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Identification of outcomes in clinical studies for pelvic venous disorders

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ABSTRACT

Objective: There is increasing recognition that health systems need to measure and improve the value of patient care by measuring outcomes. Chronic pelvic pain secondary to pelvic venous insufficiency can have a significant impact on the quality of life (QOL) of women affected. Despite growing recognition, pelvic venous disorders (PeVDs), an important cause of chronic pelvic pain, remain underdiagnosed. Developing a core outcome set (COS) for benchmarking care delivery enhances the standardization of care. However, there is no consensus regarding a standardized minimum set of outcomes for PeVD. We aimed to generate a list of outcomes reported in previous PeVD treatment studies to lay the foundation for developing a COS for PeVD.

Methods: This scoping review was undertaken according to the PRISMA-ScR guidelines. Initially, screening, full-text review and extraction was conducted on studies published between 2018 and 2023. Subsequently, the search was expanded using 1-year intervals, until, over a 1-year interval, no new outcomes were recorded. Closely related outcomes were classified into domains, and domains into three core areas: disease-specific, treatment-related, and QOL-related outcomes.

Results: Of the 1579 records identified, 51 publications were included. From these studies, 108 different outcomes were identified. The median number of outcomes per study was 8 (interquartile range, 6-13). Closely related outcomes were organized into 42 outcome domains, which were then categorized into 3 core outcome areas; 47.6% (20/42) were disease specific, 35.7% (15/42) treatment related, and 16.7% (7/42) were QOL related. Of the 51 included studies, disease-specific outcomes were identified in 96.1% of the studies (49/51), treatment-related outcomes in 94.1% (48/51), and QOL outcomes in only 13.7% (7/51).

Conclusions: There was significant heterogeneity in outcomes reported in PeVD studies. Most PeVD treatment studies evaluated disease-specific and treatment-related outcomes of PeVD, but few reported outcomes that measured the impact on QOL. These findings will inform the next steps in developing a COS for PeVD. (J Vasc Surg Venous Lymphat Disord 2024;12:101865.)

Keywords: Pelvic venous disease; Pelvic venous insufficiency; Core outcome set; Outcomes; Scoping review

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Pelvic venous disorders (PeVDs) can have a significant impact on the quality of life (QOL) of women affected and, despite growing recognition, remain underdiagnosed.[1] Although pelvic pain related to pelvic venous insufficiency was first described in the late 19th century, it was not until 1948 that a connection between pelvic varicosities and pelvic pain was formally proposed.[2] The progress in diagnosing and managing the disorder has been impeded, in part owing to the use of historical nomenclature and a lack of diagnostic criteria.[3,4] Symptoms and signs of PeVD are variable and arise from reflux and/or obstruction within the pelvic venous system.[3] This results in a variety of symptoms, including chronic pelvic pain, dyspareunia, dysmenorrhea, lower limb venous incompetence, and pelvic origin extrapelvic varices.[5,6]

Several treatment options based on the underlying venous pathology have been reported, including medical, open surgical, endovascular stenting, and percutaneous

embolization therapy.[4,5,7] However, owing to variability in the reporting of treatment outcomes between studies, comparing the relative success of these interventions is difficult.[8,9] This inconsistency creates challenges in making treatment recommendations.[10]

Standardization of a core selection of outcomes and measurement properties in studies is required to overcome this heterogeneity. The International Consortium for Health Outcomes Measurement has developed >40 standard sets of outcomes.[11] These sets aim to enhance individualized care, foster uniformity in reporting clinical studies, enabling comparisons across diverse international settings. Moreover, they empower patients with the ability to make better-informed health care decisions.[12,13] The first step in developing a core outcome set (COS) is conducting a review of the literature to identify previously reported outcomes.[14,15] To date, there is no consensus regarding core outcomes and the relevant measurement tools for use in PeVD.[10] This study aimed to generate a list of outcomes reported in all primary research on PeVD, to identify and describe all reported outcomes.

METHODS

This review is reported according to the PRISMA-ScR guidelines.[16]

Inclusion and exclusion criteria. Included studies were full-text papers in English of original research studies published in indexed journals (randomized controlled trials, observational studies, cohort studies, and case-control studies), reporting on clinical interventions to treat pelvic venous insufficiency, venous reflux, pelvic venous congestion or pelvic origin varicose veins, and any outcome after the intervention. Exclusion criteria included studies focusing solely on the treatment of left renal vein compression or iliac venous obstruction, and the following study designs: case reports, editorials, commentaries, and opinion pieces.

Search strategy. A systematic search was performed in MEDLINE and EMBASE bibliographic databases accessed via the OVID platform. A comprehensive search strategy was developed with a senior librarian (J.R.). Searches included appropriate subject headings and free word searches, combined using Boolean operators. A copy of the search strategy is shown in Supplementary Table I (online only). The references of chosen papers and relevant reviews were searched to ensure the comprehensive inclusion of all relevant studies. Records were then screened in blocks based on publication date. This approach was adapted from a scoping review on outcomes in venous thromboembolism studies.[17] Initially, screening, full-text review and extraction were conducted on studies published between 2018 and 2023. Subsequently, the search was expanded using 1-year intervals, until outcome saturation was reached. Saturation was established when, over a 1-year interval, no new outcomes were recorded from any of the examined studies (ie, all outcomes had been previously recorded). The search was conducted on October 12, 2023.

Two reviewers independently screened all the titles and abstracts generated by the search to remove irrelevant references. Then, full texts of potentially eligible studies were retrieved and independently assessed for eligibility by the same two reviewers. Any discrepancies were resolved through discussion, involving a third reviewer if consensus could not be reached.

Charting the data. Two reviewers independently extracted and charted the data using a standardized data extraction form. The data extracted included author names, year of publication, country of origin, study design, number of patients, maximum follow-up period, and treatment modality. All outcomes were charted verbatim when encountered in each paper. Tools used to measure outcomes were also recorded.

Data synthesis. The list of unique outcomes was discussed among all review team members to identify closely related outcomes. These items were subsequently grouped into outcome domains, which comprehensively described closely related, unique outcomes. Where outcomes differed only in timeframe, they were grouped into one domain. To ensure meaningful classification of unique outcomes, all outcome domains were checked for internal homogeneity (ie, similarity of unique outcomes in a domain) and external heterogeneity (ie, dissimilarity of unique outcomes in separate domains).[18]

Data were analysed using SPSS v.29 (IBM Corp, Armonk, NY). Descriptive statistics were used to summarize the characteristics of the included studies, grouped based on treatment modality. Continuous variables were summarized using the median and interquartile range (IQR); discrete variables were summarized using number (%).

Quality Appraisal. Given the scoping nature of this review, the methodological quality or risk of bias of the included studies was not appraised, as recommended in the PRISMA-ScR.

RESULTS

Search results. A total of 1579 studies were identified from the search. Upon removal of duplicates, 1155 articles were screened. Full-text review was conducted on 124 articles; 51 of these studies were included[19-69] (Supplementary Table II, online only). Fig 1 shows the relevant PRISMA flow diagram. Table I summarizes the study characteristics, grouped based on treatment modality. Most studies (27/51 [52.9%]) used embolization, either with coils, plugs, or chemicals, as the sole treatment modality. Multiple interventions were reported in

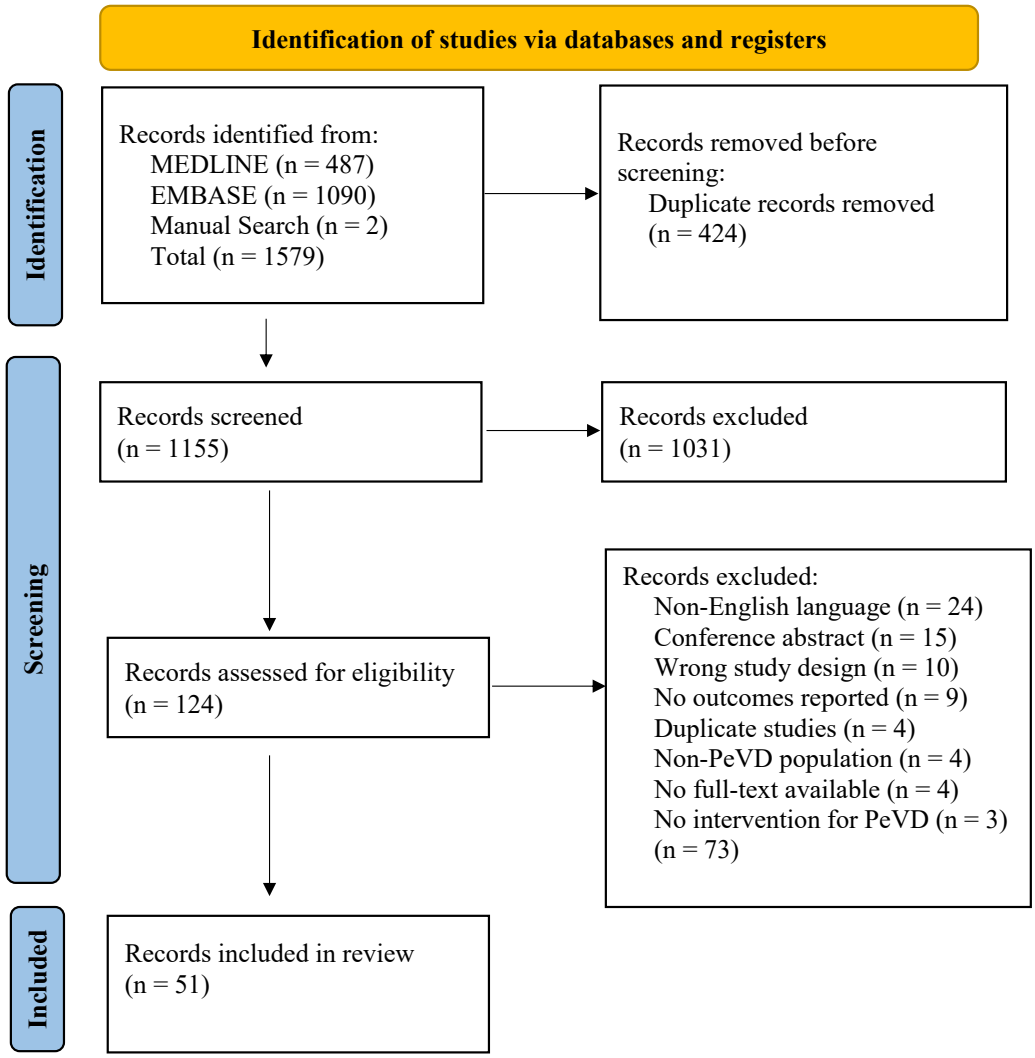


Fig 1. PRISMA (preferred reporting items for systematic reviews and meta-analyses) flow-diagram of the study selection process.

31.4% of studies (16/51). These interventions included various combinations of embolization, surgical resection, foam sclerotherapy, stenting, balloon angioplasty, and micronized purified flavonoid fraction (MPFF). MPFF alone was used in 7.8% of studies (4/51) and barrier patch implantation, compression, foam sclerotherapy alone, and stenting alone were investigated in a single study, each. Most studies (26/51 [51.0%]) were published between 2021 and 2023 , with median publication date 2020 (IQR, 2016-2022). The median sample size was 51 patients (IQR, 28-150 patients), and the median maximum follow-up period was 12 months (IQR, 3-40 months). The majority of studies (32/51 [62.7%]) were retrospective cohort studies; 29.4% (15/51) were prospective cohort studies, and 7.8% (4/51) were randomized controlled studies.

Outcomes. A total of 108 unique outcomes were recorded. These were subsequently grouped into 42 outcome domains, consisting of closely related outcomes. Overall, three core outcome areas were identified, encompassing all outcome domains: outcomes directly related to the disease process were grouped under disease-specific outcomes, those related to treatment of PeVD were grouped under treatment-related outcomes, and measures of QOL were grouped under QOL-related outcomes.

Between 2018 and 2023, 92.6% of the unique outcomes (100/108) were recorded. For studies published between 2014 and 2017, 8 new unique outcomes were added. These include in 2017, four new outcomes (regression of symptoms, mean time to return to work, postintervention Clinical-Etiology-Anatomy-Pathophysiology [CEAP], improvement in symptoms of fullness); in 2016 one new unique outcome (improvement of the leading symptom); in 2015 a further two unique outcomes were added (Change in Venous Clinical Severity Score, change in CEAP classification); and in 2014 one new outcome

Table I. Summary characteristics of included studies

Characteristic	Total (n = 51)	Embolization (n = 27)	Mixed[a] (n = 16)	MPFF (n = 4)	Other[b] (n = 4)
Sample size					
0-50	20 (39.2)	12 (44.4)	5 (31.3)	1 (25.0)	2 (50.0)
51-100	12 (23.5)	5 (37.0)	3 (18.0)	2 (50.0)	2 (50.0)
101-1500	19 (37.3)	10 (18.5)	8 (50.0)	1 (25.0)	0 (0)
Setting					
Africa	4 (7.8)	2 (7.4)	1 (6.3)	0 (0)	1 (25.0)
Asia	2 (3.9)	1 (3.7)	1 (6.3)	0 (0)	0 (0)
Europe	36 (70.6)	18 (66.7)	12 (75.0)	4 (100)	2 (50.0)
North America	6 (11.8)	3 (11.1)	2 (12.5)	0 (0)	1 (25.0)
South America	3 (5.9)	3 (11.1)	0 (0)	0 (0)	0 (0)
Study design					
Prospective cohort	15 (29.4)	7 (25.9)	4 (25.0)	3 (75.0)	1 (25.0)
RCT	4 (7.8)	2 (7.4)	1 (6.3)	1 (25.0)	0 (0)
Retrospective cohort	32 (62.7)	18 (66.7)	11 (68.8)	0 (0)	3 (75.0)
Maximum follow-up, months					
<12	20 (39.2)	6 (22.2)	7 (43.8)	4 (100)	3 (75.0)
12- 24	12 (23.5)	8 (29.6)	3 (18.8)	0 (0)	1 (25.0)
24-36	6 (11.8)	3 (11.1)	3 (18.8)	0 (0)	0 (0)
>36	13 (25.5)	10 (37.0)	3 (18.8)	0 (0)	0 (0)
Year of publication					
2013-2016	14 (27.5)	10 (37.0)	2 (12.5)	1 (25.0)	1 (25.0)
2017-2020	11 (21.6)	7 (25.9)	2 (12.5)	1 (25.0)	1 (25.0)
2021-2023	26 (51.0)	10 (37.0)	12 (75.0)	2 (50.0)	2 (50.0)

MPFF, Micronized purified flavonoid extraction; *RCT*, randomized controlled trial.
Studies are grouped based on type of intervention for pelvic venous disorders treatment.
Values are number (%).
[a]Mixed intervention: Combinations of embolization, stenting, sclerotherapy, MPFF, surgical resection, angioplasty. A breakdown of studies and their corresponding treatment modalities is shown in Supplementary Table II, online only.
[b]Other: interventions only reported in one study each: Foam sclerotherapy alone, Barrier patch Implantation, Compression, Stenting alone.

was added (average radioscopy time). In 2013, no new, unique outcomes were identified.

The median number of unique outcomes per study was 8 (IQR, 6-13 unique outcomes). The unique outcomes formed 42 closely related outcome domains. Unique outcomes and the corresponding outcome domains are listed in Supplementary Tables III, IV, and V (online only). The median number of outcome domains per study was 6 (IQR, 5-9 outcome domains). These were grouped into the three outcome areas as follows: 47.6% (20/42) were disease-specific outcome domains, 35.7% (15/42) were treatment-related outcome domains, and 16.7% (7/42) were QOL-related outcome domains. These are listed in Tables II, III, and IV, respectively.

The most frequently reported disease-specific outcome was a change in pelvic pain severity, reported in 72.5% of studies (37/51). The treatment-specific outcome most frequently reported was procedure-related complications in 66.7% of studies (34/51). Supplementary Table VI (online only) summarizes all procedure-related complication outcomes reported. The complications that were most commonly reported included coil migration and puncture site hematoma, 27.5% (14/51) and 25.5% (13/51) of studies, respectively.

Technical success was reported in 60.8% of studies (31/51). Follow-up imaging was used to evaluate different parameters of success in 35.3% of the studies (18/51). Venography was used in 17.6% of studies (9/51); parameters evaluated included complete occlusion of target veins, presence of a pelvic reservoir, and stent patency. In two studies,[35,42] single-photon emission computed tomography was used to determine the coefficient of pelvic congestion, as a marker of success. Additionally, duplex ultrasound (DUS) examination, was used for follow-up in 17.6% of studies (9/51), with a number of different parameters being assessed. Change in pelvic vein diameter was reported in 9.8% of studies (5/51), and 9.0% of studies (2/51) reported change in linear blood flow velocity in the ovarian, parametrial or uterine veins; change in reflux time, percentage reduction of blood flow in the ovarian

Table II. Disease-specific outcome domains

Outcome domain	Description	Measurement instruments	No. of studies (n = 51)
Change in pelvic pain severity	Subjective assessment of pelvic pain before and after intervention	VAS	37 (72.5)[19-24,26,27,29,32,34,35,37-42,44,47-50,53,54,56-60,62,63,65-69]
Change in pain on multiple item symptom scores	Composite outcomes, providing overall symptom improvement scores	VAS VCSS PVCSS Von-Korff Questionnaire Total symptom score	8 (15.7)[20,26,41,44,47,49,63,66]
Change in SFMP-Q parameters	Rating of pain intensity on McGill SMFP-Q	McGill SMFP-Q	1 (2.0)[67]
Percentage of patients with pelvic pain relief	Relief of pelvic pain after intervention	VAS	17 (33.3)[21-23,25,26,29,31-33,39,41,43,53,57,58,61,62]
Time to recurrence of pain	Duration of pain relief after intervention	N/A	3 (5.9)[19,22,57]
Time to clinical improvement	Time to subjective improvement in signs/symptoms, postintervention	N/A	1 (2.0)[41]
Change in CEAP classification	Reporting of CEAP class, before or after intervention	CEAP	2 (3.9)[26,68]
Change in estradiol levels at 1 week, 1 month, and 3 months postoperatively	Change in serum estradiol levels pre and postoperatively	N/A	1 (2.0)[65]
Misdiagnosis	Percentage of patients who later received alternative diagnosis	N/A	1 (2.0)[62]
Clinical success	Overall assessment of symptom improvement after treatment	N/A	27 (52.9)[20-24,28,31-34,38,40,41,45,47,50-52,54,55,57-59,62,64,68,69]
Dyspareunia	Change in pain severity during sexual intercourse.	VAS	22 (43.1)[19,21,23,25,26,32,35,38,39,44,48,51,54,57,58,61,62,64,66-69]
Dysuria, urinary urgency	Change in pain severity on urination with a strong, sudden need to urinate.	VAS IPSS	13 (25.5)[19,23,25,32,38,44,48,51,52,54,58,61,64]
Dysmenorrhea	Change in pain severity of menstrual periods.	VAS	11 (21.6)[19,32,38,44,48,51,57,58,64,67,69]
Lower extremity pain or edema	Change in pain or swelling in the lower extremities	VAS	10 (19.6)[23,25,26,37,48,54,57,58,64,66]
Lower abdominal pain or heaviness	Change in feeling of discomfort or pressure in the lower abdomen	VAS	8 (15.7)[35,37,44,52,57,62,64,68]
Pelvic varices	Difference in presence of varicose veins in the pelvic area.	N/A	5 (9.8)[21,31,39,52,58]
Lower extremity varices	Difference in presence of varicose veins in the lower extremities	N/A	5 (9.8)[25,31,40,52,54]
Perineal pain or edema	Change in pain or swelling in the perineal area	VAS	4 (7.8)[25,37,42,44]
Mortality	Death, regardless of cause	N/A	2 (3.9)[36,85]
Miscellaneous	Signs/symptoms reported in only a single study (itching, muscle cramps, hemorrhoids, atypical varicosities, pain in sacrum/coccyx, discomfort in hypogastric area, fullness)	N/A	6 (11.8)[39,44,57,58,61,68]

CEAP, Clinical-Etiology-Anatomy-Pathophysiology; *IPSS*, International Prostate Symptom Score; *N/A*, not applicable; *PVCSS*, Pelvic Venous Clinical Severity Score; SF-MPQ, short-form McGill Pain Questionnaire, *VAS*, visual analogue scale; *VCSS*, Venous Clinical Severity Score.
Values are number (%).

Table III. Treatment-related outcome domains

Outcome domain	Description	Measurement instruments	No. of studies (n = 51)
Procedure-related complications [a]	Surgical or medical complications directly related to the treatment	Clavien-Dindo classification Society for Interventional Radiology adverse event classification system	34 (66.7)[19-24,27-34,36-39,41-45,47,48,51,52,54,55,60,62,64,65,67]
Technical success	Any assessment of success of intervention	N/A	31 (60.8)[19-24,26,27,30-33,35,36,38-40,42,43,45,47-50,58-60,62,64,67,69]
Repeat intervention	Number of patients requiring more than one intervention	N/A	14 (27.5)[22,25,27,30,32,38,45,47,57,59,63,64,67,69]
Treatment duration	Total duration of PeVD treatment	N/A	10 (19.6)[19,28,32,38,41,50,53,54,62,64]
Mean volume of contrast	Mean volume of contrast agent used in operations for PeVD	N/A	6 (11.8)[22,24,27,29,60,62]
Total fluoroscopy time	Total time for fluoroscopy in PeVD treatment	N/A	4 (7.8)[32,38,44,64]
Total radioscopy time	Total time for radioscopy in PeVD treatment	N/A	1 (2.0)[22]
Radiation dose	Measure of average radiation exposure for PeVD treatment	N/A	7 (13.7)[19,22,24,29,32,40,64]
Targeted veins	Identity and number of veins targeted by intervention	N/A	21 (41.2)[5,19,20,22,27,29,31,36,38,40,41,43,46,50,52-54,60,62,63,69]
Postprocedural immobilization hours	Time from end of operation to mobilization	N/A	1 (2.0)[53]
Patient satisfaction	Measure of patient satisfaction with PeVD treatment	5-Question Likert instrument 1-10 Scale 4-Item scale, (from unsatisfied to completely satisfied)	8 (15.7)[19,21,32,38,46,63,64,66]
Diameter of embolization devices	Measure of diameter of coils/stents used for embolization/stenting	N/A	4 (7.8)[39,43,53,69]
Length of embolization devices	Measure of length of coils/stents used for embolization/stenting	N/A	5 (9.8)[39,43,51,53,69]
Number of devices used	Measure of the number of coils/plugs used for embolization treatment of PeVD	N/A	10 (19.6)[29,32,33,36,39,43,50,59,60,64]
Cost of embolization devices	Measure of cost of devices needed for embolization treatment of PeVD	N/A	2 (3.9)[32,64]

N/A, Not applicable; *PeVD*, pelvic venous disorders.
Values are number (%).
[a]Specific complications reported are outlined in Supplementary Table VI (online only).

veins, or stent patency, were also reported in 9.8% of studies (5/51).

Of the 51 studies, 49 (96.1%) reported on at least one disease-specific outcome domain, 48 (94.1%) reported on at least one treatment-related outcome domain, and 7 (13.7%) reported on at least one QOL-related outcome domain. Only 13.7% of the studies (7/51) reported on at least one outcome domain in all three core areas.[35,41,44,48,58,59,67]

Instruments used for outcomes assessments. A total of 14 instruments used to measure outcomes were identified. In the disease-specific outcome domains that involved measuring severity of subjective symptoms, the majority of studies (28/51 [54.9%]), used the visual analog scale. This scale was most commonly used to measure change in pelvic pain severity. A number of composite scores were used as outcomes; these are listed in Table II, alongside the relevant domain. In the treatment-related

Table IV. Quality of life (*QOL*)-related outcome domains

Outcome domain	Description	Measurement instruments	No. of studies (n = 51)
Postintervention QOL	Measure of QOL after treatment for PeVD with disease-specific instruments	PVVQ QOL questionnaire VAS PVCSS	3 (5.9)[44,58,59]
Ability to return to previous work, activities, or life plans	Measure of ease of return to work, activities, life plans	VAS	3 (5.9)[35,41,48]
Improvement in QOL	Change in QOL before and after treatment for PeVD	PVVQ VAS	2 (3.9)[44,58]
Time to return to work	Length of time after treatment before return to work	N/A	2 (3.9)[35,41]
Psychological impact	Assessment of psychological impact of PeVD before and after treatment	VAS	1 (2.0)[48]
Change in EQ-5D	Change in QOL score measured on EQ-5D	EQ-5D questionnaire	1 (2.0)[67]
Impact on daily life	Assessment of daily impact of PeVD before and after treatment using VAS	VAS	1 (2.0)[67]

EQ-5D, EuroQOL-5D; *N/A*, not applicable; *PeVD*, pelvic venous disorders; *PVCSS*, Pelvic Venous Clinical Severity Score; *PVVQ*, Pelvic Varicose Vein Questionnaire; *VAS*, visual analogue scale.
Values are number (%).

outcome domains, 11.8% of studies (6/51) reported procedure-related complications using the Society for Interventional Radiology adverse event classification scale (Table III). One disease-specific QOL instrument was identified, namely, the Pelvic Varicose Vein Questionnaire, which was used by Akhmetzianov et al.[44] Three more instruments were used to measure QOL, including the EuroQOL-5D questionnaire (Table IV).

DISCUSSION

This scoping review identified significant heterogeneity in the reporting of clinical studies of PeVD, with only seven studies reporting on at least one outcome from all three core areas. The most frequently reported disease-specific outcome was change in pelvic pain severity. This finding is not surprising, because pelvic pain is a cardinal symptom of PeVD and a common reason for referral and subsequent elective treatment. Other commonly reported outcomes were improvements in dyspareunia and dysuria, which have been reported previously as highly sensitive for PeVD.[70,71] A lack of standardization of the reporting of symptom severity was, however, identified. Some studies preferred the use of the 0- to 10-cm visual analog scale for measurement of symptom severity; others used unspecified measures. Further studies should identify real-world data depicting the actual clinical and QOL impact of PeVD in the different populations and continents because a significant heterogeneity might be detected. There was also significant variation in the variety of signs and symptoms reported. It is important to standardize reporting of disease-specific outcomes, including specific signs and symptoms and their severity, before and after intervention. This strategy will allow for the effective evaluation of the potential benefits of more invasive, endovascular treatment approaches to PeVD,[72] aiding clinical decision-making, where an evidence-based risk-benefit evaluation can be made.

The treatment-specific outcome most frequently reported in the study was procedure-related complications. The procedural complications that were most reported included coil migration and puncture site hematoma. This observation is likely influenced by the fact that the most prevalent intervention was embolization. Furthermore, technical success was evaluated in 60.8% of studies (31/51). The lack of uniformity of definitions of technical success was expected, given the varying treatment modalities. However, some studies used DUS examination for follow-up imaging, whereas others used venography. DUS examination has been shown to have a lower sensitivity for pelvic venous reflux compared with venography.[73,74] However, venography is a more invasive diagnostic investigation and carries a wider risk profile[3]; a standardized method of evaluating treatment success is necessary. Significantly, only two studies evaluated the cost of interventions. The lack of cost reporting prohibits cost-effectiveness analysis of treatment modalities and should be addressed in future clinical studies.[72,75,76]

The principal effect of PeVD is on a patient's QOL.[10,77] Hence, the primary clinical end point of treatment for

PeVD should be improvement of patient's QOL. The review identified that QOL outcomes were the least reported, with only 13.7% of studies (7/51) reporting on at least one QOL-related outcome domain. This finding supports the recommendation made by a recent multidisciplinary team consensus panel, namely, that the development of QOL tools to measure the health burden in women with PeVD and its change after treatment, is a research priority.[10] A development of a disease specific QOL tool is currently underway,[78] reflecting the increasing recognition of the importance of PeVD.

Our review included studies with different treatment modalities for PeVD, with the most common being embolization. Embolization is currently believed widely to be the best available treatment for PeVD owing to pelvic vein reflux.[79,80] Other interventions reported included stenting, sclerotherapy, MPFF, surgical resection, balloon angioplasty, barrier patch implantation, and compression. Given the different treatment modalities, it is unsurprising that there is some heterogeneity in the types of treatment outcomes and procedure-related complications reported. Moreover, because PeVD encompasses a heterogeneous group of disorders with a complex pathophysiology, which present with a variety of signs and symptoms, this can also partially explain the heterogeneity in the disease specific outcomes reported. This factor is to be considered when developing a COS, because it will be important to include domains that are relevant to specific classifications of PeVD and specific treatment modalities.

Future work. Future work should focus on the development and validation of a PeVD-specific COS, with special attention to differences in geography and lifestyle. This review is an important first step. An effective way to achieve this goal would be a collaboration with an international working group of PeVD experts and patient representatives. This strategy would enable fair selection and voting of the final COS, through the use of a consensus-driven, modified Delphi technique, as previously done.[11,12] This process will allow for the integration of patients' values, best available evidence, and medical expertise into deciding the most clinically relevant outcomes, to improve the reporting of PeVD research, and, ultimately, of PeVD care.[8,9,81-84]

Limitations. A limitation of this scoping review is the inclusion of low numbers of studies looking at less commonly performed treatment modalities. The strategy used to identify unique outcomes meant that unique outcome saturation, which occurred when looking at studies published in 2013, may have missed unique outcomes reported in the earlier literature or those specific to studies of less commonly used treatment modalities. This is especially true, considering that some of the largest PeVD series date back to the 1990s; however, recent papers likely reflect contemporary reporting measures and advances in the understanding and management of pelvic venous disease, making this a more practical approach. Additionally, there is lack of international consensus as per the precise definition, and classification, of PeVD. The review was scoping in nature, and thus imposed no restrictions on the definitions and methods of diagnostic confirmation of PeVD in different studies. Therefore, there inevitably was variability in said definitions. However, this concern in PeVD research is common, the solution to which may be the newly developed Symptoms-Varices-Pathophysiology (SVP) classification, which will potentially allow for homogeneity in the reporting of PeVD research.[3] Only one of the 51 included studies used the SVP classification.

CONCLUSIONS

This review identified significant heterogeneity in outcomes reported in clinical studies of PeVD. We identified 108 unique outcomes reported in 51 clinical studies. These outcomes were grouped into 42 domains that were classified into the three core areas: disease-specific outcomes, treatment-related outcomes, and QOL-specific outcomes. Disease-specific and treatment-related outcomes were reported in 96.1% and 94.1% of studies, respectively; however, only 13.7% of studies reported QOL outcomes. The results of this scoping review highlight the need and may contribute toward the development of a COS for PeVD.

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AUTHOR CONTRIBUTIONS

Conception and design: KK, MT, SG, LZ, AJK, SN, AG, AD
Analysis and interpretation: KK, TP, MT, AG
Data collection: KK, TP, HK, AG
Writing the article: KK, TP, MT, AG
Critical revision of the article: KK, TP, MT, HS, SG, LZ, AJK, SN, AG, AD
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DISCLOSURES

None.

REFERENCES

1. Kuligowska E, Deeds 3, Linda, Lu 3, Kang. Pelvic pain: overlooked and underdiagnosed gynecologic conditions. *Radiographics*. 2005;25:3–20.
2. Taylor HC. Vascular congestion and hyperemia; their effect on structure and function in the female reproductive system. *Am J Obstet Gynecol*. 1949;57:211–230.
3. Meissner MH, Khilnani NM, Labropoulos N, et al. The symptoms-varices-pathophysiology classification of pelvic venous disorders: a report of the American vein & lymphatic society international

working group on pelvic venous disorders. *J Vasc Surg Venous Lymphat Disord*. 2021;9:568–584.
4. Ignacio EA, Dua R, Sarin S, et al. Pelvic congestion syndrome: diagnosis and treatment. *Semin Intervent Radiol*. 2008;25:361–368.
5. Marcelin C, Le Bras Y, Molina Andreo I, Jambon E, Grenier N. Diagnosis and management of pelvic venous disorders in females. *Diagnostics*. 2022;12:2337.
6. Bendek B, Afuape N, Banks E, Desai NA. Comprehensive review of pelvic congestion syndrome: causes, symptoms, treatment options. *Curr Opin Obstet Gynecol*. 2020;32:237–242.
7. Chung M, Huh C. Comparison of treatments for pelvic congestion syndrome. *Tohoku J Exp Med*. 2003;201:131–138.
8. Kirkham JJ, Dwan KM, Altman DG, et al. The impact of outcome reporting bias in randomised controlled trials on a cohort of systematic reviews. *BMJ*. 2010;340:637–640.
9. Wood L, Egger M, Gluud LL, et al. Empirical evidence of bias in treatment effect estimates in controlled trials with different interventions and outcomes: meta-epidemiological study. *BMJ*. 2008;336:601–605.
10. Khilnani NM, Meissner MH, Learman LA, et al. Research priorities in pelvic venous disorders in women: recommendations from a multidisciplinary research consensus panel. *J Vasc Intervent Radiol*. 2019;30:781–789.
11. Benning L, Das-Gupta Z, Sousa Fialho L, Wissig S, Tapela N, Gaunt S. Balancing adaptability and standardisation: insights from 27 routinely implemented ICHOM standard sets. *BMC Health Serv Res*. 2022;22:1424.
12. Gwozdz AM, de Jong CMM, Fialho LS, et al. Development of an international standard set of outcome measures for patients with venous thromboembolism: an International Consortium for Health Outcomes Measurement consensus recommendation. *The Lancet Haematology*. 2022;9:e698–e706.
13. Ong WL, Schouwenburg MG, van Bommel ACM, et al. A standard set of value-based patient-centered outcomes for breast cancer: the international Consortium for health outcomes measurement (ICHOM) initiative. *JAMA Oncol*. 2017;3:677–685.
14. Boers M, Beaton DE, Shea BJ, et al. OMERACT filter 2.1: elaboration of the conceptual framework for outcome measurement in health intervention studies. 2019;46:1021–1027.
15. Williamson PR, Altman DG, Bagley H, et al. The COMET handbook: version 1.0. *Curr Contr Trials Cardiovasc Med*. 2017;18:1–50.
16. McGowan J, Straus S, Moher D, et al. Reporting scoping reviews—PRISMA ScR extension. *Journal of clinical epidemiology*. 2020;123:177–179.
17. Tritschler T, Cusano E, Langlois N, et al. Identification of outcomes in clinical studies of interventions for venous thromboembolism in non-pregnant adults: a scoping review. *J Thromb Haemostasis*. 2022;20:2313–2322.
18. Patton MQ. In: *Qualitative research & evaluation methods. 3. ed.*, [Nachdr.] ed. Thousand Oaks [u.a.]: Sage; 2005.
19. Laborda A, Medrano J, De Blas I, Urtiaga I, Carnevale FC, De Gregorio MA. Endovascular treatment of pelvic congestion syndrome: Visual analog scale (VAS) Long-term follow-up clinical evaluation in 202 patients. *Cardiovascular and interventional radiology*. 2013;36:1006–1014.
20. Meneses L, Fava M, Diaz P, et al. Embolization of incompetent pelvic veins for the treatment of recurrent varicose veins in lower limbs and pelvic congestion syndrome. *Cardiovasc Intervent Radiol*. 2013;36:128–132.
21. Thors A, Haurani MJ, Gregio TK, Go MR. Endovascular intervention for pelvic congestion syndrome is justified for chronic pelvic pain relief and patient satisfaction. *J Vasc Surg: Venous Lymphat Disord*. 2014;2:268–273.
22. Hocquelet A, Le Bras Y, Balian E, et al. Evaluation of the efficacy of endovascular treatment of pelvic congestion syndrome. *Diagn Intervent Imaging*. 2014;95:301–306.
23. Nasser F, Cavalcante RN, Affonso BB, Messina ML, Carnevale FC, De Gregorio MA. Safety, efficacy, and prognostic factors in endovascular treatment of pelvic congestion syndrome. *Int J Gynecol Obstet*. 2014;125:65–68.
24. Pyra K, Wozniak S, Roman T, et al. Evaluation of effectiveness of endovascular embolisation for the treatment of pelvic congestion syndrome–preliminary study. *Ginekol Pol*. 2015;86:346–351.
25. Hartung O. Embolization is essential in the treatment of leg varicosities due to pelvic venous insufficiency. *Phlebology*. 2015;30:81–85.
26. Daugherty SF, Gillespie DL. Venous angioplasty and stenting improve pelvic congestion syndrome caused by venous outflow obstruction. *J Vasc Surg: Venous and Lymphatic Disorders*. 2015;3:283–289.
27. Siqueira FM, Monsignore LM, RosaESilva JC, et al. Evaluation of embolization for periuterine varices involving chronic pelvic pain secondary to pelvic congestion syndrome. *Clinics*. 2016;71:703–708.
28. Freis H, Geier B, Mumme A, Strohmann B, Stucker M, Hummel T. Barrier patch implantation during Redo surgery for varicose vein Recurrences in the groin: 1-year results. *Ann Vasc Surg*. 2016;35:98–103.
29. Pyra K, Wozniak S, DrelichZbroja A, Wolski A, Jargiello T. Evaluation of effectiveness of embolization in pelvic congestion syndrome with the new vascular occlusion device (ArtVentive EOSTM): preliminary results. *Cardiovasc Intervent Radiol*. 2016;39:1122–1127.
30. Dos Santos SJ, Holdstock JM, Harrison CC, Whiteley MS. Long-term results of transjugular coil embolisation for pelvic vein reflux - results of the abolition of venous reflux at 6-8 years. *Phlebology*. 2016;31:456–462.
31. Abdelsalam H. Clinical outcome of ovarian vein embolization in pelvic congestion syndrome. *Alex J Med*. 2017;53:15–20.
32. Guirola JA, SanchezBallestin M, Sierre S, Lahuerta C, Mayoral V, De Gregorio MA. A randomized trial of endovascular embolization treatment in pelvic congestion syndrome: fibered platinum coils versus vascular plugs with 1-year clinical outcomes. *J Vasc Intervent Radiol*. 2018;29:45–53.
33. Dorobisz TA, Garcarek JS, Kurcz J, et al. Diagnosis and treatment of pelvic congestion syndrome: single-centre experiences. *Adv Clin Exp Med*. 2017;26:269–276.
34. Abd Elkhalek YI, Bassiouny AMMF. Trans-catheter ovarian vein coiling in management of symptomatic females having chronic pelvic congestion. *Egypt J Radiol Nucl Med*. 2018;49:815–818.
35. Gavrilov SG, Karalkin AV, Turischeva OO. Compression treatment of pelvic congestion syndrome. *Phlebology*. 2018;33:418–424.
36. Whiteley MS, LewisShiell C, Bishop SI, et al. Pelvic vein embolisation of gonadal and internal iliac veins can be performed safely and with good technical results in an ambulatory vein clinic, under local anaesthetic alone - results from two years' experience. *Phlebology*. 2018;33:575–579.
37. Gavrilov SG, Moskalenko YP, Karalkin AV. Effectiveness and safety of micronized purified flavonoid fraction for the treatment of concomitant varicose veins of the pelvis and lower extremities. *Curr Med Res Opin*. 2019;35:1019–1026.
38. De Gregorio MA, Guirola JA, AlvarezArranz E, SanchezBallestin M, Urbano J, Sierre S. Pelvic venous disorders in women due to pelvic varices: treatment by embolization: experience in 520 patients. *J Vasc Intervent Radiol*. 2020;31:1560–1569.
39. Gavrilov SG, Vasilyev AV, Krasavin GV, Moskalenko YP, Mishakina NY. Endovascular interventions in the treatment of pelvic congestion syndrome caused by May-Thurner syndrome. *J Vasc Surg: Venous Lymphat Disord*. 2020;8:1049–1057.
40. Jambon E, Le Bras Y, Petitpierre F, et al. MRI associated factors of clinical efficacy of embolization in patients with pelvic venous insufficiency. *Diagn Intervent Imaging*. 2020;101:667–676.
41. Gavrilov SG, Sazhin A, Krasavin G, Moskalenko E, Mishakina N. Comparative analysis of the efficacy and safety of endovascular and endoscopic interventions on the gonadal veins in the treatment of pelvic congestion syndrome. *J Vasc Surg: Venous Lymphat Disord*. 2021;9:178–186.
42. Gavrilov SG, Karalkin AV, Moskalenko YP, Grishenkova AS. Efficacy of two micronized purified flavonoid fraction dosing regimens in the pelvic venous pain relief. *Int Angiol*. 2021;40:180–186.
43. Gavrilov SG, Krasavin GV, Mishakina NY, Efremova OI, Zolotukhin IA. The effect of venoactive drug therapy on the development and severity of post-embolization syndrome in endovascular interventions on the gonadal veins. *J Personalized Med*. 2021;11:521.
44. Akhmetzianov RV, Bredikhin RA. Clinical efficacy of conservative treatment with micronized purified flavonoid fraction in female patients with pelvic congestion syndrome. *Pain and Therapy*. 2021;10:1567–1578.
45. MacHer J, Brahmbhatt A, Shetty A, et al. Predicting pelvic congestion syndrome: concomitant pelvic pain diagnoses do not affect venography or embolization outcomes. *J Clin Imaging Sci*. 2021;11:61.

46. Gavrilov SG, Grishenkova AS, Mishakina NY, Krasavin GV. Use of a novel Likert scale instrument to assess patient satisfaction following endovascular and surgical treatment of pelvic venous disorders. *Phlebology*. 2022;37:241–251.
47. Neuenschwander J, Sebastian T, Barco S, Spirk D, Kucher N. A novel management strategy for treatment of pelvic venous disorders utilizing a clinical screening score and non-invasive imaging. *Vasa*. 2022;51:182–189.
48. Jambon E, Le Bras Y, Coussy A, et al. Embolization in pelvic venous disorders using ethylene vinyl alcohol copolymer (Onyx) and Aetoxysclerol: a prospective evaluation of safety and long-term efficacy. *Eur Radiol*. 2022;32:4679–4686.
49. Sozutok S, Piskin FC, Balli HT, Onan HB, Kaya O, Aksungur EH. Efficacy of the endovascular ovarian vein embolization technique in pelvic venous congestion syndrome. *Pol J Radiol*. 2022;87:e510–e515.
50. Gavrilov SG, Mishakina NY, Vasilyiev AV, Kirsanov KV. Retrospective analysis of complications after gonadal vein interventions for pelvic venous disorder. *J Surg Res*. 2023;283:249–258.
51. Chen H, Wu Z, Huang Q, et al. Proximal coil occlusion preceding distal sclerotherapy in patients with pelvic congestion syndrome: a multicenter, retrospective study. *J Vasc Surg Venous Lymphat Disord*. 2023;11:149–155.
52. Smak Gregoor AM, Hamer MA, van den Bos RR, Moelker A, van Rijn MJ, Malskat WSJ. Efficacy of endovascular treatment of pelvic varicose veins: a single-center retrospective observational study. *J Vasc Surg Venous Lymphat Disord*. 2022;11:389–396.e2.
53. Gavrilov SG, Mishakina NY, Grishenkova AS. Venous thromboembolism after interventions on the ovarian veins in patients with pelvic venous disorder. *Ann Vasc Surg*. 2022;91:191–200.
54. Shahat M, Hussein RS, Ahmed AKS. Foam sclerotherapy in pelvic congestion syndrome. *Vasc Endovasc Surg*. 2023;57:456–462.
55. Marcelin C, Izaaryene J, Castelli M, et al. Embolization of ovarian vein for pelvic congestion syndrome with ethylene vinyl alcohol copolymer (Onyx R). *Diagn Intervent Imaging*. 2017;98:843–848.
56. Sulakvelidze L, Tran M, Kennedy R, Lakhanpal S, Pappas PJ. Presentation patterns in women with pelvic venous disorders differ based on age of presentation. *Phlebology*. 2021;36:135–144.
57. Reinboldt-Jockenhofer F, Traber J, Holzer LI, von Weymarn A, Dissemond J, Duewell S. Impact of ovarian vein embolization in recurrent varicose veins of the lower extremity. *Vasa*. 2022;51:212–221.
58. Senechal Q, Echegut P, Bravetti M, et al. Endovascular treatment of pelvic congestion syndrome: visual analog scale follow-up. *Front Cardiovasc Med*. 2021;8:751178.
59. Gong M, He X, Zhao B, Kong J, Gu J, Su H. Ovarian vein embolization with N-butyl-2 cyanoacrylate glubran-2 R for the treatment of pelvic venous disorder. *Front Surg*. 2021;8:760600.
60. Gavrilov SG, Mishakina NY, Efremova OI, Kirsanov KV. Complications and adverse events of gonadal vein embolization with coils. *J Pers Med*. 2022;12:1933.
61. Tsukanov YT, Tsukanov AY, Levdanskiy EG. Secondary varicose small pelvic veins and their treatment with micronized purified flavonoid fraction. *Int J Angiol*. 2016;25:121–127.
62. Gavrilov SG, Sazhin AV, Akhmetzianov R, et al. Surgical and endovascular treatment of pelvic venous disorder: results of a multicentre retrospective cohort study. *J Vasc Surg Venous Lymphat Disord*. 2023;11:1045–1054.
63. Wilczko J, Szary C, Bodziony A, et al. May the number of pregnancies predict the progression and the outcome of venous disease treatment? *Diagnostics*. 2023;13:2535.
64. De Gregorio MÁ, Yamamoto-Ramos M, Fredes A, et al. A comparative study of a small series of patients (50 patients) with pelvic varicose veins treated with plugs alone or plugs and polidocanol. *J Clin Med*. 2023;12:5408.
65. Emad el din M, Soliman M, El kiran Y, et al. Ovarian vein surgical ablation versus endovascular technique for treatment of pelvic vein incompetence. *J Vasc Surg Venous Lymphat Disord*. 2023;11:801–808.
66. Szary C, Wilczko J, Bodziony A, et al. Does the treatment of pelvic venous insufficiency really not influence lower limb venous disease? *Diagnostics*. 2023;13:2467.
67. Hansrani V, Riding D, Seif MW, et al. Transvenous occlusion of incompetent pelvic veins to treat chronic pelvic pain in women: a randomised controlled trial. *BJOG An Int J Obstet Gynaecol*. 2023;130:1362–1369.
68. Santoshi RKN, Lakhanpal S, Satwah V, Lakhanpal G, Malone M, Pappas PJ. Iliac vein stenosis is an underdiagnosed cause of pelvic venous insufficiency. *J Vasc Surg Venous Lymphat Disord*. 2018;6:202–211.
69. Lakhanpal G, Kennedy R, Lakhanpal S, Sulakvelidze L, Pappas PJ. Pelvic venous insufficiency secondary to iliac vein stenosis and ovarian vein reflux treated with iliac vein stenting alone. *J Vasc Surg Venous Lymphat Disord*. 2021;9:1193.
70. Beard RW, Reginald PW, Wadsworth J. Clinical features of women with chronic lower abdominal pain and pelvic congestion. *BJOG An Int J Obstet Gynaecol*. 1988;95:153–161.
71. Herrera-Betancourt AL, Villegas-Echeverri JD, López-Jaramillo JD, López-Isanoa JD, Estrada-Alvarez JM. Sensitivity and specificity of clinical findings for the diagnosis of pelvic congestion syndrome in women with chronic pelvic pain. *Phlebology*. 2018;33:303–308.
72. Black CM, Thorpe K, Venrbux A, et al. Research reporting standards for endovascular treatment of pelvic venous insufficiency. *J Vasc Intervent Radiol*. 2010;21:796–803.
73. Champaneria R, Shah L, Moss J, et al. The relationship between pelvic vein incompetence and chronic pelvic pain in women: systematic reviews of diagnosis and treatment effectiveness. *Health Technol Assess*. 2016;20:1–108.
74. Zucker EJ, Ganguli S, Ghoshhajra BB, Gupta R, Prabhakar AM. Imaging of venous compression syndromes. *Cardiovasc Diagn Ther*. 2016;6:519–532.
75. Glick HA, Doshi JA, Sonnad SS, Polsky D. *Economic evaluation in clinical trials. Handbooks in health economic evaluation series Second edition ed*. Oxford: Oxford University Press; 2015.
76. Polsky D, Glick H. Costing and cost analysis in randomized controlled trials: caveat emptor. *Pharmacoeconomics*. 2009;27:179–188.
77. Bałabuszek K, Toborek M, Pietura R. Comprehensive overview of the venous disorder known as pelvic congestion syndrome. *Ann Med*. 2022;54:22–36.
78. Weill Medical College of Cornell University. Development of a patient-reported outcome measure for women with chronic pelvic pain (PROM for CPP). Accessed January 19, 2024. https://clinicaltrials.gov/study/NCT06083597?term=NCT06083597&rank=1.
79. Kashef E, Evans E, Patel N, Agrawal D, Hemingway AP. Pelvic venous congestion syndrome: female venous congestive syndromes and endovascular treatment options. *CVIR Endovascular*. 2023;6:25.
80. Borghi C, Dell'Atti L. Pelvic congestion syndrome: the current state of the literature. *Arch Gynecol Obstet*. 2016;293:291–301.
81. McLachlan S, Kyrimi E, Dube K, Hitman G, Simmonds J, Fenton N. Towards standardisation of evidence-based clinical care process specifications. *Health Inf J*. 2020;26:2512–2537.
82. Shiffman RN, Shekelle P, Overhage JM, Slutsky J, Grimshaw J, Deshpande AM. Standardized reporting of clinical practice guidelines: a proposal from the conference on guideline standardization. *Annals of internal medicine*. 2003;139:493–498.
83. Kirkham JJ, Gorst S, Altman DG, et al. Core outcome set–STAndards for reporting: the COS-STAR statement. *PLoS Med*. 2016;13:e1002148.
84. Tugwell P, Boers M. OMERACT conference on outcome measures in rheumatoid arthritis clinical trials: introduction. *J Rheumatol*. 1993;20:528–530.

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Supplementary Table I (online only). Search strategy

Database	Search terms
Embase	(exp Pelvis OR pelvis OR pelvic)
	AND
	(exp Vein Insufficiency OR exp venous reflux OR vein insufficiency OR venous reflux OR varicose veins OR venous incompeten* OR venous syndrome* or congestion syndrome* OR venous disease* OR venous disorder* OR vein* disorder* OR venous insufficien* OR varicose vein*)
MEDLINE	(exp Pelvis OR pelvis OR pelvic) AND (exp Venous Insufficiency OR exp Varicose Veins OR venous insufficiency OR varicose veins OR venous incompeten* OR venous syndrome* or congestion syndrome* OR venous disease* OR venous disorder* OR vein* disorder* OR venous insufficien* OR varicose vein*)

Supplementary Table II (online only). Details of all included studies

Author	Year	Country	Study design	Number of patients	Max. Follow-up	Interventions	Veins targeted
Hansrani et al	2023	UK	RCT	60	12	Venography + coil embolization or venography alone	OV IIV
Szary et al	2023	Poland	RC	243	6	Coil embolization or coil embolization + lower leg varicose vein treatment	OV
Emad el din et al	2023	Egypt	RCT	50	3	Coil embolization or resection	OV
De Gregorio et al	2023	Spain	PC	50	12	Plugs or polidocanol foam (VPPF)	OV Hypogastric
Wilczko et al	2023	Poland	RC	297	3	Coil embolization or sclerotherapy	OV IIV
Chen et al	2023	China	RC	147	12	Coil embolization + sclerotherapy	OV IIV
Gavrilov et al	2023	Russia	RC	272	0.1	Coil embolization or resection	OV
Gavrilov et al	2023	Russia	RC	277	36	Coil embolization or resection	OV
Shahat et al	2023	Egypt	RC	40	12	Foam sclerotherapy	OV IIV
Smak Gregor et al	2023	Netherlands	RC	156	40.1	Coil, plug, or glue embolization	OV IIV
Gavrilov et al	2023	Russia	RC	361	60	Coil embolization or resection	OV
Gavrilov et al	2022	Russia	RC	150	1	Coil embolization	OV
Gavrilov et al	2022	Russia	PC	100	6	Coil embolization or resection	OV
Jambon et al	2022	France	PC cohort	73	29.2	Onyx embolization	OV Pelvic varicosities
Reinboldt-Jockenhöfer et al	2022	Germany	RC	95	94	Coil embolization	OV
Neuenschwander et al	2022	Switzerland	RC	43	8.3	Coil embolization or stenting	OV IIV

(Continued on next page)

Supplementary Table II (online only). Continued.

Author	Year	Country	Study design	Number of patients	Max. Follow-up	Interventions	Veins targeted
Sozutok et al	2022	Poland	RC	144	12	Coil embolization	OV
Lakhanpal et al	2021	USA	RC	38	6	Stenting	CIV
Akhmetzianov et al	2021	Russia	RCT	83	2	MPFF or Placebo	NA
Gavrilov et al	2021	Russia	PC	125	1	MPFF	NA
Gavrilov et al	2021	Russia	PC	70	1	Coil embolization ± MPFF	OV
Gong et al	2021	China	RC	21	102	Glue embolization	OV
Gavrilov et al	2021	Russia	RC	95	36	Coil embolization or resection	OV
Macher et al	2021	USA	RC	78	6	Coil ± glue embolization	OV
Senechal et al	2021	France	RC	327	82	Onyx embolization ± stenting	OV IIV RV
Sulakvelidze et al	2021	USA	RC	1280	12	Coil ± glue embolization or stenting	OV CIV
Gavrilov et al	2020	Russia	PC	12	36	Coil embolization ± stenting	OV CIV
Jambon et al	2020	France	RC	168	138	Coil or Onyx embolization	OV IIV
De Gregorio et al	2020	Spain	RC	520	60	Coil or plug embolization	OV IIV
Gavrilov et al	2018	Russia	PC	65	2	MPFF	NA
Guirola et al	2018	Spain	RCT	100	12	Coil or plug embolization	OV IIV
Whiteleyet al	2018	UK	RC	112	24	Coil embolization	OV IIV
Abd Elkhalek et al	2018	Egypt	RC	10	3	Coil embolization	OV
Dorobisz et al	2017	Poland	RC	10	22.5	Coil embolization	OV
Gavrilov et al	2017	Russia	PC	74	0.5	Compression	NA
Marcelin et al	2017	France	PC	17	69	Onyx embolization	OV
Santoshi et al	2017	USA	RC	227	3	Chemical ± coil embolization ± stenting or stenting alone or venoplasty ± embolization	OV CIV EIV IVC
Abdelsalam et al	2016	Egypt	PC	11	36	Coil embolization	OV
Dos Santos et al	2016	UK	RC	28	96	Coil embolization	OV
Tsukanov et al	2016	Russia	PC	48	1	MPFF	NA
Siqueira et al	2016	Brazil	RC	22	35	Embolization	OV IIV
Freis et al	2016	Germany	RC	67	1	Barrier patch implantation	Groin varicose veins
Pyra et al	2016	Poland	PC	12	6	ArtVentive EOS embolization	OV
Daugherty et al	2015	United States	RC	19	59	Balloon angioplasty, stenting and coil embolization	OV CIV IVC
Hartung et al	2015	France	RC	119	12	Coil embolization ± stenting	OV IIV
Pyra et al	2015	Poland	PC	24	3	Coil embolization	OV
Nasser et al	2014	Brazil	RC	113	12	Coil embolization	OV Pelvic Varicose Veins

Supplementary Table II (online only). Continued.

Author	Year	Country	Study design	Number of patients	Max. Follow-up	Interventions	Veins targeted
Thors et al	2014	USA	RC	15	48	Coil or plug embolization	OV
Laborda et al	2013	Spain	PC	202	60	Coil embolization	OV
Meneses et al	2013	Chile	PC	10	12	Coil embolization	OV IIV
Hocquelet al	2014	France	RC	33	59	Coil embolization	OV IIV

CIV, Common iliac vein; *EIV*, external iliac vein; *IIV*, internal iliac vein; *IVC*, inferior vena cava; *MPFF*, micronized purified flavonoid fraction; *NA*, not applicable; *OV*, ovarian vein; *PC*, prospective cohort study; *RC*, retrospective cohort study; *RCT*, randomized controlled trial; *RV*, renal vein.

Supplementary Table III (online only). Breakdown of disease-specific unique outcomes and outcome domain groupings

Unique disease-specific outcomes	Disease-specific outcome domains
Pelvic pain relief	Percentage of patients with pelvic pain relief
Change in pelvic pain (VAS) VAS score of CPP intensity 1 month/5 years after treatment	Change in pelvic pain severity
Mean of cumulated pelvic symptoms Change in 9-item VAS score Change in pain on PVCSS score Change in pain on VCSS Change in pain on Von-Korff questionnaire Change in pain on PCS score Total Symptom Score	Change in pain on multiple item symptom scores
SFMPQ - pain rating index	Change in SFMPQ Parameters
SFMPQ - current pain (VAS 0-100)	
SFMPQ - current pain intensity (0-5)	
Time to recurrence of pain	Time to recurrence of pain
Time to pain reduction/ elimination	Time to clinical improvement
Change in CEAP clinical class Postintervention CEAP classification	Change in CEAP classification
Change in estradiol levels 1 week,1 month,3 months postoperatively	Change in serum estradiol levels pre and postoperatively
Misdiagnosis	Misdiagnosis
Recurrence of symptoms Increase in CPP within 30 days after treatment	Clinical success
Clinical remission rate	
Complete response	
Partial response	
Clinical success	
No symptom improvement	
Improvement of the leading symptom	
Pelvic varices	Varices in pelvis
Vulval varices	
Lower limb varicosities	Lower extremity varices
Lower abdominal pain	Lower abdominal pain or heaviness
Lower abdominal heaviness	
Lower abdominal discomfort	
Discomfort in hypogastric area	
Dyspareunia	Dyspareunia
Tenderness in the perineum	Perineal pain or edema
Edema in the perineum	
Dysmenorrhea	Dysmenorrhea
Dysuria	Dysuria, urinary urgency
Urinary urgency	
Lower extremity edema	Lower extremity pain or edema
Lower extremity pain	
Mortality	Mortality
Itching Fullness	Miscellaneous
Signs of atypical varicosis	
Hemorrhoids	
Muscle cramps	
Pain after standing Pain in sacrum/coccyx	
Total Unique outcomes	Total outcome domains
50	20

(Continued)

Supplementary Table III (online only). Continued.

CEAP, Clinical-Etiology-Anatomy-Pathophysiology; *PVCSS*, Pelvic Venous Clinical Severity Score; *SF-MPQ*,short-form McGill Pain Questionnaire; *VCSS*, Venous Clinical Severity Score.

Supplementary Table IV (online only). Breakdown of treatment-related unique outcomes and outcome domain groupings

Unique treatment-related outcomes	Unique treatment-related outcome domains
Repeat intervention	Repeat intervention
Procedural success	Technical success
Treatment efficacy	
Technical success	
Cost of embolization devices	Cost of embolization devices
Total number of territories treated	Targeted veins
Identity and number of occluded veins	
Side of intervention Identity and number of stented veins	
Operating Time	Treatment duration
Total fluoroscopy Time	Total fluoroscopy time
Postprocedural immobilization hours	Postprocedural immobilization hours
Radiation dose	Radiation dose
Mean dose area product	
Mean radioscopy time	Total radioscopy time
Mean volume of contrast	Mean volume of contrast
Mean coil diameter Mean stent diameter	Diameter of embolization devices
Patient satisfaction Possibility of recommending treatment to other patients (0-10)	Patient satisfaction
Mean length of coils used Mean length of stents used	Length of treatment devices
Number of coils per territory	Quantity of embolization devices
Total number of coils used Total number of plugs used	
Adverse effects of treatment	Procedure-related complications
Coil migration	
Contrast extravasation	
Puncture site hematoma	
Migration of embolization glue	
Allergic reaction	
Thrombosis of veins in pelvis	
PES	
Duration of PES	
Coil protrusion	
Pain along embolized vein	
Calf deep vein thrombosis	
Parametrial vein thrombosis	
Hyperthermia	
Pulmonary embolism	
Any other venous thromboembolism	
Surgical wound pain	
Bleeding	
Wound complications	
Ileus	
Stent migration	
Postprocedural pain	
Total unique	Total domains
47	15

PES, Postembolization syndrome.

Supplementary Table V (online only). Breakdown of quality of life (*QOL*)-related unique outcomes and outcome domain groupings

Unique QOL-related outcomes	QOL-related outcome domains
Postintervention QOL	Postintervention QOL
Improvement in QOL	Improvement in QOL
Ability to return to previous work, activities, or life plans	Ability to return to previous work, activities, or life plans
Difficulty walking	
Impact on daily working life	
Time of disability	
Time to restoring usual daily activity	Time to return to work
Mean time to return to work	
Psychological impact	Psychological impact
Impact on daily life	Impact on daily life
Change in EQ-5D	Change in EQ-5D
Total unique 11	Total domains 7

EQ-5D, EuroQOL-5D.

Supplementary Table VI (online only). Breakdown of procedure-related complications

Complications	No. of studies (n = 51)
Coil migration	14 (27.5)
Migration of embolization glue	2 (3.9)
Stent migration	1 (2.0)
Puncture site hematoma	13 (25.5)
Allergic reaction	8 (15.7)
Contrast extravasation	6 (11.8)
Postembolization syndrome	6 (11.8)
Duration of postembolization syndrome	3 (5.9)
Coil protrusion	5 (9.8)
Calf deep vein thrombosis	4 (7.8)
Pulmonary embolism	1 (2.0)
Parametrial vein thrombosis	3 (3.9)
Thrombosis of pelvic vein or uterine vein	3 (5.9)
Other venous thromboembolism	5 (9.8)
Hyperthermia	4 (7.8)
Pain along embolized vein	3 (5.9)
Postprocedural pain	3 (5.9)
Surgical wound pain	2 (3.9)
Bleeding	3 (5.9)
Wound complications	2 (3.9)
Ileus	2 (3.9)

Values are number (%).