

# Outcomes of dedicated iliac venous stents during pregnancy and postpartum

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## ABSTRACT

**Objective:** The aim of this study was to assess the performance of dedicated iliac venous stents during subsequent pregnancy and postpartum, including stent patency and stent integrity, as well as incidence of venous thromboembolism and bleeding complications.

**Methods:** This study included retrospective analysis of prospectively collected data of patients attending a private vascular practice. Women of child-bearing age who had received dedicated iliac venous stents were included in a surveillance program and then, for any subsequent pregnancies, followed the same pregnancy care protocol. This included an antithrombotic regime of 100 mg aspirin daily until gestation week 36, and subcutaneous enoxaparin at a dose dependent on risk of thrombosis: low-risk patients, those stented for non-thrombotic iliac vein lesion, received a prophylactic dose of 40 mg/day from the third trimester; high-risk patients, those stented for thrombotic indication, received a therapeutic dose of 1.5 mg/kg/day from the first trimester. All women underwent follow-up with duplex ultrasound assessment of stent patency during pregnancy and at 6 weeks postpartum.

**Results:** Data was analyzed for a total of 10 women and 13 post-stent pregnancies. Stents were placed for non-thrombotic iliac vein lesions in seven patients, and for post-thrombotic stenoses in three patients. All stents were dedicated venous stents, and four crossed the inguinal ligament. All stents remained patent during pregnancy, at 6 weeks postpartum, and latest follow-up (median time post-stent, 60 months). There were no cases of deep vein thrombosis or pulmonary embolism, and no bleeding complications. There was only one reintervention case due to in-stent thrombus, and one case of asymptomatic stent compression.

**Conclusions:** Dedicated venous stents performed well through pregnancy and post-partum. A protocol including the use of low dose antiplatelets in combination with anticoagulation at either a prophylactic or therapeutic dose depending on the patient's risk profile appears safe and effective. (*J Vasc Surg Venous Lymphat Disord* 2023;11:768-73.)

**Keywords:** Iliac vein; May Thurner syndrome; Pregnancy; Stent patency; Thrombotic; Venous thromboembolism

Venous stenting has become the preferred treatment of iliac vein lesions, including non-thrombotic iliac vein lesions (NIVL), post-thrombotic lesions (PT), and lesions found after thrombus removal in the setting of an acute iliofemoral DVT. Favorable long-term patency rates after treatment with self-expanding dedicated and non-dedicated venous stents have been widely reported<sup>1-7</sup>; however, concerns remain about stenting women of childbearing age. This is because pregnancy is a hypercoagulable state,<sup>8</sup> and any prolonged bed rest during the postpartum period, especially after a complicated

delivery, poses an additional risk. During pregnancy, decreased venous tone and pressure of the gravid uterus on the abdomino-pelvic veins cause significant hemodynamic changes. There is also an increase in clotting factors (I, II, VII, IX, and X), decreased fibrinolysis, and a reduction in the natural anticoagulant, protein S.<sup>8</sup>

The concern with stenting women of child-bearing age relates to not only the hypercoagulable state of pregnancy but also the possibility of the gravid uterus compressing the stent or the inflow vessels, potentially causing thrombosis and eventually stent occlusion. Pregnancy-associated venous thromboembolism (VTE) makes up about 10% of all VTE in women,<sup>9</sup> and remains one of the leading causes of maternal death during pregnancy.<sup>10</sup> The incidence of deep vein thrombosis (DVT) specifically, is more than five times higher during pregnancy and approximately 20 times higher during puerperium compared with non-pregnant women.<sup>9,11-14</sup> Previous VTE is a major risk factor for recurrent VTE in pregnancy,<sup>11</sup> and more than two-thirds of DVT that occurs in women is on the left side. It is unclear in the literature whether women with clinically relevant venous outflow obstruction should wait until after pregnancy

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to undergo venous stenting or if venous stents are safe during pregnancy. Furthermore, an anticoagulation regime to protect stent patency while pregnant could increase the risk of bleeding. Due to the scarcity of literature on this topic, there are no clear guidelines on the management of pregnant patients who have venous stents.

The current literature on the performance of venous stents during pregnancy includes only six studies to date, encompassing 66 patients and 74 pregnancies (Table 1), in which non-dedicated venous stents, including the Wallstent endoprosthesis (Boston Scientific Corporation) and the Protégé (Medtronic) represent the majority of cases. Dedicated venous stents are considered an improved version of the Wallstent, and these vary in design, including closed-cell, open-cell and hybrid designs, and also have variable crush resistance and flexibility.<sup>12</sup> In line with the increased availability and use of dedicated venous stents, it is important to assess their performance during pregnancy. To our knowledge, only four cases of dedicated venous stents have been included in previous reports: three Venovo stents (BD Interventional)<sup>17,18</sup> and one Vici stent (Boston Scientific Corporation).<sup>19</sup> The current study adds to the literature and is unique in the sense that it is a series of patients treated exclusively with self-expanding nitinol dedicated venous stents, the majority being Sinus Venous (Optimed Medizinische Instrumente GmbH). Previous research is also limited by a lack of standardization of antithrombotic treatment, with inconsistencies in timing, duration, and dosage of anticoagulation and antiplatelet therapy. Further, three of the previous studies included only women with non-thrombotic lesions.<sup>17-19</sup>

In the current series, all patients received a dedicated antithrombotic protocol during pregnancy and puerperium. The objectives of this study were to assess the performance of dedicated venous stents during pregnancy and postpartum, including stent patency and stent integrity, as well as safety and efficacy of a dedicated antithrombotic protocol.

## METHODS

This study includes retrospective analysis of prospectively collected data. The institutional review board approved the study, including that no consent was required because data was collected according to usual clinical care and de-identified before analyses. All women of child-bearing age (18-45 years old) who had undergone femoro-iliac stenting for acute DVT, or post-thrombotic or non-thrombotic iliac vein lesions between 2015 and 2022 were identified from a prospectively maintained database at the Vascular Care Centre in Wollongong, NSW, Australia. Those in this surveillance program who subsequently became pregnant then followed the Vascular Care Centre's pregnancy care protocol. All pregnancies were managed with a

## ARTICLE HIGHLIGHTS

- **Type of Research:** Single-site, prospective cohort study
- **Key Findings:** Among 10 women who had received dedicated iliac venous stents for either a non-thrombotic or thrombotic indication, and 13 post-stent pregnancies, during which a dedicated protocol for stent thrombosis prevention was followed, there was a 100% patency rate, no bleeding complications, and no venous thromboembolism during pregnancy or puerperium.
- **Take Home Message:** Dedicated iliac venous stents perform well during subsequent pregnancy with no stent occlusion or fracture. The antithrombotic regimen of anticoagulation and antiplatelets used in this cohort was safe and effective. Child-bearing age should not be a contraindication to venous stenting.

multidisciplinary team (MDT) approach including obstetricians specialized in high-risk pregnancies, vascular surgeons, hematologists, and the patient's general practitioner.

In terms of the antithrombotic treatment, the protocol included 100 mg aspirin daily up until gestation week 36, and the anticoagulation regime was determined by risk stratification of patients by the MDT into low vs high risk of thrombosis. Patients who were stented for NIVL were considered low risk while patients stented for thrombotic lesions were considered high risk. Anticoagulation with low molecular weight heparin (LMWH) was started from the first trimester in the high-risk group with the dose individualized depending on the specific risk profile, and in the third trimester in the low-risk group with a prophylactic dosage of 40 mg/day. All women underwent serial clinical follow-ups and duplex ultrasounds to assess stent patency and integrity at 3, 6, and 8 months of pregnancy and at 6 weeks postpartum. A scheduled delivery with either induction of labor or elective caesarean section was planned for all patients to minimize bleeding complications. The plan included stopping anticoagulation 24 hours prior to delivery, to be restarted within 24 hours postpartum if considered safe by the obstetrician in charge.

Data analyzed included: patient characteristics (age, number of pregnancies after stenting, time between stenting and delivery, and indication for stenting); stent details (number, size, location, and design); anticoagulation and antiplatelet treatment (prior, during, and after each pregnancy); stent patency and stent integrity (compression, stenosis, or fracture) during pregnancy and at 6 weeks postpartum; any bleeding complications and incidence of VTE (DVT or PE).

**Table I.** Summary of research to-date that has examined stent performance during subsequent pregnancy

Reference	No. Patients	No. pregnancies	Indication for stenting		Stents used			
			Thrombotic lesion	Non-thrombotic lesion	Wallstent	Protege	Vici	Venovo
Hartung et al, 2009 <sup>3</sup>	6	8	n = 3	n = 3	n = 6	–	–	–
Jørgensen et al, 2013 <sup>15</sup>	24	24	n = 24	–	Stent type(s) not reported			
Dasari et al, 2017 <sup>16</sup>	12	16	n = 11	n = 1	n = 4	n = 8	–	–
Shammas et al, 2020 <sup>17</sup>	1	1	–	n = 1	–	–	–	n = 1
Pappas et al, 2022 <sup>18</sup>	15	17	–	n = 15	n = 13	–	–	n = 3
Speranza et al, 2022 <sup>19</sup>	8	8	–	n = 8	n = 7	–	n = 1	–

## RESULTS

**Patient characteristics.** There was a total of 10 women in the surveillance program who became pregnant after venous stenting (Table II). Three of these patients were nulliparous at the time of stenting, whereas the remaining seven women had at least one previous pregnancy prior to the stenting. Among these 10 women, there was a total of 13 post-stent pregnancies, with three of these patients having two pregnancies each. The mean age at the time of stenting was  $30.1 \pm 4.9$  years (range, 28-38 years). None of the non-thrombotic patients had previous VTE, and none of the thrombotic patients had documented thrombophilia. The only patient who was on lifelong anticoagulation as per hematology advice was one of the two patients who had been stented for recurrent iliofemoral DVT.

**Stenting indications.** The majority of women had received a stent for a non-thrombotic iliac vein lesion ( $n = 7$ ). Of the three patients who had a thrombotic indication for stenting, two received stents in the acute setting following clot removal for iliofemoral DVT (one of them in the immediate postpartum of her first pregnancy), and the third patient was stented for occlusive post thrombotic syndrome. All patients who had received stents electively had disabling symptoms and had failed alternative management, with most patients being stented for chronic pelvic pain (CPP) as their main concern (Table II). Five patients became pregnant within 12 months of stenting, including four within 3 months. At the beginning of our experience, pregnancy advice was not standardized, but after a few unplanned pregnancies, anecdotally attributed by the patients to the resolution of their dyspareunia and post-coital pain, we started recommending contraception for 6 months post-stenting, and changed our postoperative protocol to anticoagulation and antiplatelets for the same period of time.

**Stent details.** All women had stent placement into the left common iliac vein (CIV). Only one of these stents landed in the distal CIV. For five women, the stent landed

in the external iliac vein (EIV), including one which was bilateral due to bilateral stenoses as well as concerns of caging the contralateral side. Four women had a second stent inserted, which continued along the left EIV into the common femoral vein (CFV), crossing the inguinal ligament.

Of the 15 stents used, there was one closed-cell design (Vici; Boston Scientific Corporation), one hybrid design (Sinus-Obliquos; Optimed Medizinische Instrumente GmbH), and the remaining 13 stents were open-cell design (Sinus-Venous; Optimed Medizinische Instrumente GmbH). The majority of the stents were 16 mm in diameter; one patient received an 18-mm stent; and two of the stents that landed in the CFV were 14 mm. Sizing was based on measurements of the veins by venography prior to 2018. After that time, intravascular ultrasound (IVUS) was used routinely to determine vein diameters.

**Pharmacological antithrombotic regime before, during, and after pregnancy.** The post-stenting anti-thrombotic regime evolved over time, with non-thrombotic patients in this series receiving antiplatelets only, whereas patients who were stented for thrombotic complications had anticoagulation for at least 6 months in addition to antiplatelets. All patients were on 100 mg aspirin/daily prior to pregnancy and were advised to continue this throughout the pregnancy up until gestation week 36. All patients followed this regime, except one during her first post-stent pregnancy. All non-thrombotic patients were considered at low risk for thrombosis and received prophylactic doses of subcutaneous LMWH 40 mg/daily during the third trimester and until 6 weeks postpartum. All three patients stented for thrombotic complications received anticoagulation from the first trimester, throughout pregnancy and puerperium. Two of these received a therapeutic dose (1.5 mg/kg daily) of LMWH with the dose adjusted as per Factor Xa levels as the pregnancy progressed and the patient's weight changed. The third patient only received 40 mg/daily of LMWH during her first post-stent pregnancy, because her stent for an iliofemoral DVT had

**Table II.** Patient, stent, and pregnancy data for women with dedicated iliac venous stents who subsequently became pregnant

Age at stenting, years	Indication for stent	Main symptom	CEAP score	VCSS pain score	Pelvic pain VAS (0-10)	Number of stents	Stent type	Stent size, mm	Across inguinal ligament	Total length, mm	Months from stent to pregnancy 1	Months from stent to pregnancy 2	Latest follow up post-stent, months
33	NIVL	CPP and leg pain	4	2	6	1	Sinus Venous	18	No	100	21	-	69
35	NIVL	CPP	0	0	8	1	Sinus Obliquos	16	No	60	24	-	62
28	NIVL	Leg pain	4	2	0	1	Sinus Venous	16	No	120	3	-	56
31	NIVL	CPP and leg pain	3	2	5	1	Sinus Venous	16	No	120	2	49	60
33	NIVL	CPP and leg pain	3	2	7	2	Sinus Venous × 2	16, 16	No	150	2	-	59
28	NIVL	CPP and leg pain	4	3	8	2	Sinus Venous × 2	16, 16	Yes	220	7	-	51
21	NIVL	CPP and leg pain	3	2	5	1	Sinus Venous	16	No	120	1	50	60
26	IFDVT					2	Sinus Venous × 2	16, 16	Yes	200	20	56	60
28	IFDVT					2	Vici + Sinus Venous	16, 14	Yes	220	6	-	82
38	PTS	Leg pain	3	2	0	2	Sinus Venous × 2	16, 14	Yes	220	12	-	72

CPP, Chronic pelvic pain; IFDVT, iliofemoral deep vein thrombosis; NIVL, non-thrombotic iliac vein lesion; PTS, post-thrombotic syndrome; VAS, Visual Analog Scale.

remained patent for 2 years with no anticoagulation for the previous 18 months. This is the same patient who also stopped taking aspirin during this pregnancy.

**Pregnancy and delivery.** All patients had a scheduled delivery for between 36 and 38 weeks, although two patients went into labor and safely delivered ahead of their scheduled delivery date. The remainder had an induction of labor and vaginal delivery or elective caesarean section. All patients delivered healthy babies.

**Stent performance.** Duplex scans throughout pregnancy showed widely patent stents, and all stents remained patent at 6 weeks postpartum and the latest follow-up duplex ultrasound at  $63.1 \pm 8.9$  months post-stent (median, 60 months). There was no incidence of VTE or bleeding, and the only complications (Table III) were one case of in-stent non-occlusive thrombus and one case of stent compression; only the former required reintervention so far.

The sole case of in-stent sub-occlusive thrombus during pregnancy was the patient who, despite having had an extensive iliofemoral DVT requiring clot removal and stenting postpartum after her first pregnancy, was treated with only a prophylactic dose of LMWH, and also did not take aspirin during her first post-stent pregnancy (her second pregnancy). Duplex ultrasound at 6 weeks postpartum showed that the stent had moderate in-stent stenosis. This did not resolve despite 6 months of therapeutic anticoagulation, and the patient subsequently underwent prophylactic balloon

angioplasty with a good result. Two years later, she became pregnant again, and during this pregnancy, she was treated as a high-risk patient and received a therapeutic dose of LMWH and aspirin throughout the pregnancy. The 6-week postpartum duplex ultrasound after this last pregnancy showed no evidence of in-stent stenosis.

The patient who had had significant compression identified at the duplex ultrasound at 6 weeks postpartum was the only one with a closed-cell (Vici) stent. Interestingly, at the time of insertion, the stent underwent balloon fenestration because it was caging the contralateral side. Duplex measurement at the proximal CIV stent throughout the pregnancy was 9.4 mm, and at 6 weeks postpartum, was 5.7 mm (40% stenosis). This patient had received a 16-mm Vici stent to treat a lesion in the left CIV, after clot removal for extensive recurrent iliofemoral DVT, in 2015 in a different institution. Six years later, prior to her pregnancy, severe in-stent and EIV and CFV stenoses were found, despite her being on lifelong anticoagulation, so she underwent balloon angioplasty and stent extension into the EIV with a Sinus-Venous stent. The patient has not received treatment for the compression yet because she remains asymptomatic, and at the time of writing this article, is only 8 weeks postpartum.

## DISCUSSION

Among women who received dedicated venous stents and subsequently became pregnant, no loss of stent patency, structural damage to the stents, incidence of

**Table III.** Complications during pregnancy and postpartum in women with dedicated iliac venous stents

Complications	No. events per total pregnancies
Deep venous thrombosis	0/13
Pulmonary embolism	0/13
Bleeding	0/13
In-stent thrombus	1/13
Stent compression	1/13
Stent fracture	0/13

DVT or PE, or bleeding complications were found in the current study. These findings are consistent with the literature but add to previous research because our series is the largest series to date for exclusively dedicated venous stents and a consistent and well-described antithrombotic treatment regime. This is also the first series to publish on the performance of Sinus Venous and Sinus Obliquos stents (Optimed Medizinische Instrumente GmbH) in pregnancy and puerperium.

An anti-thrombotic regime in all thrombotic patients is advisable, regardless of whether they have had a stent or not, particularly considering the adjusted odds ratio for the impact of previous VTE on development of recurrent VTE in pregnancy is 24.8.<sup>11</sup> A previous study of 24 thrombotic patients who underwent stenting after thrombolysis for DVT and later became pregnant reported a single VTE event<sup>15</sup>; however, this patient had documented anti-phospholipid antibodies and was erroneously prescribed anticoagulation at standard prophylaxis dosage with no aspirin instead of at a therapeutic dosage with aspirin. Among studies of patients stented for NIVL lesions, no VTE events were reported, despite inconsistent anticoagulation regimes, with prophylactic anticoagulation prescribed throughout pregnancy, only during the last trimester, or not at all.<sup>18,19</sup>

The only in-stent sub-occlusive thrombosis in the current study was a patient who despite having had extensive DVT requiring clot removal and stenting in her previous pregnancy was prescribed prophylactic rather than therapeutic LMWH and did not take aspirin. The decision was based on the fact that she did not have any documented thrombophilia and was not on lifelong anticoagulation. Our protocol has now changed, and all patients stented for thrombotic complications receive therapeutic anticoagulation throughout pregnancy regardless of whether they have documented thrombophilia or not.

An important finding in the current study and previous research is no significant bleeding complications when prophylactic or therapeutic anticoagulation was used, even with concurrent low dose aspirin; this is supported by a recent Cochrane review.<sup>20</sup> Although Speranza et al<sup>19</sup> support anticoagulation in patients with risk

factors or history of VTE, they suggested this might not be needed in patients without risk factors. However, pregnancy is a hypercoagulable state and the bleeding risk with LMWH is low.<sup>17</sup> Accordingly, we agree with Pappas et al<sup>18</sup> that although pregnancy-related stent complications are uncommon, all women with venous stents and not only those considered high risk, should be treated with prophylactic LMWH anticoagulation.

There was evidence of mechanical stent compression by the gravid uterus in one case of 13 pregnancies (8%) in the current study; this was the only closed-cell stent design (Vici stent), and the stent integrity was altered because the stent had been balloon-fenestrated at the time of insertion. The current results for dedicated venous stents compare favorably with others that reported on non-dedicated venous stents, with no structural stent damage reported in several studies that included combinations of non-thrombotic and thrombotic patients.<sup>13,17-19</sup> However, among 12 patients, all but one of whom were stented due to thrombotic disease, there was one asymptomatic compression in a Protégé stent that was identified 12 months post second delivery.<sup>16</sup> Interestingly, four of six patients stented with Wall-stent had evidence of stent or inflow vessel compression on duplex ultrasound at 8 months of pregnancy.<sup>13</sup> Anticoagulation was selectively prescribed, no patency loss occurred, and at postpartum follow-up, the stents were back to normal. Further assessment and comparison of stent designs in terms of the impact of pregnancy is necessary.

The main limitation of our study is its small size. Also, despite three patients having two pregnancies each, it is still unknown whether multiple pregnancies could affect stent structure over time. The strengths were that the patients were followed-up prospectively, with a median follow-up time of 60 months, and they followed a protocol including serial imaging, multidisciplinary input and a tailored anti-thrombotic regime. The latter supports good outcomes in patients and is appropriate until more evidence comes available to guide management of women with iliac venous stents during subsequent pregnancies.

In conclusion, dedicated venous stents performed well through pregnancy with no patency loss, and no DVT or PE. Only one asymptomatic stent compression was seen on a fenestrated Vici stent but none with Sinus Venous or Sinus Obliquos and one asymptomatic in-stent sub-occlusive thrombosis in a patient who received insufficient anticoagulation. There were no bleeding complications from the anti-thrombotic regime. A protocol of low-dose antiplatelets in combination with anticoagulation at either a prophylactic or therapeutic dose depending on the patient's risk profile appears safe and effective; however, studies that report on a larger sample size of patients are necessary.

## AUTHOR CONTRIBUTIONS

Conception and design: LV

Analysis and interpretation: TL

Data collection: LV

Writing the article: LV, TL

Critical revision of the article: LV, TL

Final approval of the article: LV, TL

Statistical analysis: Not applicable

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Overall responsibility: LV, TL

LV and TL contributed equally to this article and share co-senior authorship.

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