mesmo pigmentações temporárias podem gerar frustração e insatisfação no curto prazo. Nesse sentido, avaliar a incidência e a intensidade da pigmentação nos primeiros 60 dias não apenas é relevante, como traz informações mais alinhadas à experiência real do paciente no pós-procedimento imediato.

A HPE por deposição de melanina em geral tem resolução mais rápida e tende a clarear uma vez retirado o estímulo inflamatório, enquanto a HPE por hemossiderina tende a se estender por mais tempo e ser de tratamento mais desafiador ^{(14) (24)}. As opções de tratamento como laser Q-switched, clareadores tópicos e peelings, geralmente são menos eficazes para tratar depósitos de hemossiderina comparados a melanina ⁽⁴⁴⁾. Os resultados são variáveis e a aplicabilidade dos mesmos depende das características de pele de cada paciente, com as opções para peles de fototipos elevados sendo mais restritas^(45, 46). Nesses casos, a prevenção por meio de técnica adequada, preparo de pele, controle de volumes e uso de métodos auxiliares, como a combinação de laser transdérmico com escleroterapia, se destaca como uma estratégia potencialmente mais eficaz.

Considerando o cenário atual, em que a flebologia estética é frequentemente subestimada do ponto de vista científico, a adoção de modelos metodológicos robustos, mesmo em estudos com desfechos estéticos, contribui para elevar o nível de evidência e orientar condutas mais fundamentadas. Esperamos que os achados contribuam para tomada de decisões clínicas mais embasadas e direcionadas à escolha terapêutica ideal.

7. REFERÊNCIAS BIBLIOGRÁFICA

1. De Maeseneer MG, Kakkos SK, Aherne T, Baekgaard N, Black S, Blomgren L, et al. Editor's Choice – European Society for Vascular Surgery (ESVS) 2022 Clinical Practice Guidelines on the Management of Chronic Venous Disease of the Lower Limbs. *European Journal of Vascular and Endovascular Surgery*. 2022;63(2):184–267.
2. Lurie F, Passman M, Meisner M, Dalsing M, Masuda E, Welch H, et al. The 2020 update of the CEAP classification system and reporting standards. *J Vasc Surg Venous Lymphat Disord*. 2020;8(3):342–52.
3. Salim S, Machin M, Patterson BO, Onida S, Davies AH. Global Epidemiology of Chronic Venous Disease: A Systematic Review With Pooled Prevalence Analysis. *Ann Surg*. 2021;274(6):971–6.
4. Santiago F, Piscoya-Díaz M, Chi YW. A Sonographic Study of Thigh Telangiectasias. *Phlebology the Journal of Venous Disease*. 2017;33(7):500–1.
5. Onida S, Davies AH. Predicted Burden of Venous Disease. *Phlebology the Journal of Venous Disease*. 2016;31(1_suppl):74–9.
6. Mallick R, Lal BK, Daugherty C. Relationship between patient-reported symptoms, limitations in daily activities, and psychological impact in varicose veins. *J Vasc Surg Venous Lymphat Disord*. 2017;5(2):224–37.
7. Santiago FR, Ulloa J, Régnier C, Peudon T, Braund E, Fradet-Aubignat C, et al. The impact of lower limb chronic venous disease on quality of life: patient and physician perspectives. *J Comp Eff Res*. 2022;11(11):789–803.
8. Bertanha M, Jaldin RG, Moura R, Pimenta REF, Mariúba JVO, Lúcio Filho CEP, et al. Sclerotherapy for Reticular Veins in the Lower Limbs: A Triple-Blind Randomized Clinical Trial. *JAMA Dermatol*. 2017;153(12):1249–55.
9. Gloviczki P, Lawrence PF, Wasan SM, Meissner MH, Almeida J, Brown KR, et al. The 2023 Society for Vascular Surgery, American Venous Forum, and American Vein and Lymphatic Society clinical practice guidelines for the management of varicose veins of the lower extremities. Part II: Endorsed by the Society of Interventional Radiology and the Society for Vascular Medicine. *J Vasc Surg Venous Lymphat Disord*. 2024;12(1):101670.
10. Tan M, Moreno HB, Bechter-Hugl B, Giancesini S, Connor D, Parsi K, et al. Sclerotherapy: Indications and safety volumes. *Phlebology*. 2024;39(2):135–8.
11. Frullini A, Cavezzi A. Sclerosing foam in the treatment of varicose veins and telangiectases: history and analysis of safety and complications. *Dermatol Surg*. 2002;28(1):11–5.
12. Rao J, Wildemore JK, Goldman MP. Double-blind prospective comparative trial between foamed and liquid polidocanol and sodium tetradecyl sulfate in the treatment of varicose and telangiectatic leg veins. *Dermatol Surg*. 2005;31(6):631–5; discussion 5.

13. Jia X, Mowatt G, Burr JM, Cassar K, Cook J, Fraser C. Systematic review of foam sclerotherapy for varicose veins. *Br J Surg*. 2007;94(8):925–36.
14. Bossart S, Daneluzzi C, Cazzaniga S, Ramelet AA, Uthoff H, Seyed Jafari SM, et al. Skin hyperpigmentation after sclerotherapy with polidocanol: A systematic review. *J Eur Acad Dermatol Venereol*. 2023;37(2):274–83.
15. Groot D, Rao J, Johnston P, Nakatsui T. Algorithm for Using a Long-Pulsed Nd:YAG Laser in the Treatment of Deep Cutaneous Vascular Lesions. *Dermatologic Surgery*. 2003;29(1):35–42.
16. Ross EV, Domankevitz Y. Laser Treatment of Leg Veins: Physical Mechanisms and Theoretical Considerations. *Lasers in Surgery and Medicine*. 2005;36(2):105–16.
17. Chang CJ, Nelson JS. Cryogen spray cooling and higher fluence pulsed dye laser treatment improve port-wine stain clearance while minimizing epidermal damage. *Dermatol Surg*. 1999;25(10):767–72.
18. Das A, Sarda A, De A. Cooling Devices in Laser therapy. *J Cutan Aesthet Surg*. 2016;9(4):215–9.
19. Miyake K, Ramacciotti E. Cryo-laser and cryo-sclerotherapy guided by augmented reality for telangiectasias, feeder, and small varicose vein treatment – The CLaCS technique white paper report. *J Phlebol Lymphol*. 2019;12:1
20. Miyake RK, Chi YW, Franklin IJ, Giancesini S. State of the art on cryo-laser cryo-sclerotherapy in lower limb venous aesthetic treatment. *J Vasc Surg Venous Lymphat Disord*. 2020;8(5):893–5.
21. Goldman MP, Kaplan RP, Duffy DM. Postsclerotherapy hyperpigmentation: a histologic evaluation. *J Dermatol Surg Oncol*. 1987;13(5):547–50.
22. Verma KK, Friedmann DP. Combination Foam and Liquid Sclerotherapy for Lower Extremity Reticular and Telangiectatic Veins: A Single-Center Retrospective Study. *Dermatol Surg*. 2024;50(11):1034–8.
23. Scultetus AH, Villavicencio JL, Kao TC, Gillespie DL, Ketron GD, Iafrati MD, et al. Microthrombectomy reduces postsclerotherapy pigmentation: multicenter randomized trial. *J Vasc Surg*. 2003;38(5):896–903.
24. Bossart S, Ramelet A-A, Seyed Jafari SM, Yawalkar N, Feldmeyer L, Heidemeyer K. Revealing the origin of postsclerotherapy hyperpigmentation: Identification of melanin and hemosiderin as causative pigments in a histopathological study. *Phlebology*. 0(0):02683555251357095.
25. Fitzpatrick TB. The validity and practicality of sun-reactive skin types I through VI. *Arch Dermatol*. 1988;124(6):869–71.
26. CK DAS, Caffaro RA, Castelli Júnior V, Bernardi WH, Kikuchi R, Santos RH, et al. The impact of dermatoscopy on the pretreatment assessment of lower limbs telangiectasias: a prospective study. *Int Angiol*. 2022;41(5):413–9.

27. Gonzalez Ochoa AJ, Carrillo J, Manríquez D, Manrique F, Vazquez AN. Reducing hyperpigmentation after sclerotherapy: A randomized clinical trial. *J Vasc Surg Venous Lymphat Disord*. 2021;9(1):154–62.
28. Honigman RJ, Phillips KA, Castle DJ. A review of psychosocial outcomes for patients seeking cosmetic surgery. *Plast Reconstr Surg*. 2004;113(4):1229–37.
29. Pandis N, Chung B, Scherer RW, Elbourne D, Altman DG. CONSORT 2010 statement: extension checklist for reporting within person randomised trials. *Bmj*. 2017;357:j2835.
30. Bull RH, Clements D, Collarte AJ, Harding KG. The impact of a new intervention for venous leg ulcers: A within-patient controlled trial. *Int Wound J*. 2023;20(6):2260–8.
31. Wang F, Schilsky RL, Page D, Califf RM, Cheung K, Wang X, et al. Development and Validation of a Natural Language Processing Tool to Generate the CONSORT Reporting Checklist for Randomized Clinical Trials. *JAMA Netw Open*. 2020;3(10):e2014661.
32. Kunishige JH, Goldberg LH, Friedman PM. Laser therapy for leg veins. *Clin Dermatol*. 2007;25(5):454–61.
33. Kauvar AN, Khrom T. Laser treatment of leg veins. *Semin Cutan Med Surg*. 2005;24(4):184–92.
34. Spencer JM, Amonette R. Tanning beds and skin cancer: artificial sun + old sol = real risk. *Clin Dermatol*. 1998;16(4):487–501.
35. Tessari L, Cavezzi A, Frullini A. Preliminary experience with a new sclerosing foam in the treatment of varicose veins. *Dermatol Surg*. 2001;27(1):58–60.
36. Stücker M, Kobus S, Altmeyer P, Reich-Schupke S. Review of published information on foam sclerotherapy. *Dermatol Surg*. 2010;36 Suppl 2:983–92.
37. Funk W, Podmelle F, Guiol C, Metelmann HR. Aesthetic satisfaction scoring - introducing an aesthetic numeric analogue scale (ANA-scale). *J Craniomaxillofac Surg*. 2012;40(5):439–42.
38. Ly BCK, Dyer EB, Feig JL, Chien AL, Del Bino S. Research Techniques Made Simple: Cutaneous Colorimetry: A Reliable Technique for Objective Skin Color Measurement. *J Invest Dermatol*. 2020;140(1):3–12.e1.
39. Huikeshoven M, Koster PH, de Borgie CA, Beek JF, van Gemert MJ, van der Horst CM. Redarkening of port-wine stains 10 years after pulsed-dye-laser treatment. *N Engl J Med*. 2007;356(12):1235–40.
40. Weatherall IL, Coombs BD. Skin color measurements in terms of CIELAB color space values. *J Invest Dermatol*. 1992;99(4):468–73.
41. Shriver MD, Parra EJ. Comparison of narrow-band reflectance spectroscopy and tristimulus colorimetry for measurements of skin and hair color in persons of different biological ancestry. *Am J Phys Anthropol*. 2000;112(1):17–27.

-
42. Miyake RK FR, Duarte FH. New leg veins air-cooled treatment using 1064 nm laser combined with sclerotherapy: technique description and one-year follow-up. *Lasers in Medical Science*; 2003/09/012003. p. 145–9.
43. Fonseca MM, Mocelin FJ, Grill MH, Giancesini S, Miyake K, Argenta R, et al. Nd:Yag Laser Combined With Injection Sclerotherapy in the Treatment of Reticular Veins and Telangiectasias (CLaCS Method): A Triple-Blind Randomized Clinical Trial Comparing Two Sclerosing Agents Associated With Same Laser Patterns. *Phlebology the Journal of Venous Disease*. 2023;38(3):165–71.
44. Zhang L, Ng K, Pham JP, Thoo S, Yang A, Kang M, et al. Pigmentation of lower limbs: Contribution of haemosiderin and melanin in chronic venous insufficiency and related disorders. *Phlebology*. 2023;38(10):657–67.
45. Rabello CP, Francisco J, Machado KE. Alterações Pigmentares Pós-Tratamentos Estéticos Em Pessoas De Pele Negra. *Infarma - Ciências Farmacêuticas*. 2019;31(1):5–12.
46. Rocha CA, Kalil CLPV, Zagonel L, França P, Campos V. Eficácia De Ácidos Graxos Poli-Insaturados Ômega-3 Orais Para Prevenir A Hiperpigmentação Pós-Inflamatória Em Fototipos Altos Após Laser 1340nm Fracionado Não Ablativo. *Surgical & Cosmetic Dermatology*. 2024;17.

ANEXO 1 – APROVAÇÃO DO COMITÊ DE ÉTICA E PESQUISA

HOSPITAL LEFORTE



PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: Estudo de segurança, aberto, prospectivo, cruzado, com controle ativo comparando as técnicas CLaCs (Cryo-laser Cryo-sclerotherapy) e escleroterapia com espuma de polidocanol, para tratamento de pequenas varizes dos membros inferiores.

Pesquisador: ANELISE RODRIGUES BEZERRA DOS SANTOS

Área Temática:

Versão: 2

CAAE: 38043920.0.0000.5485

Instituição Proponente:

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 4.532.514

Apresentação do Projeto:

Introdução:

A eficácia do tratamento de veias varicosas de diversos calibres utilizando-se espuma de polidocanol é mundialmente conhecida e aceita. Apesar da sua eficácia, indiscutível, quando tratamos pacientes com queixas estéticas em relação a varicosidades em membros inferiores, algumas complicações tidas como menores podem ser uma barreira ao tratamento. A mais frequente e limitante é a ocorrência de hiperpigmentação pós procedimento, com uma incidência média de 31.6% de pigmentação (matting/manchas) da pele após tratamento com espuma de polidocanol uma vez que desencadeia uma reação inflamatória intensa que pode resultar em hiperpigmentação. (1). Em contrapartida, a técnica denominada CLaCS (Cryo-laser Cryo-Sclerotherapy), uma associação de escleroterapia física com Laser Nd:Yag 1064 de pulso longo e escleroterapia química com glicose 75% de forma sinérgica, descreve uma ocorrência zero de hiperpigmentação pós procedimento utilizando para análise mais de 600 pacientes. Ainda há pouca literatura a respeito, relatando incidência de no máximo 1.3% de

Endereço: Rua Barão de Iguape, 209, andar mezanino.

Bairro: Liberdade

CEP: 01.507-000

UF: SP

Município: SAO PAULO

Telefone: (11)3345-2265

E-mail: cep@leforte.com.br

ANEXO 1 – APROVAÇÃO DO COMITÊ DE ÉTICA E PESQUISA

HOSPITAL LEFORTE



Continuação do Parecer: 4.532.514

manchas no início de curva de aprendizado. (2,3)

Levando em consideração a ausência de informações que comparam ambas as técnicas de modo controlado, o intuito da pesquisa é justamente verificar se essa diferença é real. Designando um estudo de segurança comparando técnica padrão x técnica nova.

Hipótese:

Com igual eficácia, a hipótese é de que haja diferenças rapidamente perceptíveis após uma rodada de tratamento com os dois procedimentos e que

CLaCS possa apresentar uma superioridade de resultado quando comparado com a espuma de polidocanol.

Metodologia Proposta:

1. Visita de triagem, aplicação do consentimento informado e foto documentação 2. Visita para realizar sessão única para ambos os procedimentos e avaliação de Escala análoga visual de dor após cada um dos dois tratamentos 3. Uma visita 7 a 10 dias após os procedimentos para foto documentação e avaliação de complicações precoces como equimoses e microtrombos intravenosos. Drenagem de microtrombos será realizada quando indicada. 4. Uma visita 30-35 dias após os procedimentos para foto documentação e avaliação de escala análoga numérica estética. 5. Uma visita 60-65 dias após os procedimentos para foto documentação e avaliação de escala análoga numérica estética.

Critério de Inclusão:

- pacientes acima de 18 anos que assinarem o consentimento informado
- Paciente com pequenas varicosidades em ambos membros inferiores, com diâmetro interno da veia (em ortostase) até 1.5mm na imagem do ultrassom em modo B, com distribuição bilateral semelhante, associadas ou não a telangiectasias, e que não tenham contraindicações para nenhum dos dois procedimentos propostos.

Critério de Exclusão:

Endereço: Rua Barão de Iguape, 209, andar mezanino.

Bairro: Liberdade

CEP: 01.507-000

UF: SP

Município: SAO PAULO

Telefone: (11)3345-2265

E-mail: cep@leforte.com.br

Página 02 de 06

ANEXO 1 – APROVAÇÃO DO COMITÊ DE ÉTICA E PESQUISA

HOSPITAL LEFORTE



Continuação do Parecer: 4.532.514

- História de alergia ou reação sistêmica após o uso de polidocanol
- Idade inferior a 18 anos
- Gestação ou puerpério/amamentação
- Uso de medicamentos sistêmicos e/ou tópicos que possam induzir hiperpigmentação da pele (P. EX isotretinoína, ácido retinóico)
- Infecção ou lesão tecidual local
- Presença de insuficiência de veias safenas magnas, safenas parvas, pélvicas e/ou perfurantes conectadas às áreas a serem tratadas

Objetivo da Pesquisa:

Objetivo Primário:

Análise de segurança, comparando a incidência de hiperpigmentação da pele para ambos os tratamentos, 30 e 60 dias pós procedimento.

Objetivo Secundário:

Comparar o desaparecimento/redução do diâmetro interno das veias após um único tratamento, verificados com Ultrassom – eficácia exploratória

Comparar a ocorrência de outros eventos adversos maiores e menores

Gerar banco de dados com as imagens obtidas, obedecendo as leis atuais vigentes, em especial a Lei Geral de Proteção de Dados.

Avaliação dos Riscos e Benefícios:

Riscos: quebra do anonimato. Com o intuito de minimizar este risco, todos os dados armazenados no sistema RedCap e dados pessoais sensíveis não serão armazenados

Benefícios: tratamento único e gratuito com duas técnicas de alto padrão para tratamento de varizes.

Comentários e Considerações sobre a Pesquisa:

Estudo prospectivo, comparativo, sem óbices éticos. Carta de resposta ao parecer emitido pelo CEP anteriormente, com os ajustes realizados.

Considerações sobre os Termos de apresentação obrigatória:

A notificação está de acordo para análise deste CEP, não tendo nenhum tipo de pendência documental, seguindo a resolução 466-2012 e a norma operacional 001-2013.

Endereço: Rua Barão de Iguape, 209, andar mezanino.

Bairro: Liberdade

CEP: 01.507-000

UF: SP

Município: SAO PAULO

Telefone: (11)3345-2265

E-mail: cep@leforte.com.br

ANEXO 1 – APROVAÇÃO DO COMITÊ DE ÉTICA E PESQUISA

HOSPITAL LEFORTE



Continuação do Parecer: 4.532.514

Recomendações:

Não há recomendações.

Conclusões ou Pendências e Lista de Inadequações:

Não há pendências.

Considerações Finais a critério do CEP:

Assim, mediante a importância social e científica que o projeto apresenta a sua aplicabilidade e conformidade com os requisitos éticos, somos de parecer favorável à realização do projeto classificando-o como APROVADO pois o mesmo atende aos requisitos fundamentais da Resolução 466/12 e suas complementares do Conselho Nacional de Saúde/MS.

O pesquisador responsável deve encaminhar a este CEP relatórios semestrais, bem como qualquer tipo de notificação de evento adverso e informar a finalização do estudo.

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_1612515.pdf	07/12/2020 11:31:53		Aceito
Projeto Detalhado / Brochura Investigador	1_Protocolo_v2_13_out_2020.pdf	07/12/2020 11:31:09	Elizabeth Rodrigues	Aceito
Projeto Detalhado / Brochura Investigador	1_Protocolo_v2_13_out_2020.docx	07/12/2020 11:31:01	Elizabeth Rodrigues	Aceito
Projeto Detalhado / Brochura Investigador	1_Protocolo_v2_13_out_2020_alteracoes_destacadas.pdf	07/12/2020 11:30:52	Elizabeth Rodrigues	Aceito
Projeto Detalhado / Brochura Investigador	1_Protocolo_v2_13_out_2020_alteracoes_destacadas.docx	07/12/2020 11:30:43	Elizabeth Rodrigues	Aceito
Outros	00_carta_resposta_parecer.docx	04/12/2020 12:50:18	Elizabeth Rodrigues	Aceito
Recurso Anexado pelo Pesquisador	00_carta_resposta_parecer.pdf	04/12/2020 12:48:43	Elizabeth Rodrigues	Aceito
Cronograma	cronograma.docx	04/12/2020 12:48:08	Elizabeth Rodrigues	Aceito
Cronograma	cronograma.pdf	04/12/2020 12:47:58	Elizabeth Rodrigues	Aceito
TCLE / Termos de Assentimento / Justificativa de	2_TCLE_v1_13_out_2020.docx	04/12/2020 12:39:22	Elizabeth Rodrigues	Aceito

Endereço: Rua Barão de Iguape, 209, andar mezanino.

Bairro: Liberdade

CEP: 01.507-000

UF: SP

Município: SAO PAULO

Telefone: (11)3345-2265

E-mail: cep@leforte.com.br

ANEXO 1 – APROVAÇÃO DO COMITÊ DE ÉTICA E PESQUISA

HOSPITAL LEFORTE



Continuação do Parecer: 4.532.514

Ausência	2_TCLE_v1_13_out_2020.docx	04/12/2020 12:39:22	Elizabeth Rodrigues	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLE_uso_imagem.docx	04/12/2020 11:35:42	Elizabeth Rodrigues	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	2_TCLE_Acervo_Dados_Versao_1_15_Out_2020.docx	04/12/2020 11:34:35	Elizabeth Rodrigues	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	2_TCLE_Acervo_Dados_Versao_1_15_Out_2020.pdf	04/12/2020 11:33:13	Elizabeth Rodrigues	Aceito
Outros	5a_Declaracao_cumprimento_LGPD.pdf	20/10/2020 13:02:19	Elizabeth Rodrigues	Aceito
Outros	guia_LGDP.pdf	20/10/2020 09:33:11	Elizabeth Rodrigues	Aceito
Outros	5a_Declaracao_cumprimento_LGPD.docx	20/10/2020 09:32:24	Elizabeth Rodrigues	Aceito
Projeto Detalhado / Brochura Investigador	1_Protocolo.docx	12/09/2020 12:41:58	Elizabeth Rodrigues	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	2_TCLE_v1_14_jul_2020.docx	12/09/2020 12:41:46	Elizabeth Rodrigues	Aceito
Outros	5a_Declaracao_de_anuencia.pdf	14/08/2020 10:16:48	Elizabeth Rodrigues	Aceito
Outros	5b_Declaracao_anuencia_Instituto_Circular.pdf	14/08/2020 10:16:28	Elizabeth Rodrigues	Aceito
Outros	5a_Declaracao_de_anuencia.docx	14/08/2020 10:06:04	Elizabeth Rodrigues	Aceito
Outros	5b_Declaracao_de_anuencia_Intituto_circular.docx	14/08/2020 10:04:37	Elizabeth Rodrigues	Aceito
Outros	6e_Declaracao_confidencialidade.docx	14/08/2020 09:28:33	Elizabeth Rodrigues	Aceito
Outros	6d_Declaracao_Ministerio_Saude.docx	14/08/2020 09:28:19	Elizabeth Rodrigues	Aceito
Outros	6c_Declaracao_de_Infraestrutura.docx	14/08/2020 09:27:57	Elizabeth Rodrigues	Aceito
Outros	6b_Declaracao_vinculo_pesquisador_instituicoes.docx	14/08/2020 09:27:47	Elizabeth Rodrigues	Aceito
Outros	6a_Declaracao_de_responsabilidade_pesquisador.docx	14/08/2020 09:27:36	Elizabeth Rodrigues	Aceito
Outros	6e_Declaracao_confidencialidade.pdf	14/08/2020 09:27:21	Elizabeth Rodrigues	Aceito

Endereço: Rua Barão de Iguape, 209, andar mezanino.

Bairro: Liberdade

CEP: 01.507-000

UF: SP

Município: SAO PAULO

Telefone: (11)3345-2265

E-mail: cep@leforte.com.br

ANEXO 1 – APROVAÇÃO DO COMITÊ DE ÉTICA E PESQUISA

HOSPITAL LEFORTE



Continuação do Parecer: 4.532.514

Outros	6d_Declaracao_Ministerio_saude.pdf	14/08/2020 09:27:09	Elizabeth Rodrigues	Aceito
Outros	6c_Declaracao_infraestrutura.pdf	14/08/2020 09:26:54	Elizabeth Rodrigues	Aceito
Outros	6b_Declaracao_vinculo.pdf	14/08/2020 09:26:42	Elizabeth Rodrigues	Aceito
Declaração de Pesquisadores	6a_Termo_de_responsabilidade.pdf	14/08/2020 09:25:05	Elizabeth Rodrigues	Aceito
Orçamento	4_orcamento.docx	14/08/2020 09:24:51	Elizabeth Rodrigues	Aceito
Outros	00_Carta_submissao.pdf	14/08/2020 09:24:43	Elizabeth Rodrigues	Aceito
Folha de Rosto	Folha_rosto.pdf	14/08/2020 09:23:59	Elizabeth Rodrigues	Aceito

Situação do Parecer:

Aprovado

Necessita Apreciação da CONEP:

Não

SAO PAULO, 09 de Fevereiro de 2021

Assinado por:

Marcelo José de Carvalho Cantarelli
(Coordenador(a))

Endereço: Rua Barão de Iguape, 209, andar mezanino.

Bairro: Liberdade

CEP: 01.507-000

UF: SP

Município: SAO PAULO

Telefone: (11)3345-2265

E-mail: cep@leforte.com.br

ANEXO 2 – TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO

Termo de consentimento Livre e Esclarecido

Título do estudo: Estudo de segurança, aberto, prospectivo, cruzado, com controle ativo comparando as técnicas ClaCs (Cryo-Laser Cryo-Sclerotherapy) e escleroterapia com espuma de polidocanol, para tratamento de pequenas varizes dos membros inferiores.

Nome do Pesquisador: Anelise Rodrigues

Nome da Instituição: CLÍNICA DRA ANELISE RODRIGUES

Av Andre Antonio Maggi 478 conj 1903 – Ed Concorde – Bairro Alvorada
Cuiabá- MT CEP 78049-080

Telefone para Contato 24 horas: (65)99916-4598

Nome do participante:

Número do participante:

Introdução

Você está sendo convidado a participar do projeto de pesquisa “Estudo de segurança, aberto, prospectivo, cruzado, com controle ativo comparando as técnicas ClaCS (*Cryo-laser Cryo-sclerotherapy*) e escleroterapia com espuma de polidocanol para tratamento de pequenas varizes dos membros inferiores”

Aqui você encontrará os principais pontos da pesquisa ao qual está convidado a participar, deixando claro os objetivos que temos com ela, os procedimentos aos quais será submetido durante as consultas, seus direitos, riscos e benefícios.

Leia este Termo de Consentimento Livre e Esclarecido com atenção e leve o tempo que precisar para decidir se quer ou não participar. Sua participação não gerará custos e você pode discutir sua participação com sua família, amigos ou seu médico regular. Gostaríamos de esclarecer que sua participação é voluntária e que poderá recusar-se a participar ou retirar o seu consentimento, ou ainda descontinuar sua participação se assim o preferir, sem penalização alguma seja ela moral ou financeira e ainda sem, prejuízo ao seu cuidado.

Se você concordar em participar da pesquisa, você deverá assinar e datar duas vias deste termo de consentimento, rubricando todas as páginas de cada uma delas. Uma via original será entregue a você e a outra ficará com o pesquisador. Seu nome não será utilizado em qualquer fase da pesquisa, o que garante seu anonimato, e a divulgação dos resultados será feita de forma a não identificar os voluntários. Se você não assinar este termo de consentimento, não poderá participar deste estudo. Caso tenha participado de outro estudo no último ano, você também não poderá entrar nesse estudo.

Por que fui convidado?

Você está sendo convidado para participar deste estudo por apresentar varicosidades em membros inferiores, ou seja, há vasos sanguíneos dilatados na superfície da pele das pernas, em especial coxas e regiões próximas ao joelho. Os sintomas das varizes podem variar em gravidade, indo do desconforto ocasional à ulceração grave da pele. Apesar das causas que levam a formação e aparecimento dessas dilatações não estarem claras, apresentam um componente familiar e uma incidência maior no sexo feminino. Existem diversas formas de tratamento, que são indicados de acordo com o tipo de varizes e sintomas de cada paciente, podendo ser cirúrgicos ou não. Neste estudo serão realizados 2 tipos de tratamentos minimamente invasivos, não cirúrgicos. Você só será aceito para participar do estudo se seu caso tiver indicação para tratamento com os procedimentos propostos.

Objetivos do estudo

Esse estudo será conduzido com o objetivo de comparar a formação de manchas, após 30 e 60 dias de procedimento, entre os participantes que realizarem o tratamento com espuma de polidocanol e com a técnica denominada CLaCS (*Cryo-Laser Cryo-Sclerotherapy*). Neste estudo será realizada apenas uma sessão de tratamento em ambas as pernas, e somente nas áreas a serem estudadas.

Durante o projeto serão avaliados também:

- Comparar a eficácia dos tratamentos quanto a redução do diâmetro das veias após um único tratamento;
- Efeitos colaterais sentidos após o tratamento com os dois procedimentos;

A finalidade dos tratamentos oferecidos é melhorar os sintomas relacionados a circulação sanguínea. A melhoria do aspecto estético da área a ser tratada constitui um benefício secundário; entretanto, não há garantias desse resultado

Tratamentos:

1 - CLaCS (*Cryo-Laser Cryo-Sclerotherapy*)

CLaCS é a abreviação de Crio-laser Crio-escleroterapia. Trata-se de um tratamento relativamente novo, minimamente invasivo, para eliminar pequenas varicosidades dos membros inferiores, e que vem se mostrando eficaz. Ele é baseado na combinação de 2 técnicas para tratar as varicosidades: laser transdérmico e Escleroterapia (“aplicação”) com glicose 75%, associados ao resfriamento da pele para diminuir as dores e chance de queimadura. A luz emitida pelo laser passa pela pele sem causar danos, atinge o sangue dentro do vaso doente e provoca um dano térmico na parede do vaso dilatado (varicosidade); a glicose provoca um dano químico nesse mesmo vaso, potencializando a ação do laser. Esses danos na parede do vaso resultam na diminuição e desaparecimento do vaso, processo que pode levar alguns dias ou meses após o tratamento; não há resultado imediato.

Esse tipo de tratamento pode ser realizado no consultório médico, por ser menos invasivo, e não impede a retomada das atividades rotineiras imediatamente, além de possuir efeitos duradouros.

2 - Escleroterapia com espuma de polidocanol

A escleroterapia com espuma de polidocanol, amplamente utilizado como alternativa à cirurgia, se baseia na injeção de polidocanol, um anestésico, junto a bolhas de ar formadas por seringas ligadas entre si por um cano cirúrgico. A injeção da espuma induz a destruição e a cicatrização do vaso dilatado. É uma técnica que dispensa anestesia e pode ser realizada em ambulatório, mas, em contrapartida, cerca de 1 a cada 3 pacientes relatam o aparecimento de manchas escuras (hiperpigmentação) nas regiões tratadas.

Programação do estudo

Visita Inicial - Screening

Na visita inicial, caso aceite participar, deverá assinar este documento em duas vias, conforme comentado anteriormente. Após isso, os membros inferiores (pernas) direita e esquerda serão avaliadas e fotografadas para posteriores comparações. Essas imagens serão utilizadas na divulgação científica dos dados obtidos.

Visita para tratamento

Nesta data, caso realmente deseje continuar a participar do estudo, os procedimentos serão realizados em ambos membros, sendo a CLaCS realizada em uma perna e a escleroterapia com espuma de polidocanol realizada na outra perna, a realização de ambas as técnicas em cada membro é essencial para medidas de comparação entre os grupos, já que a resposta pessoal poderá interferir nos resultados obtidos dentre as duas técnicas. A determinação de quais membros (perna direita ou esquerda) receberão qual tratamento será realizada de forma aleatória. Ao final de cada tratamento você receberá um questionário a respeito de dor no procedimento.

Visitas de acompanhamento

Entre os dias 7 e 10 após o tratamento está planejado um retorno para nova aquisição de imagens e avaliação clínica da formação de hematomas e coágulos em decorrência dos procedimentos aos quais os membros foram submetidos. Nesse momento é importante que você relate qualquer observação ou desconforto sentido à equipe que te atender. Se neste momento for detectada formação de coágulos com necessidade de drenagem, a drenagem deverá ser feita nessa ocasião (é feita uma punção da veia no local do coágulo com uma agulha mais grossa e o coágulo é retirado). Caso você não deseje realizar a drenagem quando for indicada, há uma chance maior de formação de manchas nos locais tratados.

Entre os dias 30 e 35 após o tratamento haverá uma nova visita, na qual a foto dos membros será repetida para análise e comparação dos efeitos de ambos tratamentos. Também é importante relatar a sua percepção e observações desde o último contato com a equipe médica, e você deverá responder a um questionário de satisfação que será fornecido na data.

Visita final

Entre os dias 60-65 após o tratamento haverá uma nova visita, na qual a foto dos membros será mais uma vez repetida para análise e comparação dos efeitos de ambos tratamentos. Também é importante relatar a sua percepção e observações desde o último contato com a equipe médica, e novamente você deverá responder ao questionário de satisfação que será fornecido na data.

Direitos e responsabilidades dos participantes

Se você for incluído(a) neste estudo, para sua segurança, será importante que você seja totalmente franco com a equipe do estudo e você precisará:

- Comparecer a todas as visitas agendadas;
- Seguir as recomendações da equipe do estudo;
- Informar a equipe do estudo sobre quaisquer doenças ou lesões que você sofrer;
- Avisar a equipe do estudo sobre quaisquer efeitos adversos ou problemas que ocorrerem;

Possíveis efeitos adversos e desconfortos

Existe a possibilidade da formação manchas nas regiões tratadas e o foco deste estudo é avaliar e comparar esse surgimento. Isso pode gerar um desconforto aos participantes, bem como é necessário ter em mente as possíveis consequências do tratamento que incluem: edema (inchaço), hematomas (roxos), reação alérgica sistêmica ao esclerosante, alergia cutânea, hiperpigmentação, úlceras, tromboflebite, trombose e, muito raramente, AVC, embolia pulmonar e óbito (< 0,01% dos casos). Qualquer sintoma deverá ser informado à equipe de pesquisa, a qual garantirá atendimento na rede pública ou privada de acordo com as condições de atendimento no momento da ocorrência.

Quem você deve contatar para mais informações?

Se a qualquer momento você sentir qualquer desconforto, ou se tiver qualquer dúvida, entre em contato com o médico do estudo **Dra. Anelise Rodrigues** ou alguém da equipe dele no endereço informado na primeira página deste TCLE e pelo telefone: **(65)99916-4598**.

O CEP (Comitê de Ética em Pesquisa) é um órgão que tem por objetivo proteger o bem-estar dos participantes da pesquisa. Ele é responsável pela avaliação e acompanhamento dos aspectos éticos de todas as pesquisas envolvendo seres humanos. Se você tiver dúvidas e/ou perguntas sobre seus direitos como participante deste estudo, ou se estiver insatisfeito(a) com a maneira como o estudo está sendo realizado, você poderá entrar em contato com o **Comitê de Ética em Pesquisa Hospital Leforte. Telefone: (11) 3345-2247 / e-mail: cep@leforte.com.br**; Endereço: Rua Barão de Iguape, 209 – Liberdade SP, 01507-000, **segunda a sexta, das 09h às 18h**.

Eu tirei todas minhas dúvidas com a Dra Anelise Rodrigues ou pessoa (s) por ela delegada(s) sobre a minha decisão em participar nesse estudo, fui esclarecido/a quanto aos tipos de esclerosantes/tratamentos a serem utilizados. Ficaram claros para mim quais são os propósitos do estudo, os procedimentos a serem realizados, seus desconfortos e riscos, as garantias de confidencialidade e de esclarecimentos permanentes. Autorizo a documentação do meu tratamento, incluindo registro fotográfico, e a publicação de meu caso em literatura científica, bem como a apresentação em congressos. Concordo voluntariamente em participar do estudo e poderei retirar o meu consentimento a qualquer momento, antes ou durante o mesmo, sem penalidades ou prejuízo ou perda de qualquer benefício que eu possa ter adquirido, ou no meu atendimento neste serviço.

Nome do participante

Assinatura do paciente/representante legal.

Data_____/_____/_____

Nome da testemunha*

Assinatura da testemunha*.

Data_____/_____/_____

*Para casos de voluntários, analfabetos, semianalfabetos ou portadores de deficiência auditiva ou visual.

Declaro que obtive de forma apropriada e voluntária o Consentimento Livre e Esclarecido deste paciente ou representante legal para a participação neste estudo.

Nome do responsável pelo estudo

Assinatura do responsável pelo estudo.

Data_____/_____/_____

ANEXO 3 – TERMO DE CONSENTIMENTO PARA ACERVO DE DADOS

Termo de consentimento Para Acervo de Dados

Título do estudo: Estudo de segurança, aberto, prospectivo, cruzado, com controle ativo comparando as técnicas ClaCs (Cryo-Laser Cryo-Sclerotherapy) e escleroterapia com espuma de polidocanol, para tratamento de pequenas varizes dos membros inferiores.

Nome do Pesquisador: Anelise Rodrigues

Nome da Instituição: CLÍNICA DRA ANELISE RODRIGUES

Av Andre Antonio Maggi 478 conj 1903 – Ed Concorde – Bairro Alvorada
Cuiabá- MT CEP 78049-080

Telefone para Contato 24 horas: (65)99916-4598

Nome do participante:

Número do participante:

No projeto de pesquisa “Estudo de segurança, aberto, prospectivo, cruzado, com controle ativo comparando as técnicas ClaCS (*Cryo-laser Cryo-sclerotherapy*) e escleroterapia com espuma de polidocanol para tratamento de pequenas varizes dos membros inferiores”. A nossa intenção também é que as informações coletadas sejam utilizadas em estudos futuros, para isso, precisamos de sua aprovação por escrito. Aqui iremos explicar quais dados serão armazenados e os seus direitos sobre eles, caso não aceite participar dessa parte da pesquisa, isso não implicará em nenhum tipo de represália. Asseguramos que sua participação no estudo e nesse segmento seja voluntária e que nenhuma informação capaz de gerar a sua identificação será utilizada nas pesquisas futuras. Os dados que serão listados abaixo serão anonimizados e informados para os próximos estudos seguindo códigos gerados após sua inclusão no estudo.

Dados a serem coletados

Neste projeto você fará exames de ultrassom e tirará fotos antes e após os tratamentos para pequenas varizes. Também responderá a questionários sobre o tratamento. A comparação entre os tratamentos é o objetivo deste estudo e apenas suas imagens (exames e fotografias) e respostas aos questionários, já anônimos e identificados por códigos serão armazenados

Direitos dos titulares dos dados

Conforme a legislação nacional, você pode retirar o seu consentimento a usos futuros a qualquer momento. Isso não retirará sua participação dos estudos já realizados, entretanto fará com que sua informação seja deletada do sistema, impedindo a utilização em estudos seguintes. Essa decisão não gerará nenhum tipo de represália.

Ao assinar as duas cópias deste documento, uma que te será entregue e outra para arquivamento pela equipe de pesquisa. Você expressa o seu consentimento na utilização dos dados informados acima para geração de um banco de dado anônimo e que será utilizado para pesquisas posteriores.

Nome do participante

Assinatura do paciente/representante legal.

Data ____/____/____

Nome da testemunha*

Assinatura da testemunha*.

Data ____/____/____

*Para casos de voluntários, analfabetos, semianalfabetos ou portadores de deficiência auditiva ou visual.

Declaro que fui orientado sobre o uso para fins acadêmico de minhas informações anonimizadas.

Nome do responsável pelo estudo

Assinatura do responsável pelo estudo.

Data ____/____/____

ANEXO 4 – TERMO DE CONSENTIMENTO PARA USO DE IMAGEM

Termo de Consentimento Para Uso de Imagem

Título do estudo: Estudo de segurança, aberto, prospectivo, cruzado, com controle ativo comparando as técnicas ClaCs (Cryo-Laser Cryo-Sclerotherapy) e escleroterapia com espuma de polidocanol, para tratamento de pequenas varizes dos membros inferiores.

Nome do Pesquisador: Anelise Rodrigues

Nome da Instituição: CLÍNICA DRA ANELISE RODRIGUES

Av Andre Antonio Maggi 478 conj 1903 – Ed Concorde – Bairro Alvorada
Cuiabá- MT CEP 78049-080

Telefone para Contato 24 horas: (65)99916-4598

Nome do participante:

Número do participante:

Você está sendo convidado a participar do projeto de pesquisa “Estudo de segurança, aberto, prospectivo, cruzado, com controle ativo comparando as técnicas ClaCS (*Cryo-laser Cryo-sclerotherapy*) e escleroterapia com espuma de polidocanol para tratamento de pequenas varizes dos membros inferiores”. Ao assinar este documento, você concorda com a liberação das imagens para finalidade didática e científica, podendo elas serem divulgadas em aulas, palestras, conferências, cursos, congressos, livros, artigos, portais de internet, revistas científicas e similares. Seu nome não será utilizado em qualquer fase da pesquisa, o que garante seu anonimato, e a divulgação dos resultados será feita de forma a não identificar os voluntários.

Neste projeto você fará exames de ultrassom e tirará fotos antes e após os tratamentos para pequenas varizes. Também responderá a questionários sobre o tratamento. A comparação entre os tratamentos é o objetivo deste estudo e apenas suas imagens (exames e fotografias) e respostas aos questionários, já anônimos e identificados por códigos serão armazenados.

Após tirar todas suas dúvidas com a Dra Anelise Rodrigues ou pessoa (s) por ela delegada(s) sobre a sua decisão em participar nesse estudo, certifique-se eu tenha sido esclarecido/a quanto aos tipos de esclerosantes/tratamentos a serem utilizados. Ficaram claros quais são os propósitos do estudo, os procedimentos a serem realizados, seus desconfortos e riscos, as garantias de confidencialidade e de esclarecimentos permanentes. A sua assinatura abaixo autoriza que a documentação de seu tratamento, incluindo registro fotográfico, resultado de exames e resposta aos questionários sejam utilizados em publicações científicas e aulas, bem como a apresentação em congressos. Ao concordar voluntariamente em participar dessa parte do estudo, seu direito de retirar este consentimento a qualquer momento, antes ou durante o mesmo, será preservado sem penalidades, prejuízo ou perda de qualquer benefício que possa ter adquirido, ou no seu atendimento neste serviço.

Nome do participante

Assinatura do paciente/representante legal.

Data ____/____/____

Nome da testemunha*

Assinatura da testemunha*.

Data ____/____/____

*Para casos de voluntários, analfabetos, semianalfabetos ou portadores de deficiência auditiva ou visual.

Declaro que obtive de forma apropriada e voluntária o Consentimento Livre e Esclarecido deste paciente ou representante legal para a participação neste estudo.

Nome do responsável pelo estudo

Assinatura do responsável pelo estudo.

Data ____/____/____

ANEXO 5– NORMAS PARA PUBLICAÇÃO DA REVISTA

Document Tip: Use Ctrl f to search for keywords.



Journal of Vascular Surgery **Venous and Lymphatic Disorders**

Aims and Scope

Journal of Vascular Surgery: Venous and Lymphatic Disorders aims to be the premier international journal of medical, endovascular and surgical care of venous and lymphatic disorders. It publishes high quality clinical research, techniques, and practice manuscripts related to all aspects of venous and lymphatic disorders, including malformations and wound care, with an emphasis on the practicing clinician. The journal seeks to provide novel and timely information to vascular surgeons, interventionalists, phlebologists, wound care specialists, and allied health professionals who treat patients presenting with vascular and lymphatic disorders. As the official publication of The Society for Vascular Surgery and the American Venous Forum, the Journal will publish, after peer review, selected papers presented at the annual meeting of these organizations, as well as original articles of affiliated vascular societies, and by members and non-members. www.jvsvenous.org

Editorial Policies.

Peer Review Process. The Editors and reviewers, by providing prompt and authoritative review, aim to optimize the quality of the published papers. All submitted manuscripts are reviewed initially by the Editors or Associate Editors. A submission may be rejected outright if it does not have sufficient merit to warrant further review or deals with subject matter outside the scope of the Journal. Otherwise, manuscripts will be sent to at least one member of the Editorial Board and two or three additional reviewers. The identities of these reviewers are kept confidential. The Journal operates a single blind peer review process. The identities of the reviewers are kept confidential, though the reviewers can see the author names, affiliations, and conflicts of interest during the review process. Reviewers are asked to give the Editors a confidential opinion on the importance, originality, and scientific merit of the manuscript and rank its importance relative to what has already been published in the JVS journals and the medical literature, and to suggest changes that will improve the paper.

A formal statistical review may be obtained to ensure that the study population was clearly defined, that the design of the study was suitable, that appropriate statistical methods were used, and that the subsequent conclusions were supported by the data and their analysis.

If your submission does meet journal requirements and determined to be suitable to forward with the review process, then your submission will typically be forwarded to an Associate Editor and sent to a minimum of two or more independent expert reviewers to assess the scientific quality of the paper. Unless otherwise acknowledged, the Journal operates using a **single-anonymized review model**. In this type of review, the names of reviewers are hidden from the author. Click [here for more information on types of peer review](#).

If two manuscripts of equal quality are received on the same subject, unless both can be accommodated in the Journal, priority in the review process will be given to the manuscript that was submitted first. The Editor will promptly contact the authors of the second manuscript to inform them of the problem and give them the option of submitting their manuscript to another journal. The Editors will convey the final decision on the disposition of the manuscript to the designated corresponding author along with the reasons for the decision and the complete or summarized comments from the reviewers.

ANEXO 5– NORMAS PARA PUBLICAÇÃO DA REVISTA

If revisions are requested, the Editors expect the authors to revise the manuscript promptly and to indicate the changes that have been made and/or explain their difference of opinion with the reviewers. Detailed instructions can be found in the [Revised Submissions](#) section. The Editors will notify the reviewers of the final decision on the manuscript and, when appropriate to the review process, the comments of other reviewers.

Confidentiality. All documents and information provided for the purpose of peer review are kept entirely confidential. To prevent unauthorized access, manuscripts are stored in a secure manner. Reviewers may not share the manuscript with other colleagues. If a reviewer wishes to seek a colleague's opinion on the scientific merit of a manuscript, the Editors must be consulted first, and the colleague must adhere to the same standards of confidentiality. When the reviewer has completed their review, they are required to delete personal electronic manuscript files and destroy any printed copies of the document. Inquiries received by individual reviewers about a manuscript should be referred to the Editors.

Conflict of Interest in Peer Review. The decisions of the Editors must be fair and objective, and they must be seen to be impartial. Because the final decision on publication rests with the Editors, their decisions must not be influenced by the Society for Vascular Surgery®, the American Venous Forum®, the affiliated vascular societies, or representatives of companies, advertisers, government, or others who might have conflicts of interest. Reviewers are instructed to decline to review any manuscript applications with which they may have a conflict of interest and should avoid reviewing any manuscript if circumstances exist that could be viewed as affecting their impartiality. For example, a reviewer should not review a manuscript submitted by a close friend, individuals from his or her institution, or a scientist with whom the reviewer has had longstanding scientific or personal conflict. When the reviewer is uncertain as to whether a conflict exists, he or she is asked to inform the Editor of the circumstances and the Editor will make the final decision.

Authorship Criteria. To qualify for authorship in a Journal of Vascular Surgery Publication, each author must have made a significant contribution to the conception or completion of the manuscript and is willing to share the responsibility for the content of the paper. Specifically, authorship is limited to those who made a direct and substantial contribution to each of the four following areas:

1. Substantial contributions to the conception or design of the work; the acquisition, analysis, or interpretation of data for the work; AND
2. Drafting the work or revising it critically for important intellectual content; AND
3. Final approval of the version to be published; AND
4. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

These guidelines are based on the "Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals" (<http://www.icmje.org/icmje-recommendations.pdf>). Each of the authors will be required to read and approve the [Application for Publication](#) submitted by the corresponding author.

Corresponding Authors. It is the authors' responsibility to designate a **corresponding author** and a **post-publication corresponding author**. The same author may serve in both roles; however, no more than one author may be designated for each role. Please include the name(s) and contact information for the corresponding author and post-publication author on the title page and in the submission module.

CORRESPONDING AUTHOR. The corresponding author acts as the pre-publication spokesperson for the co-authors in all communications with the Editorial Office and the Publisher. The corresponding author must ensure that all co-authors have reviewed and agreed to the policies of JVS-VL and confirm that the authors agree to submit the manuscript to the Journal. The corresponding author is also responsible for ensuring that the co-authors have approved the manuscript files, disclosed conflicts of interest, and verified their contributions prior to submission and before each subsequent resubmission. The corresponding author is also responsible for uploading the manuscript files in Editorial Manager and accurately completing the required fields in the submission module. Once the paper has been submitted, the corresponding author is responsible for relaying the co-authors' responses to queries from the Editorial Office, receiving and relaying the results of the peer-review process to the co-authors, and working with the co-

Page 2 of 20

ANEXO 5– NORMAS PARA PUBLICAÇÃO DA REVISTA

authors to revise and approve the manuscript before resubmitting it. Finally, the corresponding author must also relay the co-authors' proof corrections once the manuscript is accepted. There may be only one corresponding author at a time, although the authors can switch the corresponding author role to an alternate author if needed.

POST-PUBLICATION CORRESPONDING AUTHOR. The post-publication corresponding author is responsible for communicating with readers once the submission is accepted. The name and contact information for this author will be included in a footnote on the first page of the published article.

Author List Changes. Authors should carefully consider the author list prior to completing the initial submission process. After initial submission, all requests for changes to the author byline (e.g., adding an author, removing an author, or changing the order of authors) should be made in writing for consideration by the Editors. The author change request should (a) state the new author list in full, (b) include the justification for the change(s), and (c) be signed by all authors, including those being added or removed, to indicate approval of the requested change(s).

Number of Authors. There is no specific authorship limit for most submissions as long as each person contributed to the work in all four areas, as outlined in the [Authorship Criteria section](#). The Editors request that each author be carefully examined with respect to the authorship criteria listed above. The number of authors is limited to 6 for venous images. Contributors who meet fewer than all 4 of authorship criteria may not be listed as authors but may be acknowledged in the following ways:

ACKNOWLEDGEMENT. If an individual has contributed to the work but does not meet all the requirements for authorship, he or she should be recognized in the final paragraph of the manuscript. Because acknowledgment may imply endorsement by individuals of a study's data and conclusions, the corresponding author must obtain written permission from all acknowledged individuals. Examples of activities that alone (without other contributions) do not qualify a contributor for authorship, but should be acknowledged, include acquisition of funding; general supervision of a research group or general administrative support; writing assistance; technical editing; language editing; and proofreading.

COLLABORATOR GROUPS. For multicenter clinical trials and other large collaborative studies, there may be many collaborators who **do not** meet the authorship criteria, but who have made substantial contributions to the work. In this case, the collaborators should be assigned a group name such as Venous Investigators. The group name should be listed after the names of the authors on the title page and the complete list of collaborators should be included at the end of the manuscript. The full name and affiliation of each collaborator must be provided, and when practical, the contribution(s) of each collaborator should be included. In the final published article, the author names will appear in the byline followed by "for the *collaborator group name*." The collaborators will appear at the end of the article, or if the list is very long, as an online only appendix.

When every person in a group of 40 or more **qualifies for authorship** and there is also a group name, the group name will appear in the byline and the individual members will be listed in a table near the beginning of the article. When preparing the manuscript for submission, the authors must include the group name on the title page and state that each member qualifies for authorship. The authors must upload a table with their manuscript files that includes each author's name, degree(s), institution/department/division, contributions and conflicts of interest. The authors must still review and submit the Application for Publication, but they may note in the contribution and conflict of interest sections that the information has been submitted in a separate table. In these cases, even though the author names will not appear in the byline, the group name and the name of each author will be searchable in PubMed.

In general, the Journal will follow the norms described in the 10th Edition of the AMA Manual of Style for alternate collaborator/author recognition.

AUTHOR CONTRIBUTIONS. An Author Contribution Statement is published at the end of each Clinical and Experimental Research manuscript. The information for this statement is submitted as part of the Application for Publication. The order of the authors' names is at the discretion of the coauthors who may wish to add a footnote explaining the order of authorship and/or author contributions. If two authors participated equally and would qualify for "first authorship" or "senior authorship", this can be indicated on the Application for Publication and will be published in a footnote to the article.

ANEXO 5– NORMAS PARA PUBLICAÇÃO DA REVISTA

STATISTICAL ANALYSIS. For manuscripts that contain statistically-analyzed data, please identify the co-authors responsible for the statistical analysis in the "Author Contributions" section of the Application for Publication. Please include the names of individuals who provided statistical analysis, but who do not meet the criteria for authorship, in an acknowledgement paragraph at the end of the manuscript.

Conflicts of Interest. The *Journal of Vascular Surgery: Venous and Lymphatic Disorders* is committed to publishing high quality clinical research articles, reviews and reports free from commercial influence. The authors must indicate any conflict of interest or the lack thereof on the Application for Publication Form. The authors' university, institutional, and/or corporate affiliations must be acknowledged on the title page along with sources of funding. In addition, authors must disclose any commercial associations that might represent a conflict of interest with respect to the manuscript. If a company's product is mentioned in a manuscript or other article type (including Letters to the Editor and Editorials), all authors are expected to declare whether they have a consulting or employment arrangement or a royalty or stock agreement with the company.

A conflict of interest statement is published with each Clinical and Experimental Research article (see Johnston KW Rutherford RB. Disclosure of competition of interest. *J Vasc Surg* 1999; 30:200-2). If a paper is accepted for publication, the authors will be asked to clarify and update their conflict of interest statements.

Failure to disclose a conflict of interest will be dealt with according to the following article paragraph: see Johnston KW, Rutherford RB. Failure to disclose competitive interest. *J Vasc Surg* 2000; 31:1306:

"If it is brought to the Editors' attention that an author may have failed to make an appropriate disclosure, the Editors will give the author the opportunity to explain. If a satisfactory explanation is not forthcoming, the Editors will bring the issue to the attention of the author's institution for clarification. If the oversight can be explained as an honest mistake, a simple notation of the error will be published. If there was either self-deception or a deliberate attempt to conceal a significant financial competitive interest, the Editors will conclude that this may represent an attempt to deceive and may be a violation of public and professional trust. The Editors may publish a notation that the paper may be unreliable because the author did not meet the standards of honest disclosure of competitive interests required by the *Journal*." In selected cases the manuscript will be withdrawn.

Declaration of Generative AI in Scientific Writing. The below guidance only refers to the writing process, and not to the use of AI tools to analyze and draw insights from data as part of the research process. Where authors use generative artificial intelligence (AI) and AI-assisted technologies in the writing process, authors should only use these technologies to improve readability and language. Applying the technology should be done with human oversight and control, and authors should carefully review and edit the result, as AI can generate authoritative-sounding output that can be incorrect, incomplete or biased. AI and AI-assisted technologies should not be listed as an author or co-author, or be cited as an author. Authorship implies responsibilities and tasks that can only be attributed to and performed by humans, as outlined in Elsevier's AI policy for authors.

Authors should disclose in their manuscript the use of AI and AI-assisted technologies in the writing process by following the instructions below. A statement will appear in the published work. Please note that authors are ultimately responsible and accountable for the contents of the work.

DISCLOSURE INSTRUCTIONS. Authors must disclose the use of generative AI and AI-assisted technologies in the writing process by adding a statement at the end of their manuscript in the core manuscript file, before the References list. The statement should be placed in a new section entitled 'Declaration of Generative AI and AI-assisted technologies in the writing process':

Statement: *During the preparation of this work the author(s) used [NAME TOOL / SERVICE] in order to [REASON]. After using this tool/service, the author(s) reviewed and edited the content as needed and take(s) full responsibility for the content of the publication.*

This declaration does not apply to the use of basic tools for checking grammar, spelling, references etc. If there is nothing to disclose, there is no need to add a statement.

ANEXO 5– NORMAS PARA PUBLICAÇÃO DA REVISTA

Ethics in Publishing. The Journal of Vascular Surgery: Venous and Lymphatic Disorders is committed to follow the highest standards in ethical publishing. The Editors adhere to the Committee on Publication Ethics (COPE) Code of Conduct, which can be found at <http://publicationethics.org/resources/code-conduct> and also in the Ethical Guidelines for Journal Publishing and in Policies and Ethics, published by Elsevier Inc. (see www.elsevier.com/publishingethics and www.elsevier.com/journal-authors/ethics).

Plagiarism. Charges of academic dishonesty, including plagiarism, duplicate and redundant publication will be managed according to COPE Guidelines. Authors should be aware that if the Editors have concerns about the integrity of a submitted manuscript, the Editorial Office may contact the institution(s) of the author(s) to request an investigation.

SIMILARITY CHECK. Submitted manuscripts are subject to IThenticate [Similarity Check](#) screening. Authors may not reuse verbatim or rephrased text from their own previously published work or the work of others without proper attribution. While duplication in the methods section is acceptable and often preferred for accurate and reproducible study methods, authors must be sure to reference the original source of previously published methods.

It is the authors' responsibility to obtain written permission from the owner of the original work when using any idea, image, or table that does not belong to the author(s). Please be sure that you have properly cited each of the sources of information used to write your manuscript and that you have obtained permission to publish anything that belongs to another person or publisher.

Scientific Misconduct. Misconduct in science was defined by the National Academy of Sciences, National Academy of Engineering, and the Institute of Medicine in 1992 as fabrication (i.e., making up) of data or results, falsification (i.e., changing) of data or results, or plagiarism (i.e., unauthorized use of the words, data, or ideas of another person without giving appropriate credit) in proposing, performing, or reporting research. Misconduct in science does not include unintentional errors in the scientific method or in experimental design or data interpretation. In dealing with alleged scientific misconduct, the appropriate steps in the process include informing the authors of the allegations, requesting clarification, determining whether the misconduct did or did not occur, and, to the extent possible, establishing the intent, ascertaining whether there were mitigating factors, and making recommendations for appropriate action.

If a charge of scientific misconduct appears to be justified, it is the Editors' responsibility to refer the matter to the appropriate individual at the authors' university or institution where the work was done. The university or institution has the responsibility to investigate alleged scientific misconduct. If the charge of scientific misconduct is substantiated, the Journal will publish a retraction. The decision to issue a retraction generally must be made by the authors and/or the appropriate authorities at the university or institution who have access to the full details of the investigation. A published retraction will include the title of the original article, the same first author in the original paper, the reasons why the article is being retracted, and a bibliographic reference to the original paper. The retraction will be listed under a separate heading in the Table of Contents.

Consult "Responsible science: ensuring the integrity of the research process" for further information. Vol. 1. Washington: National Academy Press, 1992.

Institutional Review. Manuscripts that involve research conducted on human subjects must follow the principles outlined in the Declaration of Helsinki (<http://www.wma.net/en/30publications/10policies/b3>) and include a statement in the Methods section stating that the experimental protocol and informed consent were approved by their Institutional Review Board, and that all subjects gave informed consent. Manuscripts that report animal experiments must include a statement in the Methods section stating that the study was approved by the Institutional Review Board and that the animal care complied with the *Guide for the Care and Use of Laboratory Animals*, Institute of Laboratory Animal Resources, Commission on Life Sciences, National Research Council. Washington: National Academy Press, 1996 (http://nap.edu/openbook.php?record_id=5140). The Editors reserve the right to reject a manuscript if the authors fail to make these statements in the manuscript or if, at the request of the Editor, they do not provide appropriate

ANEXO 5– NORMAS PARA PUBLICAÇÃO DA REVISTA

documentation that their studies had appropriate approval by their Institutional Review Board and that informed consent was obtained from each patient.

Clinical Trial Registration. In accordance with the International Committee of Medical Journal Editors (ICMJE), the Journal of Vascular Surgery Publications requires that prospective clinical trials be registered in a public trials registry at or before the time of first patient enrollment as a condition of consideration for publication. Relevant trials that began before July 1, 2007 must be registered prior to editorial review. Registration in any registry that is a primary register of the WHO International Clinical Trials Registry Platform (ICTRP) or in ClinicalTrials.gov is acceptable. Registration must be indicated by providing the unique study number assigned by the approved registry on the Application for Publication form.

A CLINICAL TRIAL is defined by the ICMJE as any research project that prospectively assigns people or a group of people to an intervention, with or without concurrent comparison or control groups, to study the cause-and-effect relationship between a health-related intervention and a health outcome.

HEALTH-RELATED INTERVENTIONS are those used to modify a biomedical or health-related outcome; examples include drugs, surgical procedures, devices, behavioral treatments, educational programs, dietary interventions, quality improvement interventions, and process-of-care changes.

HEALTH OUTCOMES are any biomedical or health-related measures obtained in patients or participants, including pharmacokinetic measures and adverse events.

Unregistered Trials. Authors of unregistered trials, or those with inadequate information in the registry, will be given an opportunity to explain the reason that they failed to comply with this requirement, but it is expected that studies that fit the definition of a clinical trial be registered regardless of the country of origin since these rules are international.

For more information, see the [ICMJE policies](#) on Clinical Trial Registration.

Publication Consent. Publication consent is distinct and different than informed consent for a medical procedure or treatment. If your institution does not have a standard publication consent form, you may use the JVS Publication Consent [form](#). This form must bear the signature of the patient/volunteer, and in cases where the patient/volunteer is a minor or incapable of signing the consent form, the signature of either both living parents or guardians is required. To protect the patient(s') privacy, the authors are required to archive the completed consent form in compliance with the standards of their institution and produce it only at the request of the Editorial Office. The author **SHOULD NOT** upload the form with the manuscript files in Editorial Manager at the time of submission. Publication consent is required in the instances listed below.

IDENTIFIABLE PATIENTS. Special care must be taken to exclude photographs/images that contain identifiable individual characteristics such as a patient's face, case number, initials, etc. Written consent for the publication of photographs and other case details that could identify a patient must be obtained prior to manuscript submission.

VENOUS IMAGES. Publication consent is required for all Venous Images. A statement regarding the patient(s') agreement to publish their case details and images must be included in the text. The authors must be able to provide publication consent forms if requested by the Editorial Office, but they **SHOULD NOT** upload them in Editorial Manager.

Permission to Reproduce Published Material. Permission to reproduce material published in Journal of Vascular Surgery Cases, Innovations and Techniques that is outside the scope of the (CC BY-NC-ND) user license must be obtained from the Publisher [online](#). Authors will be consulted, whenever possible, regarding reproduction or republication of their material.

Editors' and Publisher's waiver of responsibility. Statements and opinions expressed in articles and communications are those of the author(s) and not necessarily those of the Editors or *Publisher*. The Editors and *Publisher* disclaim any responsibility or liability for such material. Neither the Editors nor the *Publisher* guarantee, warrant, or endorse any product or service advertised in the Journal of Vascular Surgery Publications, and they do not

ANEXO 5– NORMAS PARA PUBLICAÇÃO DA REVISTA

warrant any claim made by the manufacturer of such product or service.

Originality of Manuscript. The authors must certify that their article is original, has been written by the stated authors, has not been published previously, and is not under consideration for publication by another journal. If data have previously appeared on a public Web site, the authors must reference that publication in the manuscript and describe the previous publication on the Application for Publication. These and other warranties are attested to at the time of submission and when the Copyright Transfer form is signed.

The authors are required to produce the data on which the manuscript is based for examination by the Editors or their assignees, should they request it. The authors are responsible for keeping their original data and experimental notes on file for a reasonable period of time in case a question should arise about the manuscript after it has been published. The authors should consider including a footnote in the manuscript indicating their willingness to make the original data available to other investigators through electronic media to permit alternative analysis and/or inclusion in a meta-analysis.

MAJOR UPDATES TO A PREVIOUSLY PUBLISHED STUDY. For a major update of the results of a previously published study, the authors must submit copies of the previous papers with their manuscript, so that the Editors can determine whether the new paper provides significant new information or statistical power to warrant publication. In general, major updates to a previously published study should increase the number of patients by at least 50% or the reported mean follow up by at least 2 years.

PREVIOUS PRESENTATIONS AND ABSTRACTS. If the work has been presented previously at a meeting as an oral presentation or poster or has been published as an abstract, only a more detailed report will be considered for publication in the JVS journals. However, the authors are expected to submit the details of the previous presentations and provide the abstract if different from the submitted abstract. In general, manuscripts will not be considered if the work had been published previously in full-length conference proceedings, on public web-site or social media site, or as a book chapter.

PREPRINTS. A preprint is the authors' drafted manuscript prior to peer review. Posting un-refereed manuscripts to a community pre-print server (e.g., medRxiv, bioRxiv, Research Square, etc.) will not disqualify a manuscript for publication unless the preprint is indexed on MEDLINE or PubMed, or unless the preprint has been disseminated so widely as to make publication redundant. Authors who have shared their preprint online must provide a link to the preprint on the title page of the manuscript submitted to JVS-VL. Once the manuscript is under review by the Journal, the authors are prohibited from sharing revised versions of the manuscript. Once the manuscript is accepted for publication the author must ensure that the preprint includes a link to their JVS-VL article via its Digital Object Identifier (DOI).

MEDIA RELEASES. The Editors recognize that news organizations have the right to disseminate information that may have been obtained from a presentation at a scientific meeting or through direct discussions with the author. It is the author's responsibility to inform the Editors that the work has been reported previously by a journalist and explain the circumstances. In doing so, the authors should supply the Editors with the original media report. If the results of the study may potentially have a major impact on patient management, the authors can request the Editor's consideration of prompt review and publication. Once submitted to the JVS-VL, discussion of the contents of a manuscript with the media must be delayed until the review process is complete and the manuscript is posted at the Journal's Web site pending publication, unless the Editors provide prior approval. If the authors provide additional information to the media during the peer review process, the article may be rejected or withdrawn from publication. In some instances, the Editors may ask the authors to prepare a brief press release summarizing the manuscript. However, as with all papers, further discussion of the results with the media must be deferred until the acceptance and postings of the manuscript.

MULTIPLE PUBLICATION. A joint publication or secondary publication of a full-length paper in another journal may be considered if the manuscript contains important information that deserves to be disseminated to a significantly different readership than that of the Journal of Vascular Surgery Publication. The Editors may grant permission for secondary publication in another journal if the original report in the Journal of Vascular Surgery Publication is appropriately acknowledged and the secondary publication follows the initial publication in the *Journal*. Abstracts or full-length summaries of papers presented at meetings may be published simultaneously in another journal with permission of the Editors of both journals, providing an appropriate acknowledgment is made in each journal.

ANEXO 5– NORMAS PARA PUBLICAÇÃO DA REVISTA

Instructions for Authors

Using our Online Submission Software. All new and revised manuscript files, required forms, and associated content must be submitted electronically through [Editorial Manager](#). Use of *Editorial Manager* requires an internet connection, a valid email address, Adobe Acrobat Reader ([free download](#)), and Microsoft Word 2003 - 2010. Authors must create an Editorial Manager user profile before beginning the submission process. Manuscripts that do not meet all submission requirements will be returned to the author for correction.

CLASSIFICATIONS. During the submission process, authors are asked to select 1-6 terms to classify the content of their manuscript. These classification terms allow the Editor to select the most qualified reviewers to evaluate each submission. Authors are encouraged to review the list of classifications prior to beginning the submission process to ensure that they select the most appropriate ones: [View Classification List](#).

Electronic Forms Required for Submission

APPLICATION FOR PUBLICATION. This form is required for all submissions except Invited Commentaries and Editorials. This form must be completed by the corresponding author and reviewed and approved by each author. The information collected on this form is provided to reviewers and Editors assigned to review the manuscript. A Conflict of Interest Statement will be published with each accepted Experimental and Clinical Research article based on the information provided on this form. Authors are required to specify their contributions and meet the requirements for authorship. [Download](#).

PATIENT PUBLICATION CONSENT FORM (IF APPLICABLE). This form is required if your manuscript includes data which might reveal the identity of one of more patients. It also must be completed for ALL Venous Image submissions. If your institution has a standard form to obtain publication consent, that form may be used in place of this document. Consent forms SHOULD NOT be submitted with your manuscript files but must be available upon request by the Editorial Office. A statement regarding the patient(s) publication consent MUST be included in the text of your manuscript. [Download](#).

REVIEWER RESPONSE FORM. This form is required for all revised submissions. [Download](#).

Text Formatting Instructions. All text files must be prepared using: Microsoft Word, double spaced with Times New Roman 12-point font. Authors should consult the American Medical Association's *Manual of Style (AMA Manual of Style: A Guide for Authors and Editors)*. Iverson C, Christiansen S, Flanagan A, et al. 10th ed. New York: Oxford University Press, 2007) (AMA-10).

GRAMMAR. Manuscripts must conform to standard English usage and are subject to editing in conformance with the policies of the Journals. Authors are encouraged to have their work professionally edited prior to submission and may use [Elsevier Language Services](#) for this purpose. If a paper is submitted with significant errors in grammar or syntax, it may be rejected or returned for correction prior to editorial review.

DRUGS AND DEVICES. Generic drug names from the United States Adopted Name (USAN) should be used. Proprietary drug names may be cited in parentheses. Generic equipment names should be used whenever possible, and the proprietary name of the equipment must be cited in parentheses after the proprietary name. Cite the manufacturer and the city, state, and country of manufacture.

UNITS OF MEASURE. Measurements of height and weight should be stated in metric units. Hematologic and clinical chemistry measurements can be stated in System International (SI) units or non-SI units.

ABBREVIATIONS. Only standard abbreviations should be used; avoid unusual or coined abbreviations. The first time **any** abbreviation is used, it should be included in parentheses after the words it replaces. Abbreviations should not be used in the title or abstract.

ANEXO 5– NORMAS PARA PUBLICAÇÃO DA REVISTA

Guidelines for Reporting on Venous and Lymphatic Disorders. Manuscripts should conform to the guidelines for reporting on vascular surgery. Authors must include a paragraph placing the manuscript into an appropriate perspective with the most recent clinical practice guidelines if a relevant guideline exists from any society or group. The following have been developed by the Document Oversight Committee and accepted by the Society for Vascular Surgery and/or the American Venous Forum:

The 2020 update of the CEAP classification system and reporting standards

[J Vasc Surg Venous Lymphat Disord. 2020;8:342-352](#)

Reporting standards of the Society for Vascular Surgery for thoracic outlet syndrome.

[J Vasc Surg 2016;3:23-35](#)

Reporting standards for adverse events after medical device use in the peripheral vascular system.

[J Vasc Surg 2013;58:776-86](#)

Venous severity scoring: An adjunct to venous outcome assessment.

[J Vasc Surg 2000;31:1307-12](#)

Reporting standards in venous disease: an update.

[J Vasc Surg 1995;21:635-45](#)

Reporting standards in venous disease.

[J Vasc Surg 1988;8:172-81](#)

Sex in Research. Authors are required to report the sex of patients, animals, tissues and cells studied. Authors must declare how this information was ascertained, i.e. self-reported, administrative data, or genetic evaluation. Studies that research one sex must include a statement explaining why the study did not include both sexes. For more information, please see the [editorial](#):

Gloviczki P, Lawrence PF. Reporting sex as a biologic variable in research published in the Journal of Vascular Surgery Publications. *J Vasc Surg Venous Lymphat Disord* 2019;7:7

Research Formats. Authors should use the appropriate guidelines when writing any health research manuscript. Format reporting guidelines are available on the [EQUATOR Network Web site](#), which also provides guidance on selecting a relevant [guideline](#). Meeting these basic reporting standards will improve the value of your manuscript and facilitate the peer review process. The following guidelines are endorsed by the Journal of Vascular Surgery Publications:

[CONSORT](#): Randomized Controlled Trials

[RECORD](#): For studies involving administrative data, registries, databases

[STROBE](#): Observational Studies

[PRISMA](#): Meta-Analyses and Systematic Reviews

[ARRIVE](#): Animal Research: Reporting of In Vivo Experiments

Full details are available at <http://www.consort-statement.org/>. This article provides a checklist of the items that should be included in the report of the methods, results and discussion and the suggested details of a flow diagram that provides information on patient flow through the study. [See Reporting Standards](#).

Standards have been published that provide guidelines for reporting meta-analyses of the randomized controlled studies: See Moher D, Cook DJ, Eastwood S, Olkin I, Rennie D, Stroup DF. Improving the quality of reports of meta-analyses of randomized controlled trials: the QUORUM statement. *Lancet* 1999;354:1896-900.

ANEXO 5– NORMAS PARA PUBLICAÇÃO DA REVISTA

Reporting standards have been published that provide guidelines for observational studies: See Stroup DF, Berlin JA, Morton SC, Olkin I, Williamson GD, Rennie D, et al. Meta-analysis of observational studies in epidemiology: a proposal for reporting. Meta-analysis of Observational Studies in Epidemiology [MOOSE] group. JAMA 2000;283:2008-12.

Preparing Your Manuscript File. The manuscript file for most submissions includes a title page, article highlights, table of contents summary, abstract, manuscript body and references. Detailed instructions for how to format the manuscript file are described below. Tables, figures, forms and supplemental materials are submitted as separate files and should not be embedded in the manuscript file. Please see the Article Type for specific word limits and requirements.

TITLE PAGE. A complete title page is required for all submissions and must appear at the beginning of the manuscript file. The title page must include:

Manuscript Title. Must be concise and accurately reflect the content of the manuscript. Must be declarative, stating the topic and results when possible, rather than posing a question. Correct formatting will aid researchers in locating your article on *Medline* once it has been published. Please make sure that your title:

IS NOT in the form of a question.

DOES NOT include "The First..." since these statements can not always be verified. DOES

NOT include a colon or any other punctuation to make it two parts.

DOES NOT Restate the article type: i.e. Experimental Research, Clinical Research, etc.,

****UNLESS** it is a Systematic Review, Meta-analysis, Clinical Practice Guidelines, Reporting Standards or a Randomized Controlled Trial.

DOES NOT State the type of statistical analysis, i.e. Multivariable Analysis.

DOES NOT include the names of the authors, your institution, or the number of patients.

Authors. Complete author names, degrees, corresponding institutions, departments, and divisions, in the order that they should appear in the final printed article

Byline can include non-Latin characters for author names, as long as the characters can be encoded in Unicode (e.g., Chinese, Japanese, Korean, Arabic). These characters can only be used for author names, not author affiliations or titles. Non-Latin characters should be enclosed in parentheses after the transliterated version, e.g. "Zhe Li (李喆), Xueyan Li (李雪燕), Shanshan Nai (能姗姗), Qizhi Geng (耿奇志), Ji Liao (廖蓓), Xingzhi Xu (许兴智) and Jing Li (李静)."

Corresponding Author(s). Please include the name(s), mailing address, phone number and email address for the **corresponding author** and **post-publication corresponding author** on the title page. See section on [Corresponding Authors](#) for more information.

Presentation Information (if applicable). Example: This study was presented in the plenary International Forum at the 2014 Vascular Annual Meeting of the Society for Vascular Surgery, Boston, Mass, June 5-7, 2014.

***Sponsoring Societies.** The author will also have the opportunity to indicate whether the manuscript was presented at a sponsoring society's annual meeting in the submission module. Doing so will allow the Editorial Office to report to the society about manuscript submission and acceptance rates, link the paper with a related society discussion, and add a society banner to the final published paper.

Keywords. Authors may use any five terms they choose to help readers identify this work. They may use the U.S. National Library of Medicine's [MeSH Tools for Finding Keywords](#) to generate these keywords.

TABLE OF CONTENTS SUMMARY AND ARTICLE HIGHLIGHTS. Authors of Clinical and Experimental Research submissions are required to include article highlights and a summary for the table of contents in the manuscript file. It must appear just before the abstract and be formatted using this [template](#) or it will not be accepted for review.

ABSTRACT. An abstract is required for all manuscripts except Venous Images, Letters to the Editor, Invited

ANEXO 5– NORMAS PARA PUBLICAÇÃO DA REVISTA

Commentaries, Editorials, and Presidential Addresses. Tables, figures, reference citations, and trademarked names should not appear in the abstract. Because many readers only have access to the abstract, it is essential that it contain numerical results and not simply summary conclusions.

Unstructured: Evidence Summaries, Practice Management, and Vascular and Endovascular Technique manuscripts require short, unstructured abstracts. Include the abstract after the title page in the manuscript file. Though an unstructured abstract does not have section headings, it must describe what is unique and important about the paper, the primary concerns of the patient(s), the important clinical findings, and the main diagnoses and interventions in a clear and organized manner. The final sentence of the abstract should describe the outcomes and the "take-away" lesson.

Structured: Experimental Research, Clinical Research, Education Corner and Review articles must include a structured abstract after the title page in the manuscript file. The abstract must clearly state the main factual points of the article. The abstract should be informative, not descriptive. Detailed results should be included in the abstract because many readers only have access to abstracts and not the entire article. A structured abstract will include combinations of the following headings that apply and are informative, as described in detail in previous publications:

Objective: including a precise statement of the exact question(s) addressed by the study and, if appropriate, the hypothesis

Methods: the basic study design and setting (i.e., community referral center, ambulatory or hospitalized patients), the patient/subject selection method and number, eligibility criteria, proportion withdrawn, and the exact treatment or interventions

Results: main outcome measure(s), the main results should be stated with statistical significance

Conclusions: only conclusions supported by the study and their clinical application may be stated

Haynes RB, Mulrow CD, Huth EJ, Altman DG, Gardiner MJ. More informative abstracts revisited. *Ann Intern Med* 1990;113:69-76

Ad Hoc Working Group for Critical Appraisal of the Medical Literature. A proposal for more informative abstracts of clinical articles. *Ann Intern Med* 1987;106:598-604

MANUSCRIPT BODY. The usual sections for a full experimental or clinical research manuscript include Introduction, Methods, Results, Discussion, and Conclusion. Subheadings may be useful in the Methods and Results sections to help clarify the content in longer papers. Methods must be described in sufficient detail to allow others to reproduce the work. For established methods, appropriate references and a brief description are sufficient; but for new methods, appropriate details are required.

Please do not include statements that claim that this is the first time a procedure has been performed, reported, etc., as these claims are difficult to verify and may not be accurate.

If the description of the method is very long, the techniques should be summarized and referenced, and the details provided as an appendix that will be published on the internet but not in print. For human studies, the following details are generally important: eligibility (inclusion and exclusion criteria), randomization methods, blinding methods, total consecutive patients enrolled, and number of exclusions or drop outs and reasons.

REFERENCES. References should be cited consecutively in the text by superscript Arabic numbers in the order in which they are first mentioned in the text, a table, or a figure. References should not be cited alphabetically. The format for references is described in detail in "Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals" (<http://www.icmje.org/icmje-recommendations.pdf>).

Articles in Press. References to articles in press must include authors' names, title of article, and name of journal. Include the online publication date if it is available.

Personal Communications and Unpublished Data are not to be Cited as References. Instead, indicate these sources in the text at the appropriate place and include the individual's preferred given name, initials, surname, title, city, and year of communication. A note of approval from the source for the statement should be appended to the manuscript.

ANEXO 5– NORMAS PARA PUBLICAÇÃO DA REVISTA

Authors. If there are six or fewer authors, list all; if seven or more, list only the first six, then et al.

Format for Journal Articles: Josa M, Khuri SF, Braunwald NS, VanCisin MF, Spencer MP, Evans DA, et al. Delayed sternal closure: an improved method of dealing with complications after cardiopulmonary bypass. *J Thorac Cardiovasc Surg* 1986;91:598-603.

Format for Books: Berger HJ, Zaret BL, Cohen LS. Cardiovascular nuclear medicine. In: Goldberger E, editor. *Textbook of clinical cardiology*. 1st ed. St Louis: CV Mosby; 1982. p. 326-45

Data References: Cite underlying or relevant datasets in your manuscript by citing them in your text and including a data reference in your Reference List. Data references should include the following elements: author name(s), dataset title, data repository, version (where available), year, and global persistent identifier. Add [dataset] immediately before the reference so we can properly identify it as a data reference. This identifier will not appear in your published article.

Verify Accuracy. The accuracy of the references, including spelling of references in foreign languages, is the responsibility of the authors and is crucial so that they can be linked to the original citation in the Web version. Authors should be certain that all references use the standard abbreviated journal names according to *Index Medicus*. This is imperative to ensure linking of references in the online version of the *Journal*. References that do not use the standard abbreviated journal names will not link.

Formatting Other Submission Files

ILLUSTRATIONS (FIGURES, CHARTS, GRAPHS). Limit illustrations to those that amplify, but do not duplicate the text. A reasonable number of line or halftone illustrations will be reproduced. You may not submit more than the maximum number of figures permitted for the selected article type. Please review the instructions for the specific article type before proceeding. Operative and pathology photographs should be in color. Figures and charts may be black and white unless sufficiently complex to require color. Original drawings or graphs should be prepared by computer software or by a professional artist.

For our staff to evaluate the quality of your images, each one must be submitted electronically via the Editorial Manager system as separate TIFF, JPEG, or EPS files. Submissions that include figures that are embedded in the text of the manuscript, or that include figures that are compiled in one file, will be returned to you for correction.

Each image must have a minimum resolution of 300 DPI at 3 inches wide. If an image includes text, it must be a minimum of 10-point font.

Cite each figure and figure panel in the manuscript text, including images that are intended to be “online-only” appendices. Number your figures consecutively in Arabic numerals according to the order that they are cited in the manuscript. (Example: Figure 1A, Figure 1B, Figure 2, Supplemental Figure 1, Supplemental Figure 2).

If a TIFF, JPEG or EPS image you uploaded appears very small in the submission PDF, it may be that the file contains a large area of white space surrounding the image. Please be sure to crop out the white space so that the reviewers can read your figures from the PDF.

Figures may be submitted as Microsoft Word or PowerPoint files if the image is sharp, all text is legible, and the figure spans at least 4 inches within the document.

Previously published images. If a figure has been previously published, the legend must give full credit to the original source, and a letter from the original source giving permission to reproduce the figure must be uploaded with the submission. Submissions with previously published images that are not accompanied by an original written permission document will be returned to the author.

Life table graphs. Life-table graphs or survival curves should be presented as series of declining horizontal steps. When the standard error of the patency rate estimate is >10%, the curve should be truncated or else should be

ANEXO 5– NORMAS PARA PUBLICAÇÃO DA REVISTA

represented with a dotted line as a means of indicating lack of reliability of the estimate. An alternative way to present the data is to use 95% Confidence Intervals, adding vertical lines to the survival curve at relevant time-points. In addition, there should be an "n" for each group at the relevant time points along the x-axis. For point estimates at a particular time point, using Kaplan-Meier analysis with later events censored is preferable to using chi-square, which does not account for censoring. Because life table graphs are preferred for in-text inclusion, data tables should be submitted only for the online version of the manuscript if the authors desire to provide this level of detail. Differences between curves should be calculated using the log-rank test.

3D radiological data. You can enrich your online article by providing 3D radiological data in DICOM format. Radiological data will be visualized for readers using the interactive viewer embedded within your article, and will enable them to: browse through available radiological datasets; explore radiological data as 2D series, 2D orthogonal MPR, 3D volume rendering and 3D MIP; zoom, rotate and pan 3D reconstructions; cut through the volume; change opacity and threshold level; and download the data. Multiple datasets can be submitted. Each dataset will have to be zipped and uploaded to the online submission system via the '3D radiological data' submission category. The recommended size of a single uncompressed dataset is 200 MB or less. Please provide a short informative description for each dataset by filling in the 'Description' field when uploading each ZIP file. Note: all datasets will be available for download from the online article on ScienceDirect. So please ensure that all DICOM files are **anonymized** prior to submission. For more information see: <https://www.elsevier.com/books-and-journals/content-innovation/3d-radiological-data#instructions>

FIGURE LEGENDS. Legends must be numbered, double spaced and uploaded as a separate Word document. Indicate original magnification and stain for photomicrographs.

VIDEOS. Videos that add to the understanding of the text are encouraged. All videos should be in MP4 format. The preferred codec is H264. Please do not submit videos that exceed 150 MB. Authors will be asked to resubmit modified files if necessary. Editing and formatting video is the author's responsibility. As with all other manuscript files, videos must be the original unpublished work of the authors. By submitting video files, the authors grant the Journal permission to publish the files in full or in part in the *Journal of Vascular Surgery: Venous and Lymphatic Disorders* in all formats and media now known or hereafter developed.

Author Summaries. Authors of Clinical, Experimental Research, and Review articles are encouraged to submit a 5-minute video summary of their manuscript.

Video Demonstrations: Authors should consider adding narration or explanatory captioning to video demonstrations of new techniques and procedures.

Editor Summary Videos: The Editor highlights select articles from each issue of *JVS-VL* in an Editor Summary Video which appears on YouTube and JVSVENOUS.ORG.

TABLES. Tables should enhance, not duplicate, the text. Results should not be summarized in a table; use a graph instead. Number your tables consecutively in Roman numerals according to the order of citation in the text. All tables must be cited, including tables intended to be supplemental "online-only". Example: (Table I, Table II, Supplemental Table I, Supplemental Table II.) Supplemental tables are counted in the table limit for each article type. Tables must be created in a Microsoft Word using 12 pt. Times New Roman font. Tables must be uploaded together in one Word document, with each table starting on a new page and including a legend for each table. Tables may not be embedded in manuscript document. **Manuscripts with tables that do not meet these requirements will be returned to the author.**

Supplemental Tables. The Editors expect that the authors will only submit tables that are essential to the manuscript; however, tables that are not required to understand the manuscript, but that explain the work in greater detail, should be online-only. For example, a table summarizing the articles used in a meta-analysis should be online-only. Also, patient risk factors can frequently be included as an online table.

Abbreviations used in the tables should be explained in a footnote; however, abbreviations that have been defined in the body of the text do not need to be spelled out or explained in the table. If a table or any data therein have

ANEXO 5– NORMAS PARA PUBLICAÇÃO DA REVISTA

been previously published, a footnote in the table must give full credit to the original source, and the original *Publisher's* permission to reproduce the table must be provided.

Revised Submissions. Revised submissions must include all of the files required for a new submission, (updated manuscript file without editing marks, figures, tables, etc.) plus a redline manuscript and a completed reviewer response form.

REDLINE MANUSCRIPT. A redline manuscript is required for all revised submissions and must meet all of the formatting requirements of the non-redlined manuscript. The redline manuscript must include the abstract and title page. The redline manuscript must be created using "Track Changes" in Microsoft Word and must show every change that has been made in the revision. Manually highlighting, underlining or otherwise indicating the changes made is not enough. Once all the changes are shown, the redline must be saved as a PDF. This will ensure that the author will be able to cite the correct page and line numbers in the [Reviewer Response form](#). Detailed instructions about how to create a redline document may be found [here](#).

Requirements for Specific Submission Types

SUBMISSION TYPE	ABSTRACT STRUCTURE	ABSTRACT (WORDS)	BODY (WORDS)	FIGURES AND/OR TABLES	REFERENCES	SPECIAL RULES
CLINICAL RESEARCH	Structured	250-400	3500	6 print +4 Online Only	50	Requires 10 or more Patients
EDITORIAL	None	None	1000	0	10	Be sure to submit an original title.
EDUCATION CORNER	Structured	250-400	3500	5 print +5 Online Only	30	None
EVIDENCE SUMMARY	Unstructured	150	1500	5 print +5 Online Only	50	None
EXPERIMENTAL RESEARCH	Structured	250-400	4500	6 print +4 Online Only	50	Most Experimental Research manuscripts will be accepted for JVS Vascular Science.
INVITED COMMENTARY	None	None	500	0	10	Be sure to submit an original title.
LETTER TO THE EDITOR	None	None	350	1	10	None
PRACTICE MANAGEMENT	Unstructured	150-200	3000	5 print +5 Online Only	30	None
REVIEW ARTICLE	Structured	250-400	3500-5000	5 print +5 Online Only	75-125	Authors should include the type of review in the title of the manuscript, without making it two parts.
SPECIAL ARTICLE	None			Editor will determine upon invitation.		
VENOUS IMAGE	None	None	350	4	5	Descriptions of images must be included in the text, since figure legends will not be published. Patients must consent to publication

Article Type Descriptions

CLINICAL RESEARCH ARTICLES involve human clinical information, descriptions of patient populations, clinical applicability results and conclusions and must include 10 or more patients. Clinical Research includes:

ANEXO 5– NORMAS PARA PUBLICAÇÃO DA REVISTA

Randomized Controlled Trials. Any research project that prospectively assigns people or a group of people to an intervention, with or without concurrent comparison or control groups, to study the cause-and-effect relationship between a health-related intervention and a health outcome. Authors must be sure to provide the clinical trial [registration number](#) and include a statement in the methods regarding [Institutional Review Board](#) approval and patient consent.

Observational Studies. Any study that observes individuals or measures outcomes without attempting to affect the outcome. Cohort, Case Control and Cross-sectional are types of observational study designs. Authors must state whether their study is retrospective or prospective and include the study dates and number of patients. Authors must be sure to include a statement in the methods regarding [Institutional Review Board](#) approval and patient consent. If formal IRB approval was waived, a statement to express this must be included in the methods. The authors should also disclose whether identifiable private information was reviewed for the study, or the process for deidentifying private information.

Cohort. Prospective cohort studies follow one or more patient populations that are free of the outcome of interest for a predetermined period. Individuals who develop the outcome during the study period are compared with those who did not so to investigate the causes of disease, suggesting links between risk factors and health outcomes. The authors must describe the cohort(s), report the length of follow-up, and state which independent variables and outcomes were measured and how. The number of individuals unavailable for follow-up and whether they differed from those with complete follow-up should be included. For retrospective cohort studies, the authors describe if/how investigators were blinded when formulating the hypothesis and determining the dependent and independent variables.

Case-Control. Retrospective study comparing those who have an outcome or event (cases), and those who have not (controls). The source of cases and controls must be described as well as inclusion and exclusion criteria.

Cross-sectional. Study that analyzes data collected from a population, or a representative subset, at a specific point in time.

EDITORIALS. The Editors may solicit an Editorial on an important manuscript or topic to emphasize or explain the significance and relevance of the work to a venous disease specialty audience or to present different views to assist the readers in deciding on the application of the results and conclusions. The editorial should be objective and authoritative and should not exceed 1000 words in length. Even though Editorials are solicited, there is no prior commitment to publish them.

EDUCATION CORNER. Manuscripts for this section will be both invited papers as well as unsolicited submissions from authors with an interest in the training and education of vein and lymphatic specialists. The goal of this section is to discuss issues in the current training and education in venous and lymphatic disease, including patient-specific education, continuing education, as well as national and international workforce issues.

EVIDENCE SUMMARY. Articles in this section summarize the available evidence on a practice issue related to venous and lymphatic disease management. There is a 1500-word limit of the published evidence, often in tabular form, relating to the subject. The goal of this section is to give the readers a focused discussion which will positively influence their practice.

EXPERIMENTAL RESEARCH ARTICLES do not include human clinical information but may include those studies in which only group samples of human blood or tissue are used and the results/conclusions are research oriented. Occasionally, Experimental Research articles will be considered for publication in the *JVS-VL*; however, most Experimental Research manuscripts will be considered for publication in the [JVS – Vascular Science](#).

Clinical Relevance Paragraph. For Experimental Research articles, the *Journal* requires a 100-word paragraph that describes the clinical relevance of the paper as it relates to its current or future clinical application. This paragraph will be printed immediately below the conclusion section of the abstract of the article but will not be included in the abstract that is available on *Medline*. The purpose of this section is to encourage clinicians to read this work and to help them understand its significance.

ANEXO 5– NORMAS PARA PUBLICAÇÃO DA REVISTA

INVITED COMMENTARY. Upon acceptance of a manuscript, the Editor may request an expert commentary to accompany the published article. Authors who are invited to submit a commentary are asked to help explain how the study fits into the literature and whether it has implications for clinical practice. Authors should provide a unique title for their commentary. Authors should not repeat data or results from the article, since the commentary and article will be published together. However, the first reference must be to the article the commentary is about. Proper citation of the related article improves the online discoverability of the commentary. Authors may cite a few additional references if necessary, but the commentary is intended to be a discussion of the current article, not a literature review. Invited authors should also be mindful that the authors of the related article will not be asked for a rebuttal. Please be tactful and professional when making critical comments.

LETTERS TO THE EDITOR/RESPONSES. Readers are encouraged to submit letters to the Editor regarding recently published JVS-VL articles. The title of a letter should express the main question or opinion of the authors. Letters should address the Editor, not the author, and include the original article as the first reference. Letters should not exceed 350 words and ten references. One illustration or table may be included if it amplifies a recent JVS-VL article by extending or clarifying the original manuscript content, or by presenting an opposing interpretation of the results or conclusions. Letters may also be used to submit brief original observations or opinions, although authors may not submit case reports in letter format. The authors of the original article may be provided with an opportunity to respond in a Letter to the Editor. If the authors respond in a timely fashion, both the Letter to the Editor and the authors' response will be published together.

PRACTICE MANAGEMENT. Manuscripts for this section will be both invited and unsolicited papers focusing primarily on issues of interest to the practicing specialist, including office management issues, vascular laboratory management, sociopolitical topics, recruitment, and reimbursement issues. Topics should be of interest to both academic and nonacademic practitioners.

REVIEW ARTICLES. There are several categories of review article. Authors should include the type of review in the title of the manuscript. Please do not use any punctuation in the title. Each type of review has a specific goal and audience. Review Articles may be solicited by the Editors directly or in response to suggestions by authors and will be evaluated as independent submissions and subject to peer review. Illustrations, tables, and graphs are encouraged in all review articles.

Narrative Review. Traditional narrative reviews are mainly descriptive and do not involve a systematic search of the literature. They focus on a subset of studies, based on availability and an author's selection. These reviews are often not comprehensive.

Systematic Review. Systematic reviews involve a comprehensive search strategy, reducing bias by analyzing all relevant studies on a topic; The Cochrane Collaboration (www.cochrane.org) is an example of an organization that produces systematic reviews. The PRISMA statement and checklist is recommended for an evidence-based minimum set of items for reporting in systematic reviews. The Institute of Medicine also produced standards for systematic reviews "[Finding What Works in Health Care Standards for Systematic Reviews.](#)"

Meta-analysis. A meta-analysis is a type of systematic review that combines either qualitative or quantitative data from multiple studies, using a statistical approach, to increase power and resolve uncertainty. Meta-analyses of comparative studies usually include randomized control trials, but evidence from well conducted observational studies can also be included in some meta-analyses. The PRISMA statement and checklist is recommended for an evidence-based minimum set of items for reporting in meta-analysis (<http://www.prisma-statement.org>)

Systematic review and meta-analysis. Systematic review and meta-analysis are often combined, or may be combined in a single document and are highly encouraged.

SPECIAL ARTICLE: This carefully selected group of articles includes Historical Vignettes, legal issues, ethical issues, personal reflections, opinion writings and other important topics that do not fit into a defined submission category. Special Articles must be important to the readers of JVS-VL. They can be invited articles or unsolicited submissions.

ANEXO 5– NORMAS PARA PUBLICAÇÃO DA REVISTA

INNOVATIVE TECHNIQUE. Manuscripts for this section will be either invited papers from recognized experts or unsolicited manuscripts. These articles are practical and well-illustrated descriptions and technical tips for new or established operative and/or endovenous procedures. Authors are encouraged to submit a narrated video with the publication, summarizing the advantages and disadvantages of the procedure.

VENOUS IMAGES. Submissions accepted for this section present interesting venous and lymphatic images and associated short educational summaries in a focused, report format. Illustrations and text must be confined to one printed page (350 words max, four illustrations or fewer: one for the cover and three that must fit in the right-hand column). Venous Images may be featured on the cover of the *JVS-VL*. Please indicate which image should appear on the Journal cover in the in-text figure citation. The Editor may not select an image from your accepted manuscript for the cover; however, it is required that you designate one image as the cover image before submission. Previously, published images will not be considered for this section. Descriptions of images must be included in the text, since figure legends will not be published, and only key references should be provided (with a limit of five). Images must be of professional quality and meet the basic requirements for resolution specified in **Illustrations (figures, charts, graphs)**.

Cover Image Format: Color illustrations are preferred for the cover. Cover images must not include arrows, or any other added graphics and, whenever possible, text should be cropped out. Appropriate images include radiographs, pathology, anatomy, operative findings, and other relevant clinical pictures. The images should illustrate features of venous and lymphatic disease, including technical approaches. Venous images should possess both scientific and artistic merit.

Consent. The patient must agree to publish their case details and images before the author may submit their manuscript. A statement regarding this consent must be included in the text of the manuscript. The author is responsible for obtaining written consent for publication and archiving that file. To protect the patient(s') privacy, the author **SHOULD NOT** submit the consent form to the Editorial Office. If a standard publication consent form is not available, this form may be used: [Download](#).

Other Types of Publications

PRESIDENTIAL ADDRESSES. A Presidential Address from a meeting of the Society of Vascular Surgery and affiliated societies will be published after editorial review, which may provide suggested improvements. Authors submitting Presidential Addresses must also submit a completed Application for Publication.

REPORTING STANDARDS, PRACTICE GUIDELINES, AND APPROPRIATE USE CRITERIA. These three types of documents are developed under the auspices of the Society for Vascular Surgery and/or American Venous Forum and will be published after review by the Document Oversight Committee and approval by the Board of Directors of the Society for Vascular Surgery.

DEBATES. Manuscripts for this section will be invited papers describing a point/counterpoint debate between two recognized experts in the field, concerning a controversial clinical issue. These debates will be introduced by a brief case vignette. Each expert will submit a defense of their position, as well as a response to their opponent's argument. These manuscripts may be accompanied by an invited expert commentary.

OBITUARIES. The Journal will publish obituaries for individuals who have been Editor-in-Chief or Senior Editor, Founders, or recipients of the American Venous Forum Founder's Award.

LEADERS IN VENOUS SURGERY. This new section will highlight the leaders of venous disease management, with a concise one-page review of the leader's career, as well as a photograph and a video. Manuscripts are accepted from a committee of the Society for Vascular Surgery who has videotaped interviews with most of these pioneers.

SOCIETY DISCUSSIONS The discussions of papers presented at the Society for Vascular Surgery's Vascular Annual Meeting and at some of the meetings of the affiliated societies will be published with the manuscripts if they are

ANEXO 5– NORMAS PARA PUBLICAÇÃO DA REVISTA

submitted in a timely fashion; however, these discussions are subject to Editorial review and only those that enhance the text or present alternative views will be published.

After Manuscript Acceptance

Fees. Authors will be notified of an accept decision and at the same time required to pay an Article Publishing Charge (APC). For full-length articles, the APC is US \$2395; for Venous Images, the APC is US \$1100. SVS members are eligible for a 20% discount on APCs. Following payment of the fee, all manuscripts published in this journal will be made universally available at no further charge through ScienceDirect, www.sciencedirect.com and through the Journal's own website, <https://www.jvsvenous.org/>. Authors will retain copyrights for their published papers after manuscript acceptance.

You can check whether your institution has an agreement with Elsevier to cover Open Access publication of your article at <https://www.elsevier.com/open-access/agreements>.

COPYRIGHT. We offer authors a choice of user licenses, which define the permitted reuse of articles.

Role of the Publisher

PRE-PROOF. The pre-proof is a fully citable version of the manuscript prior to proofreading and formatting by the Publisher. Pre-proofs allow the fastest possible publication and are indexed by Medline. These articles can be cited using the date of access and their unique DOI (Digital Object Identifier) number. Additional changes in the article may be needed and these will be included in the final version. The pre-proof for most article types will appear online approximately 6 weeks after acceptance.

FORMATTED, COPYEDITED ARTICLE PROOF. Approximately 10 weeks from acceptance, the publisher will email the corresponding author the formatted, copyedited article proof for final approval. The corresponding author is responsible for discussing the proof with the co-authors and submitting proof corrections to the Publisher within 1-week. By approving the proof, the authors accept responsibility for the changes made in their manuscript by the copyeditor. The formatted article proof will replace the pre-proof online.

SEQUENCE OF PUBLICATION. In general, manuscripts are published in the order they are received, providing that the Journal receives revisions in a timely fashion. Under unusual circumstances, a paper may be assigned priority for early publication if, in the view of the Editors, it contains important new information that should be brought to the attention of the readers immediately.

REPRINTS. As a courtesy, the authors of articles published in the JVS-VL will have the option to request a single e-offprint at no cost. The e-offprint is an electronic link that allows free access to the full-length article. The e-offprint link may be shared with up to 25 colleagues. An individual may make a single photocopy of a published article for his or her personal use, but multiple copies cannot be made without the written permission of the Journal or from the Copyright Clearance Center at copyright.com.

CORRECTION OF ERRORS. As part of the scientific process, errors may be discovered after publication that require clarification, correction, or retraction of the paper. The Editor will handle errors on an individual basis after discussion with the authors.

APPEALS POLICY. The decisions of the Editors must be considered final. Rejected manuscripts will not be reconsidered for publication unless there is sufficient cause to merit re-review by our Editor and reviewers. There may be sufficient cause for re-review if the author inadvertently declined to transfer a manuscript to an alternate JVS Journal which led to immediate rejection or if another clerical error was made by either the author or the Editorial Office which led to rejection. Re-review may also be appropriate if the authors added critical new data that substantially changed the manuscript. Appeals should be directed to the editorial office and will be reviewed by the Editor-in-Chief. The Editor-in-Chief will make the final determination regarding the appeal.

ANEXO 5– NORMAS PARA PUBLICAÇÃO DA REVISTA

Continuing Medical Education Opportunities

REVIEWER CME PROGRAM. The Society for Vascular Surgery designates manuscript review for the *JVS-VL* for a maximum of 3 *AMA PRA Category 1 Credits™*. Physicians should only claim credit commensurate with the extent of their participation in the activity. At the end of each calendar year, the Editorial Office tallies the number of successfully completed reviews for each journal. Reviews that received a score of 30 or less are deemed unacceptable and will not merit credit. Eligible reviewers will be instructed to complete an online form at the end of the year to receive credits for this activity. Three *AMA PRA Category 1 Credits™* are awarded for each manuscript review. Physicians may claim a total of 15 *AMA PRA Category 1 Credits™* per year of manuscript review per journal. *JVS-VL* Reviewers who complete five or more reviews receive no more than 15 *AMA PRA Category 1 Credits™* per year.

[Learn more about becoming a JVS-VL Reviewer.](#)

ARTICLE-BASED CME PROGRAM. One *AMA PRA Category 1 Credits™* for CME can be obtained by successfully answering questions about the CME article from each issue of the *Journal of Vascular Surgery: Venous and Lymphatic Disorders*. Selected by the *JVS-VL* editors, the CME article contains information relevant to vascular surgery practice. The Senior Editor develops the exam questions.

Access to the CME questions is free and open to the public. After successfully answering the questions, Journal subscribers can print a CME certificate at no cost. For nonsubscribers, there is a \$10 fee per examination to receive a certificate of completion. CME accreditation is provided by the Society for Vascular Surgery.

[Access the online CME exams.](#)

Updated November 2024

This comprehensive policy and instructions for authors document is also published in the online edition of the January issue of the *Journal of Vascular Surgery: Venous and Lymphatic Disorders*. For further clarification, please contact the Editorial Office by sending an email to: jvascsurg@vascularsociety.org.



ANEXO 5– NORMAS PARA PUBLICAÇÃO DA REVISTA