Iliac vein stenting and pregnancy

Laurencia Villalba, MD, FRACS Vasc,[a,b,c] Venkata Vineeth Vaddavalli, MBBS, MS,[d] *and* Ramesh K. Tripathi, FRCS, FRACS Vasc, DFSVS,[e] *Wollongong, NS, and Brisbane, QL, Australia; and Chandigarh, India*

ABSTRACT

Venous stenting is the mainstay treatment of symptomatic iliofemoral venous outflow obstruction. However, because pregnancy and the postpartum period are hypercoagulable, concerns exist regarding stent placement in women of childbearing age. We performed a systematic review up to April 2023 of studies reporting on the performance of venous stents in women who subsequently became pregnant. The data collected included demographics, indication for stenting, stent characteristics, stent-related complications, incidence of venous thromboembolism, medical management during pregnancy, and follow-up. The indications for stenting included acute iliofemoral deep vein thrombosis in 39 patients (51%), nonthrombotic iliac vein lesions in 35 (46%), and post-thrombotic lesions in 2 patients. A total of 76 women with 87 subsequent pregnancies after stenting were included. Of the 76 women, 1 (1.14%) experienced stent occlusion, 2 (2.29%) developed asymptomatic nonocclusive in-stent thrombus, and 2 (2.29%) experienced permanent stent compression. The only patency loss occurred because of inadequate anticoagulation therapy in a patient with antiphospholipid antibodies. The two cases of permanent compression occurred in an arterial stent and a balloon-fenestrated Vici stent (Boston Scientific). Venous stents performed well through pregnancy and can be safely used in women of childbearing age. Given the increased risk of venous thromboembolism and the low bleeding risk, it is prudent to recommend anticoagulation therapy for all stented patients until more data are available. (J Vasc Surg Venous Lymphat Disord 2023;11:1276-84.)

Keywords: Iliac vein; May-Thurner syndrome; Pregnancy; Venous outflow obstruction; Venous stenting

Venous stenting is the mainstay treatment of symptomatic iliofemoral venous outflow obstruction (IFVOO), including nonthrombotic iliac vein lesions (NIVLs), post-thrombotic (PT) lesions, and lesions found after thrombus removal in the setting of acute iliofemoral deep vein thrombosis (IFDVT).[1] However, concerns remain regarding stent placement in women of childbearing age. This is because pregnancy and the postpartum period are hypercoagulable states,[2] and the uterus can compress the stent or the inflow vessels and compromise patency. Pregnancy-associated venous thromboembolism (VTE) constitute ~10% of all VTE cases in women and remains one of the leading causes of maternal death during pregnancy.[3,4] The incidence of deep vein thrombosis (DVT), specifically, is more than five times higher during pregnancy and ~20 times higher during puerperium compared with nonpregnant women.[5]

The use of venous stenting has increased exponentially in the past few years, resulting in "appropriate use criteria" practice guidelines from several international specialty societies.[6,7] The question posed is whether women of childbearing age with a diagnosis of IFVOO and who meet the appropriateness criteria for venous stenting are at high risk of stent-related complications during pregnancy. Thus, we performed a systematic review of studies reporting on outcomes of venous stents with subsequent pregnancy, including patency, stent integrity, the need for reintervention, the incidence of VTE, and management strategies during pregnancy and postpartum.

METHODS

The study design is in accordance with the PRISMA (preferred reporting items for systematic reviews and meta-analyses) 2020 guidelines.[8]

Literature search. The PubMed and Embase databases were systematically searched for all studies reported up to April 2023. The search was restricted to studies reported in the English language. The terms used were "venous stent AND pregnancy OR venous stent AND women of childbearing age OR venous stent AND young patients." No filters were applied. The abstracts and titles were screened for eligibility. Duplicate studies were removed. The reference lists of the included studies were searched manually to identify further reports.

From the Graduate School of Medicine, University of Wollongong,[a] The Wollongong Hospital,[b] and the Vascular Care Centre,[c] Department of Vascular Surgery, Wollongong; Post Graduate Institute of Medical Education and Research, Chandigarh[d]; and the University of Queensland, Brisbane.[e]

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Correspondence: Laurencia Villalba, MD, FRACS Vasc, Vascular Care Centre, Unit 104, 51 Crown St, Wollongong, NSW 2500, Australia (e-mail: laurenciavillalba@live.com; vineeth1126@gmail.com).

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Inclusion and exclusion criteria. All observational studies, including case reports on the performance of venous stents in women who subsequently became pregnant, were included. Studies reporting on venous stenting during pregnancy were excluded.

Data collection. Data from relevant studies were extracted into a standardized form by two of us (L.V. and V.V.V.). Discrepancies regarding data extraction were resolved by two of us (L.V. and R.T.). Information was obtained on study design, patient demographics, number of patients, number of pregnancies, indication for venous stenting, interval between stenting and pregnancy, stent brand, average stent diameter, stent location, mean duration of follow-up, incidence of VTE during pregnancy and postpartum, stent-related complications, reinterventions, and medical management. Stent-related complications included in-stent thrombosis, temporary and permanent stent compression, and stent fracture. Data on anti-thrombotic regimes and bleeding complications were also extracted. Due to the scarcity of data, a case report and a series of women treated for acute IFDVT with no stent-related data apart from patency were included.

Outcomes. The primary outcome of this systematic review was post-pregnancy stent patency, with the secondary outcome of interest being the development of any stent-related or thrombotic complications as well as reinterventions during or after pregnancy. Complications included DVT and PE, in-stent thrombosis, temporary and permanent stent compression, stent fracture, and major and minor bleeding. Temporary stent compression was defined as compression of the stent by the gravid uterus with a return to pregravid status after delivery, and permanent compression was defined as stent deformity caused by the gravid uterus that persisted after delivery.

Statistical analysis. Statistical analysis was performed using Microsoft Excel. Continuous variables are reported as the mean ± standard deviation and nominal variables as percentages.

Data quality assessment. The PRISMA guidelines were followed. The Joanna Briggs Institute critical appraisal tool was used to assess the quality of the studies.[9]

RESULTS

A total of seven studies were selected for full-text analysis. The study selection process is illustrated in Fig 1. Of the seven studies, five were retrospective cohort studies, one was a prospective cohort study, and one was a case report. The quality assessment of the studies was done independently by two of us (L.V. and V.V.V.) using the Joanna Briggs Institute critical appraisal tool for case series and case reports.[9] The overall quality of the studies was good. Details of the quality assessment of the studies and number of patients included in each study are listed in Tables I and II.[10-16]

Patient characteristics. A total of 76 women who subsequently became pregnant after iliac vein stenting were identified. The total number of pregnancies was 87. Of the 76 women, 5 had two and 3 had three pregnancies after stenting. The mean age of the patients at stenting was 29.52 ± 5.03 years (range, 20-39 years). The average interval between stenting and the first subsequent pregnancy was 20.82 ± 21.46 months (Table III).

Indications for stenting and stent characteristics. Most of the women (n = 39; 51%) underwent stenting after thrombus removal for acute IFDVT, followed by 35 women (46%) for NIVLs, and 2 (2.6%) for PT lesions. Within the series reporting on patients stented for NIVLs, the main indication to treat was pain. Pappas et al[14] reported pain as the indication for 14 patients, dyspareunia for 6, dysmenorrhea for 9, swelling for 10, and vulvar varices for 4 patients. Villalba et al[16] reported chronic pelvic pain and leg pain for five patients, only chronic pelvic pain for one patient, and only leg pain for one patient. Within the series with information about the stents (n = 52), the mean diameter was 15.64 ± 1.49 mm. Most patients (98%) received them on the left side, including nine across the inguinal ligament (17%). One patient received an additional stent on the right common iliac vein (CIV), and one patient (1.92%) was stented only on the right side.

Management during pregnancy. Most patients were managed according to their thrombotic profile by their obstetrician and/or vascular specialist. Patients considered at high risk of thrombosis because of a personal history of VTE or documented thrombophilia were prescribed anticoagulation at either a prophylactic or therapeutic dose. The patients stented for NIVLs had various therapeutic options. Of the 35 patients stented for NIVLs, 24 (68.57%) received prophylactic anticoagulation, 15 (42.85%) received only low-molecular-weight heparin (LMWH),[10,12,14] 9 (25.71%) received low-dose aspirin combined with LMWH,[15,16] 3 (8.57%) received low-dose aspirin only (8.57%),[14] and 7 (20%) received no anticoagulation therapy (20%).[14,15] For two patients (5.71%), the antithrombotic regimen was unknown.[13,14] Only two series reported a standardized dedicated protocol that included a defined antithrombotic regimen. Hartung et al[10] prescribed prophylactic anticoagulation for all patients, independently of whether they had been stented for NIVL or thrombotic lesions from the third trimester of pregnancy until 1-month postpartum. All the patients were followed up with duplex ultrasound, and those who showed signs of stent compression by the gravid uterus were switched to therapeutic anticoagulation. Villalba and Larkin[16] prescribed all patients low-dose aspirin until pregnancy week 36. The low-risk

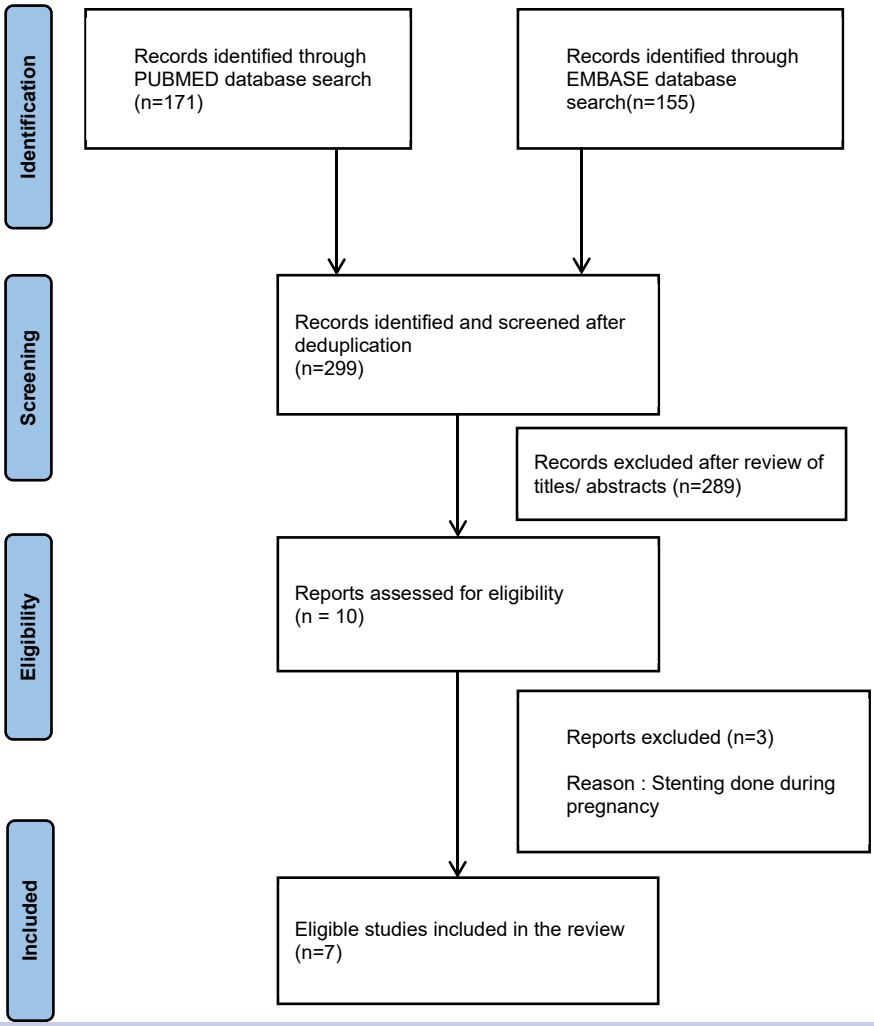

Fig 1. Flow chart showing the selection process for the studies.

patients (those stented for NIVL) received prophylactic anticoagulation only from the last trimester until 6 weeks postpartum, and the high-risk patients received therapeutic doses from the first trimester onward.[16]

Complications during pregnancy and postpartum. Within the 87 pregnancies, only one case of stent occlusion and associated DVT (1.14%) occurred. This event occurred in a patient who had successful thrombus removal for an IFDVT at which she received a stent in the background of having antiphospholipid antibodies. However, the patient was erroneously prescribed LMWH at a prophylactic dose rather than a therapeutic dose and received no aspirin[11] (Table IV). One case of acute femoral vein DVT unrelated to the stent developed in a patient initially treated for NIVLs.[15] The patient was not receiving aspirin or any antithrombotic medication before the DVT.

Two cases of asymptomatic nonocclusive in-stent thrombus were detected by ultrasound surveillance after delivery (2.29%) and were treated with balloon angioplasty. One of the patients had been stented for a NIVL, and it is unclear whether she received prophylactic anticoagulation during pregnancy.[14] The other had received her stent in the setting of a previous postpartum IFDVT and was only prescribed prophylactic anticoagulation and no aspirin because she had not required anticoagulation for 2 years. This patient had a third pregnancy afterward. She was treated with low-dose aspirin and therapeutic LMWH, and her postpartum duplex ultrasound showed no in-stent thrombus.[16]

Regarding stent compression by the gravid uterus, one series noted reversible compression of a Wallstent (Boston Scientific Corp) by the gravid uterus after the eighth month of pregnancy in four patients.[10] All the stents returned to pregravid status after delivery. Two cases of permanent stent compression were found. One occurred with a Protégé stent (Medtronic) and one with a "balloon fenestrated" Vici stent (Boston Scientific Corp), which had been altered at the time of insertion because of

Table I. Quality assessment of included studies using Joanna Briggs Institute critical appraisal tool

Question	Hartung et al[10]	Jørgensen et al[11]	Dasari et al[12]	Shammas et al[13]	Pappas et al[14]	Speranza et al[15]	Villalba et al[16]
Were there clear criteria for the inclusion in the case series?	Yes	Yes	Yes	NA	Yes	Yes	Yes
Was the condition measured in a standard, reliable way for all participants included in the case series?	Yes	Yes	Yes	NA	Yes	Yes	Yes
Were valid methods used for identification of the condition for all participants included in the case series?	Yes	Yes	Yes	NA	Yes	Yes	Yes
Did the case series have consecutive inclusion of participants?	Yes	Yes	No	NA	Yes	No	Yes
Did the case series have complete inclusion of participants?	Unclear	Yes	Yes	NA	Yes	Yes	Yes
Was there clear reporting of the demographics of the participants in the study?	Yes	Yes	Yes	No	Yes	Yes	Yes
Was there clear reporting of clinical information of the participants?	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Were the outcomes or follow-up results of cases clearly reported?	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Was there clear reporting of the presenting sites'/clinics' demographic information?	Yes	Yes	Yes	No	Yes	Yes	Yes
Was the statistical analysis appropriate?	Yes	Yes	Yes	NA	Yes	Yes	Yes

NA, Not applicable.

concerns regarding contralateral caging.[12,16] No stent fracture has been reported. No bleeding complications from anticoagulation therapy were reported. The mean duration of follow-up after pregnancy was 40.19 months (range, 24-63 months).

DISCUSSION

This review encompasses patients from centers all over the globe across the past three decades. The results show that dedicated and nondedicated venous stents perform well throughout pregnancy and postpartum. The long-term outcomes of venous stents are unknown at present, and caution is advised when stenting young patients because their life expectancy could be ≤50 years. However, most patients who would benefit from venous stenting are young, and ∼60% of them are women.[17,18] In the particular case of acute IFDVT, age is an important part of the selection criteria advocated by multiple societies.[1,6,19] Thus, young patients with a low risk of bleeding and a high risk of long-term post-thrombotic syndrome (PTS) are those who should be offered treatment because the incidence of recurrent DVT and PTS is decreased by stenting any underlying stenotic lesions.[20] Previous VTE is a major risk factor for recurrent VTE in pregnancy, with an adjusted odds ratio of 24.8.[5,21] Thus, for women of childbearing age who present with IFDVT, it would make sense to offer thrombus removal and stenting to decrease the risk factors for pregnancy-related recurrent VTE. This review reports excellent patency rates in these patients, with only one patient experiencing patency loss because of inadequate anticoagulation. In women of childbearing age with disabling symptoms due to NIVLs, the decision to stent should be based on the clinical presentation rather than the fear of potential pregnancy, because, regardless of the configuration, venous stents perform well through pregnancy and postpartum.

If considering the alternative (deciding not to stent a severe symptomatic obstructive lesion), one should remember that more than two thirds of DVT cases that occur in women are on the left side[22] and that 56% of patients who developed extensive DVT during pregnancy had evidence of May-Thurner syndrome.[23] DVT in pregnant women occurs more frequently in the left leg (85%) than in nonpregnant individuals (55%) and is more often proximal, with 72% in the iliofemoral veins compared with 9% in those who are not pregnant.[24] Pregnant women also have a greater risk of embolic complications and PTS.[25] Pregnancy is a hypercoagulable state, and venous stasis is worse in the presence of iliofemoral outflow obstruction, increasing the risk of thrombosis.

The results from our review suggest that venous stents do not increase this risk. In fact, it could be argued that

Table II. Summary of research to date on stent performance during subsequent pregnancy

Investigator	Patients, No.	Pregnancies, No.	Stenting indication, No.		Stent brand, No.						Stent location (no.)
			Thrombotic lesion	Nonthrombotic lesion	Wallstent	Protégé	Vici	Venovo	Sinus-Venous	Sinus-Obliquus	
Hartung et al,[10] 2009	6	8	3	3	6	0	0	0	0	0	LCIV-IVC (6)
Jørgensen et al,[11] 2013	24	24	24	0	NR	NR	NR	NR	NR	NR	NR
Dasari et al,[12] 2017	12	16	11	1	4	8	0	0	0	0	LCIV- IVC (2); LCIV-LEIV (6); LCIV-LEIV-LCFV (4)
Shammas et al,[13] 2020	1	1	0	1	0	0	0	1	0	0	LCIV (1)
Pappas et al,[14] 2022	15	17	0	15	13	0	0	3	0	0	LCIV-IVC (3); LCIV-LEIV (2); IVC-LCIV-LEIV (9); LEIV-LCFV (1); IVC-RCIV-REIV (1)
Speranza et al,[15] 2022	8	8	0	8	7	0	1	0	0	0	LCIV-IVC (1); LCIV-LEIV (3); LCIV (4)
Villalba et al,[16] 2023	10	13	3	7	0	0	1	0	13	1	LCIV (1); LCIV-LEIV (4); LCIV-LEIV-LCFV (4); LCIV-LEIV, RCIV (1)

LCIV, Left common iliac vein; *IVC*, Inferior vena cava; *LEIV*, Left external iliac vein; *LFV*, Left femoral vein; *LCFV*, Left common femoral vein; *RCIV*, right common iliac vein; *REIV*, Right external iliac vein.

the use of venous stents lowers the risk by addressing one of the factors of the Virchow triad. Furthermore, no structural damage to the stents was found, suggesting that pregnancy does not adversely affect the stents and that the stents do not adversely affect pregnancy. The only permanently compressed stents were an arterial stent (Protégé) and a balloon-fenestrated Vici stent. None of the other stents was permanently affected by the gravid uterus. However, more than one half of the braided Elgiloy stents that were surveyed throughout pregnancy showed temporary compression, which could increase the risk of thrombosis. No pregnancy-related outcomes with the Zilver Vena stent (Cook Medical Inc) are yet available. Intuitively, it might be preferable to use stents with a greater chronic outward force in women of childbearing age. However, larger studies are required to confirm this. In terms of management during pregnancy, most vascular specialists have reported prophylactic anticoagulation dosages for women with venous stents, regardless of their thrombotic risk, and have found it safe, consistent with the reported literature.[26]

An interesting topic is the management of patients presenting with untreated symptomatic IFVOO during pregnancy. In the case of IFDVT, some authorities, including the American College of Obstetricians and Gynecologists,[27] have advocated for the need to rule out May-Thurner syndrome in pregnant women with acute left lower extremity DVT because of its high incidence and morbidity. However, the best management remains unclear. Concern regarding radiation exposure is a major barrier to the diagnostic and treatment options offered to pregnant patients. However, clinical examination and duplex ultrasound are sufficient to diagnose iliofemoral

Table III. Patient age at stenting, stent and subsequent pregnancy timing, and follow-up

Investigator	Patients, No.	Age at stenting, years	Delay between stenting and subsequent pregnancy, months	Stent diameter, mm	Follow-up duration, months
Hartung et al,[10] 2009	6	26.5	33.5 (median)	16 (median)	NA
Jørgensen et al,[11] 2013	24	NA	NA	NA	NA
Dasari et al,[12] 2017	12	28 ± 4.97	23.25 ± 28.26	14.6 ± 0.98	29.4 ± 34.7
Shammas et al,[13] 2020	1	NA	NA	18	24
Pappas et al,[14] 2022	15	35.29 ± 4.1	30.9	19.73 ± 2.8	43.2 ± 24.1
Speranza et al,[15] 2022	8	30.75 ± 5.49	28.12 ± 19.8	16-18	29.3 ± 14.97
Villalba et al,[16] 2023	10	30.1 ± 4.9	9.8 ± 8.84	15.8 ± 1.02	63.1 ± 8.91

NA, Not available.
Data presented as mean ± standard deviation or range, unless otherwise noted.

Table IV. Summary of complications during subsequent pregnancy

Investigator	Patients, No.	Pregnancies, No.	Complication, No.						
			DVT	PE	Stent occlusion	In-stent thrombus	Temporary stent compression	Permanent stent compression	Stent fracture
Hartung et al,[10] 2009	6	8	0	0	0	0	4	0	0
Jørgensen et al,[11] 2013	24	24	0	0	1	0	0	0	0
Dasari et al,[12] 2017	12	16	0	0	0	0	0	1	0
Shammas et al,[13] 2020	1	1	0	0	0	0	0	0	0
Pappas et al,[14] 2022	15	17	0	0	0	1	0	0	0
Speranza et al,[15] 2022	8	8	1	0	0	0	0	0	0
Villalba et al,[16] 2023	10	13	0	0	0	1	0	1	0
Total	76	87	1	0	1	2	4	2	0

DVT. Endovascular techniques and thrombolytic therapies have also been safely performed in pregnant patients, including stenting.[28-34] Studies have reported a radiation dose resulting from catheter-directed thrombolysis in the first trimester ranging from 175 to 245 mGy, which is associated with a childhood cancer risk of 1.3% to 2%. This value is 6 to 10 times higher than the risk associated with environmental or background radiation exposure; however, appropriate positioning, shielding, and the use of intravenous ultrasound can decrease the risk.[35] Stenting a culprit lesion found after thrombus removal is recommended by multiple societal guidelines and is usually necessary to maintain flow, prevent recurrence, and decrease the risk of PTS.[21,36-38] Patients with known PT lesions or NIVLs who have not yet undergone stenting and want to become pregnant should be advised of the increased risk of worsening symptoms and VTE complications during pregnancy and postpartum. Daily exercise, leg elevation, compression garments, and calf pump devices should be recommended, and close follow-up should be organized.

As stated, PT patients should receive LMWH, because recurrent VTE is a significant risk factor for VTE in pregnancy. The literature is unclear regarding the management of patients with NIVLs. However, we know that left CIV (LCIV) stenosis is an independent risk factor for VTE. In a study by Chen et al,[39] the odds of left DVT increased by 2.69 for each 1-mm decrease in the LCIV diameter and 2.78 for each 10% increase in LCIV stenosis. With LCIV stenosis >75%, the risk of left DVT was associated with an 11-fold increase. With a LCIV diameter <2.5 mm, the risk was associated with a 13.5-fold increase. Another study by Carr et al[40] of female patients aged <45 years with a diagnosis of lower extremity DVT reported that the odds of left DVT increased by a factor of 1.68 for each 1-mm decrease in the LCIV diameter. The diameter was 4.0 mm for patients with DVT and 6.5 mm for patients without DVT. The association of LCIV stenosis and oral contraceptive use in the development of VTE has also been described by Chan et al.[41] They reported that the odds of DVT in women with 70% venous stenosis was associated with a 17-fold increase.[41]

Currently, no guidelines are available for the management of these patients, and grading of venous stenosis continues to be a challenge.[42] From the available evidence and our experience, we recommend consideration of prophylactic anticoagulation during the last trimester and 6 weeks postpartum for women with a symptomatic NIVL, in particular those with documented CIV fixed stenosis (evidence of wall thickening, trabeculae, or synechiae) of ≤5 mm on a prepregnancy duplex ultrasound scan that uses validated duplex ultrasound criteria.[43] If the stenosis is less severe and no signs of endothelial damage are present, mechanical prophylactic measures might be sufficient. Our approach is multidisciplinary, involving general practitioners, obstetricians, hematologists, and patients. Regardless of whether the patient has undergone stenting, we offer close follow-up and advice on prophylactic measures to prevent complications during pregnancy and postpartum. We also believe it is important to educate patients regarding the signs and symptoms to be aware of and when to seek attention. We also ensure they have access to institutions that can provide interventional management if DVT or pulmonary embolism should occur during pregnancy or postpartum.

A suggested protocol for women of childbearing age with treated or untreated IFVOO is depicted in Fig 2. Enoxaparin is the drug of choice, at a prophylactic dose of 40 mg daily, with therapeutic doses prescribed twice daily, starting at a weight base recommendation adjusted as the pregnancy progresses, depending on the results of regular factor Xa testing. We also recommend aspirin until week 36. Reye syndrome is a serious, but rare, condition that can occur at any age but usually affects children and adolescents after a viral infection associated with aspirin intake. We are unaware of any cases affecting children in utero and have not found

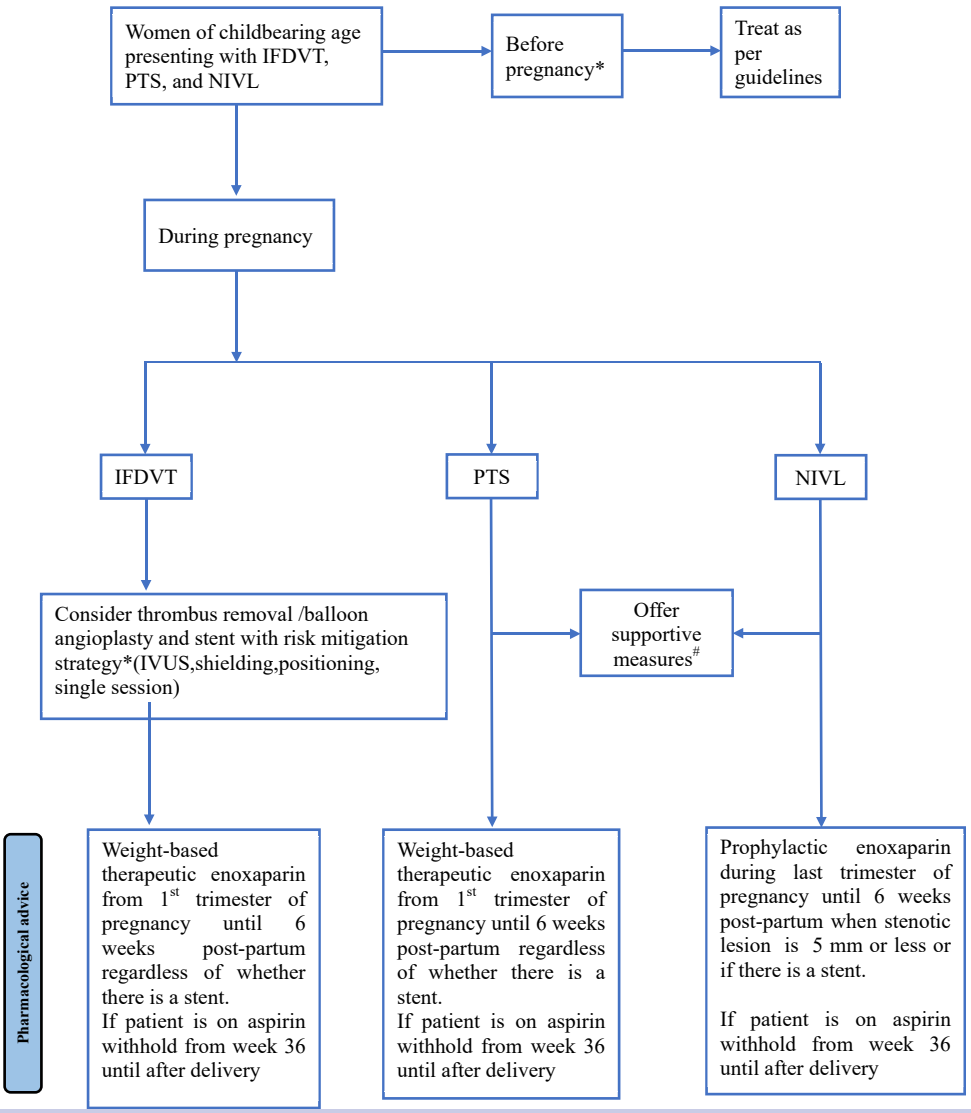

Fig 2. Suggested protocol for the management of women of childbearing age presenting with symptomatic venous outflow obstruction. *IFDVT,* Iliofemoral deep vein thrombosis; *IVUS,* intravascular ultrasound; *NIVL,* non-thrombotic iliac vein lesion; *PTS,* post-thrombotic syndrome. *If a patient presents with IFDVT and a culprit lesion is found, stenting is advised to help restore flow, decrease recurrence, and decrease the risk of PTS. #Supportive measures include exercise, leg elevation, compression garments, calf pump devices, and education.

any reports of Reye syndrome occurring in pregnancy either.

Study limitations. The major limitation of the present review is the small numbers, likely an underrepresentation of the true incidence of pregnancy after vein stenting, the lack of controls, and the retrospective nature of the studies. A publication bias is also a potential limitation.

CONCLUSIONS

Venous stents perform well throughout pregnancy and postpartum with excellent patency rates, no structural damage to the stents, and no stent-related VTE. Pregnancy-related stent complications are rare. Anticoagulation is recommended for women with previous VTE or documented thrombophilia. However, for women who have undergone stenting for NIVLs, the need for anticoagulation is less clear. Given the increased risk of VTE with pregnancy and the low bleeding risk with LMWH, it is prudent to recommend prophylactic anticoagulation to all stented patients until more data are available.

AUTHOR CONTRIBUTIONS

Conception and design: LV
Analysis and interpretation: LV, VV, RT
Data collection: LV, VV
Writing the article: LV, VV
Critical revision of the article: LV, VV, RT

Final approval of the article: LV, VV, RT
Statistical analysis: VV
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Overall responsibility: LV
LV and RT contributed equally to this article and share co-senior authorship.

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