

Factors Associated with Contralateral Deep Venous Thrombosis after Iliocaval Venous Stenting

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WHAT THIS PAPER ADDS

This study suggests that placement of iliac venous stents across the iliocaval confluence is a safe procedure. It is associated with a low incidence of contralateral iliac DVT, and if this occurs, early clot removal may be performed with good results. Acute DVT, pre-operative contralateral IIV thrombosis, pre-existing IVC filters, anticoagulation non-compliance, and malignant compression are significant factors that may increase the risk of subsequent contralateral DVT.

Background: The majority of iliac venous obstructions occur on the left side, and endovascular therapy has become the first line treatment for this condition. A left common iliac venous stent will protrude into the inferior vena cava (IVC) to some extent, thereby covering the contralateral common iliac vein (CIV) outflow. This may increase the risk of thrombosis of the contralateral iliac vein. The aim of this paper was to determine the rate of, and factors associated with, contralateral lower limb venous thrombosis after stenting, and to evaluate the results of salvage revascularisation.

Methods: A total of 376 patients (102 from UCH, Galway, Ireland, 2008–16, and 274 from, CHU Nord, Marseille, France, 2000–15) with symptomatic acute or chronic left iliocaval venous obstruction were retrospectively evaluated. Either duplex ultrasound scanning (DUS) or computed tomographic venography (CTV) was used for pre- and post-operative imaging. Data were collected from the PACS system (IMPAX, Agfa, BE) of the Radiology Department, UCH, Galway, and from the electronic medical records of Vascular Surgery department, CHU Nord, Marseille.

Results: The median age of stented patients was 46 (range 15–86 years), 80% were female (301/376). Following left CIV stent placement, 10 patients later presented with a right (contralateral) iliac deep venous thrombosis (DVT) resulting in a cumulative incidence of contralateral DVT of 4% according to Kaplan-Meier analysis. Acute DVT ($p = .001$), non-compliance with the prescribed 6 months anticoagulation ($p = 0.05$), pre-operative contralateral internal iliac vein (IIV) thrombosis ($p = 0.001$), and pre-existing IVC filter placement ($p = 0.003$) were all statistically significantly associated with contralateral DVT. All patients with symptomatic contralateral iliac DVT underwent clot removal in the acute phase. The primary patency of these limbs was 100% at 3 years.

Conclusion: Stent placement across the iliocaval confluence from the left CIV is associated with a low but definite rate of contralateral iliac vein thrombosis. Acute DVT, pre-operative contralateral IIV thrombosis, pre-existing IVC filters, and anticoagulation non-compliance are significant risk factors.

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INTRODUCTION

Percutaneous endovenous stenting has emerged during the last two decades as the method of choice to treat

venous outflow obstruction (VOO) revealed after acute or chronic obstruction¹ with excellent long-term clinical outcome and low complication rates.² Precise stenting of the proximal common iliac vein (CIV) can be challenging due to the difficulty in accurately locating the iliac vein confluence on venography and the limitations of current stent design, which may lead to proximal end stent collapse with caudal stent migration when stents are positioned exactly at the confluence with a high risk of recurrent thrombosis.^{2,3}

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To overcome the difficulties of stent placement close to the ilio caval confluence, the cranial end of the venous stent will by necessity project into the inferior vena cava (IVC) to a variable extent; which may result in partial or complete coverage of the contralateral CIV outflow.⁴ This may increase the risk of thrombosis of the patient's normal contralateral iliofemoral vein. The aim of this study was to determine the rate and factors associated with contralateral limb thrombosis after ilio caval venous stenting in two different groups and to evaluate the results of the treatment.

METHODS

Data of patients treated for symptomatic left ilio caval venous obstruction were retrospectively collected from two different hospitals: PACS system (IMPAX, Agfa, Mortsels, BE) and Philips client programs in the Radiology Department of Galway University Hospital, and the electronic medical records of the Vascular Surgery Department, CHU Nord, Marseille. An SPSS 23.0 spreadsheet was prepared and included demographics, details of the pre-operative work-up, the extent of thrombosis, disease type and extent, and procedural details, including the type and size of stent, degree of stent projection into the IVC lumen, post-operative outcome, incidence of contralateral deep vein thrombosis (DVT), and the time elapsed prior to its development. All cases of initial right lower limb DVT, initial IVC involvement and loss of follow-up were excluded. Patency was assessed by combining clinical observation, duplex ultrasound scanning (DUS), computed tomographic venography, venography, and/or IVUS (intravascular ultrasound).

Technique

Using pre-operative imaging, possible access sites were chosen in advance. The prone ipsilateral popliteal approach under ultrasound guidance was used to gain access in most patients with acute iliofemoral deep venous thrombosis (IFDVT) (70%). In patients with post-thrombotic disease, access was obtained mainly through the common femoral vein (76%), ipsilateral femoral vein (6%), and/or right internal jugular vein (18%). A permanent retrievable IVC filter was applied in 15% (55/376), mainly through the right jugular vein approach ($n = 40$), right common femoral vein (CFV) ($n = 12$) and ipsilateral popliteal vein prone approach ($n = 3$).

All patients with acute IFDVT underwent pharmacomechanical thrombolysis alone or in combination with catheter directed thrombolysis before stent placement, and then the underlying obstructing lesion was addressed.⁵ A variety of stents, which changed over time as "dedicated" venous stents emerged, were employed and extended across the iliac confluence to support all diseased segments. Stents were dilated to nominal size to ensure adequate apposition to the vessel wall and to avoid possible stent migration. Over the later period of the study, IVUS was employed to assess stent placement and stent expansion. Success was obtained once completion venography

revealed perfect in line flow with no holdup of contrast and abolition of collaterals.

Post-operative care and follow-up

All patients had intermittent pneumatic compression (Tyco, Covidien, Galway, Ireland) overnight until they mobilised. Patients were discharged with fitted thigh length stockings (20–25 mmHg) for 6 months. All patients with acute DVT or post-thrombotic lesions were prescribed anticoagulation: low molecular weight heparin (LMWH) followed by coumarin anticoagulation with a target INR (2–3) for 6 months and 1 year of clopidogrel. In underlying malignant disease, LMWH was continued alone according to guidelines.⁶ Those with recurrent DVT or known thrombophilia were recommended lifelong anticoagulation. All patients underwent post-operative DUS before discharge to assess venous patency and to exclude acute re-thrombosis.⁷ Follow-up was clinical and by repeat DUS at 1, 3, 6, and 12 month intervals and annually thereafter. If symptoms occurred during surveillance, computed tomography venography (CTV) was performed. CT scans obtained through oncology follow-up were used to assess the stent in patients with underlying malignancy.⁸

Statistical analysis

Retrospectively collected data were analysed using SPSS (23.0). Cumulative primary, primary assisted, and secondary patency rates as defined by common standards were registered¹; the freedom from contralateral iliac DVT and intention to treat, were performed by survival analysis using the Kaplan–Meier method. The predictors and incidence of contralateral iliac DVT after ilio caval vein stenting and the results of salvage revascularisation were studied using the log-rank test. Continuous variables were analysed with the Student *t* test, and the Fisher exact test was used for categorical data. In all cases, $p < .05$ was considered significant.

RESULTS

A total of 376 patients in two groups from UCHG ($n = 102$; 2008–16) and CHU, Nord ($n = 274$; 2000–15), median age 46 (15–86 years), presenting with left lower limb VOO and undergoing left ilio caval venous stenting, were included in the study. Demographics, past medical history, and aetiology of treatment of the two patient groups are presented (Tables 1 and 2). The clinical presentation was acute with IFDVT ($n = 80$) or gradual development of symptoms for chronic venous disease ($n = 296$). Fifty-three of 170 (31%) patients tested positive for thrombophilia: factor V Leiden ($n = 24$) and factor VIII deficiencies ($n = 11$), anti-thrombin III ($n = 8$), Protein C and S deficiency ($n = 10$). Anatomical and operative details from the initial stenting procedure are given in Table 2. A total of 620 venous stents of different brands and diameters were placed. The majority of stents used in this study were Wallstents (BSCL, Galway, IE) (84%) (Table 3). In 2% (12/376) of patients, anticoagulation was contraindicated, and 98% of patients were maintained on their anticoagulation treatment during follow-up. No major

Table 1. Demographics and past medical history in 376 patients with iliofemoral stent placement.

Demographics	Frequency	Contralateral DVT		<i>p</i> *
		Yes	No	
Number	376	10 (2.6%)	366	
Median age, years	46 (range 15–86)			NS
	UCHG (52)			
	CHU (42)			
Gender				NS
Female	301 (80%)	8	293	
Male	75 (20%)	2	73	
History of old DVT	114 (30%)	2	8	NS
History of	(53/170, 31%)	1	52	NS
thrombophilia				
History of	42 (13%)	3	39	NS
malignancy				
Hypertension	10 (2%)	1	9	NS
Diabetes	5 (1%)	1	4	NS
Cardiac disease	3	0	3	NS
Smoking	45 (10%)	2	43	NS

* Multivariate analysis of patient characteristics showed no significant difference in patients who developed contralateral DVT.

Table 2. Anatomical and operative details.

Operative details	Frequency	Contralateral DVT		<i>p</i>
		Yes	No	
Operative side <i>Left</i>	376	10	366	NS
Reason for treatment				
Onset acute	80 (21%)	7	73	.001
Chronic	296 (79%)	3	294	.01
Cause	42 (11%)	3	39	
Malignancy	219 (58%)	5	214	
Non-thrombotic iliac vein obstruction	114 (30%)	3	111	
Post-thrombotic obstruction	2 (0.5%)	0	2	
Retroperitoneal fibrosis				
Contralateral IIV thrombosis (at acute onset)	1 (0.2%)	1		.001
IVC thrombosis (at acute onset)	18 (4.8%)	0	18	NS
IVC filter	55 (15%)	1	54	0.003
Degree of obstruction				
Occlusive	133 (35%)	4	129	NS
Non-occlusive	243 (65%)	6	237	
Stent: upper landing site				
IVC	376 (100%)	10	0	NS
Stent: distal landing site				
Common iliac vein	205 (54%)	4		NS
External iliac vein	40 (10%)	2		
Common femoral vein	126 (33%)	4		
Femoral vein	5 (1%)	0		
Anticoagulation compliance				
Yes	375 (99%)	0		.05
No	1 (0.2%)	1		

IIV = internal iliac vein; IVC = inferior vena cava.

early complications were observed (pulmonary embolism, death, or contrast induced nephropathy). Local access complications occurred in 9% of acute DVT treatment: four cases of calf haematoma as a result of thrombolytic therapy

Table 3. Stent types and diameters.

Stent type	Frequency	Diameter, mm
Wallstent	(315, 84%)	12–18
Cook Zilver Vena stent	(40, 10%)	14–16
Optimed Sinus venous	(10, 3%)	14–16
VENITI VICI stent	(7, 2%)	14–16
Bard Luminex	(2, 0.5)	14–16
Sinus Obliquus	(2, 0.5)	14–16
Total	376 patients	

were managed conservatively by local compression and bandage, and external bleeding was seen in 2% ($n = 8$); two cases required blood transfusion.

Stent position categorisation

IVC extension of the stent was classified into three categories (Fig. 1A–E): (1) complete (> 20 mm), from the confluence to the tip of the stent protrusion into the IVC reaching the contralateral wall of the IVC with a nearly 100% “jailing” in 86%, (324/376); (2) partial (10–20 mm) in 13%, (48/376). The percentage of interruption of the contralateral venous outflow in this category would be different depending on the angle of the confluence and the size of the vessel, which was variable among these patients; $< 50\%$ coverage ($n = 8$), 50–75% coverage ($n = 28$), and > 75 –100% coverage ($n = 12$); (3) flush with the ilio caval confluence, with 0% right CIV coverage 1% (4/376).

Contralateral venous thrombosis breakdown

In the current study, 2.7% (10/376) developed right (contralateral) iliac DVT (Fig. 2A–C) following initial ipsilateral iliac stenting that occurred only with complete coverage of the contralateral CIV (Category 1). The cumulative incidence of contralateral DVT after 6 years was 4% (Fig. 3). The median time elapsed prior to its development was 225 days including three patients who developed right lower limb DVT before 30 days. The median time of follow up for the whole cohort was 35 months (Interquartile Range -IQR 31–38).

Details regarding the timing, aetiology, initial and re-interventions for right lower limb DVT are shown in Table 4. Seven patients had acute DVT presentation (7/80, 8.7%), and three cases were treated for chronic obstruction (3/296, 1%) ($p = 0.001$). One patient was non-compliant with his post-operative anticoagulation and had an IVC filter placed subsequently following the first procedure involving the left lower limb, and 5 months later presented with right iliac vein thrombosis ($p = 0.003$). A further patient with left lower extremity acute DVT was noted to have an initially thrombosed right internal iliac vein (IIV); this was the sole case of contralateral IIV thrombosis out of 94 patients who had pre-operative indirect CTV (1:94/376) (Fig. 4A). This patient developed contralateral CIV and external iliac vein (EIV) DVT 1 month later ($p = 0.001$). Three patients with underlying malignancy presented initially with acute left IFDVT. They developed later contralateral DVT because of a malignant compression effect of direct tumour growth and/or its enlarged lymph

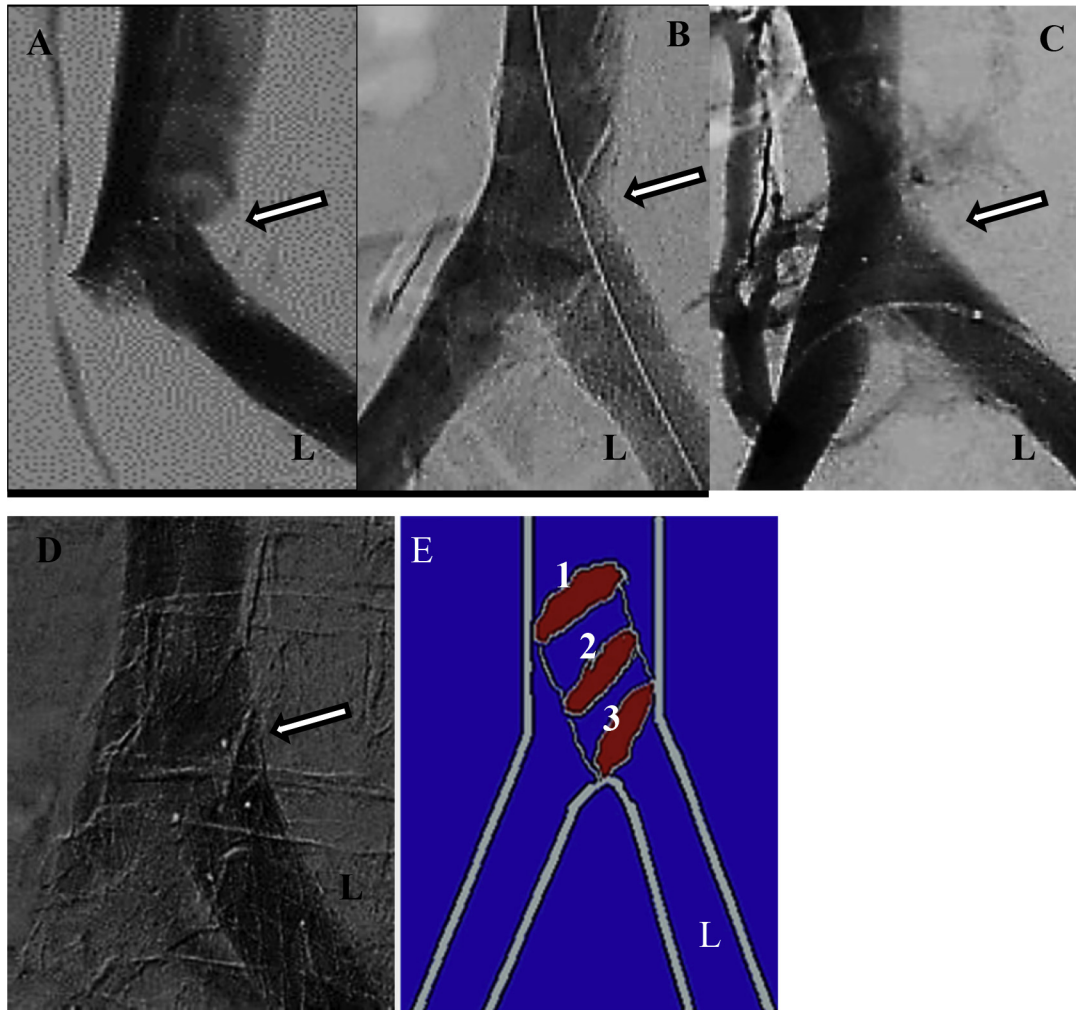


Figure 1. Venogram images showing the three categories of left ilio caval stent extension inside the inferior vena cava (IVC). (A) Complete > 2 cm, 100% coverage. (B) Partial 1–2 cm, 75–100% coverage and (C) 50–75% coverage. (D) At the ilio caval confluence, 0% coverage. (E) A diagram showing the three categories of IVC stent extension: (1) complete, (2) partial, (3) flush with the ilio caval confluence.

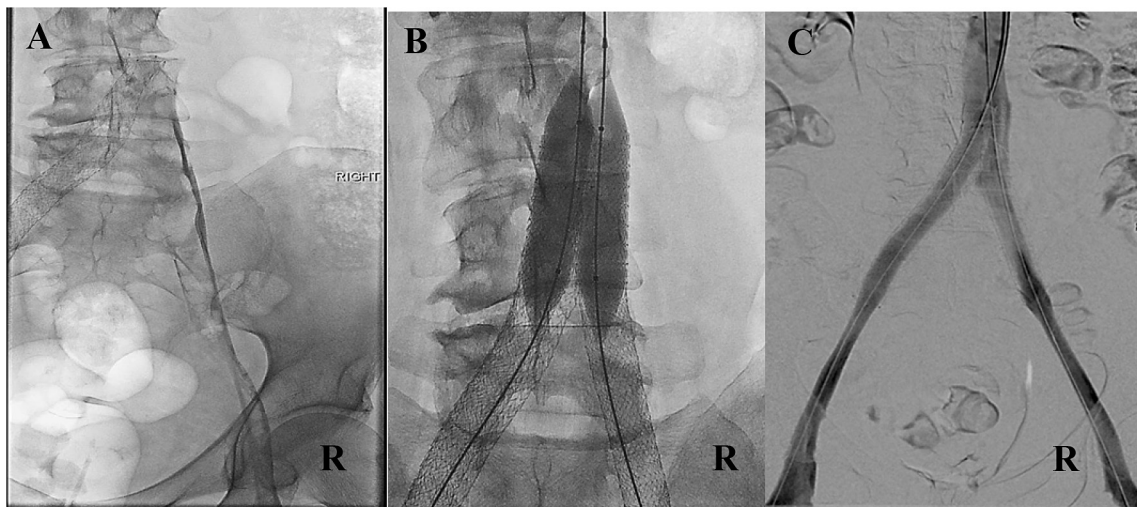


Figure 2. Venograms (A–C) in the prone position show right iliofemoral deep venous thrombosis after left iliac vein stenting extended into the distal inferior vena cava and covering the mouth of right common iliac vein, treated by catheter directed thrombolysis and double barrel ilio caval stenting technique with good completion.

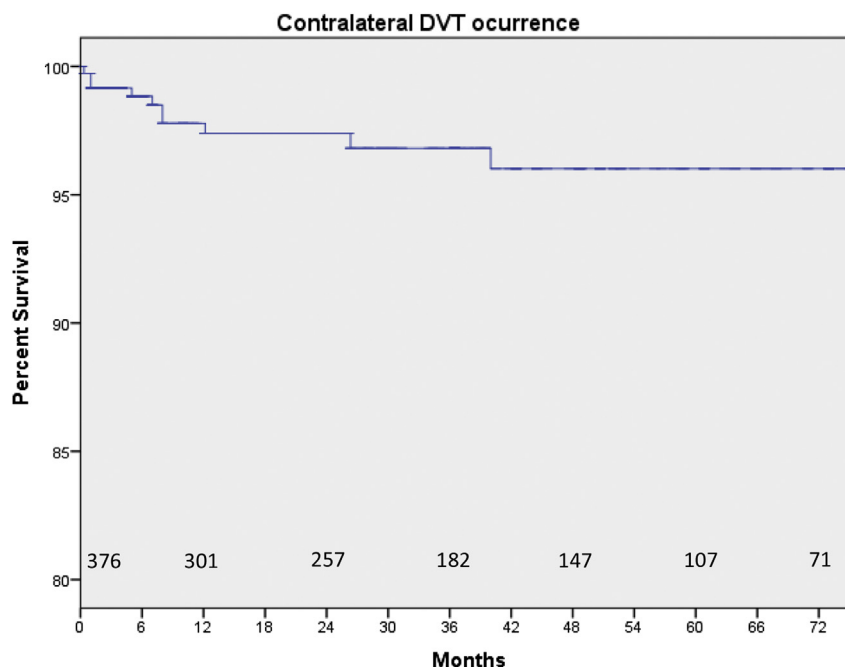


Figure 3. Freedom from contralateral deep venous thrombosis (DVT) in 376 patients (intention-to-treat analysis) with left iliac stenting with IVC extension in months. Numbers at risk at the bottom of this graph (SEM = 1.3%).

nodes. They were minimally symptomatic and treated conservatively with anticoagulation due to malignancy of poor prognosis and essentially incidentally identified radiological findings of right CIV thrombosis during standard CT follow-up (Fig. 4B).

An additional morbidly obese patient underwent left iliac vein reconstruction for chronic ilio-femoral post-thrombotic

occlusion, and presented 10 months later with bilateral extensive DVT that was worse in the right lower limb (phlegmasia cerulea dolens). Surprisingly, the stent was found to be crushed inside the IVC on pre-operative indirect CTV. The patient underwent emergency catheter directed thrombolysis over 72 hours and bilateral ilio caval stents with a double barrel technique with a good long-term outcome. Two patients developed moderately symptomatic right IFDVT seven months after the initial stenting for chronic non-thrombotic obstruction and were treated conservatively with anticoagulation. An additional patient had post-thrombotic obstruction with homozygous factor V Leiden mutation and developed extensive right IFDVT extending into the IVC.

Interventional treatment was offered for five of the 10 cases and included percutaneous mechanical thrombectomy and/or catheter directed thrombolysis in combination with contralateral iliac vein stenting. No complications were detected during or after the second procedures. Following endovascular treatment of the contralateral side, all patients followed the same post-operative protocol and follow-up regimen as per the ipsilateral ones.

The cumulative ipsilateral primary patency was 93% and 80% at 1 and 40 months respectively. The primary assisted and secondary stent patencies were 93% and 95% at 40 months. The cumulative primary stent patency for right (contralateral) DVT cases was 100% at 3 years follow-up after endovascular treatment.

DISCUSSION

This analysis showed that left ilio caval stent extension crossing the orifice of the right CIV is a safe procedure.

Table 4. Contralateral DVT details.

Details of Contralateral DVT	Frequency
Number	(10/376, 2.7%)
Median time	225 days
< 30 days	3
> 30 days	7
Gender	
Female	8 (80%)
Male	2
Etiology	
Non-thrombotic iliac vein obstruction	5 (50%)
Malignancy	3
Post-thrombotic obstruction	2
Crushed stent inside IVC	1
History of thrombophilia	1
Original left side presentation	
Acute DVT	7 (70%)
Chronic obstruction	3
Type of initially placed stent	
Wallstent	7 (70%)
Nitinol stent (Cook Zilver Vena)	3
Re-interventions	
Thrombolysis TTT alone	0
Thrombolysis plus angioplasty and stenting	5
Conservative TTT	5
Post-operative complication	0
Procedure success	5/5 (100%)

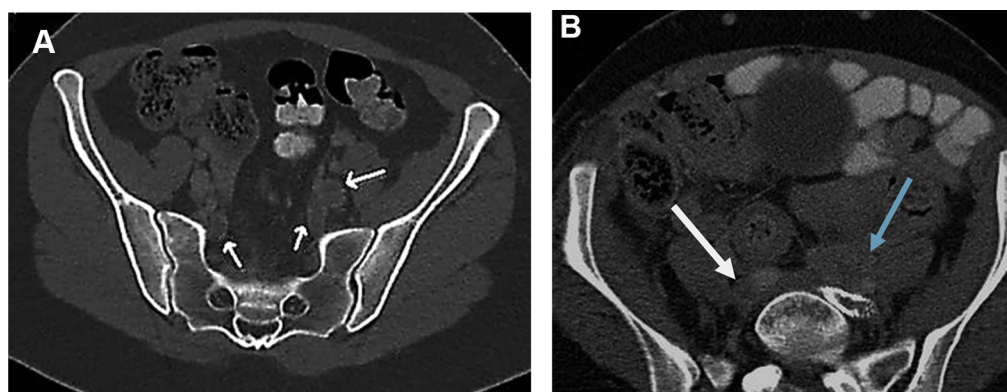


Figure 4. (A) Computed tomography (CT) venogram revealed initially thrombosed right internal iliac vein (arrow) at the same time as left iliofemoral deep venous thrombosis. (B) CT venogram showing left ovarian cancer compressing the left common iliac vein (CIV) stent with thrombosed right CIV (arrow).

Among all patients treated with left iliac stenting with IVC extension, only 10 out of 376 patients developed right IFDVT. Following the natural history and diagnostic imaging of these reported cases, other factors were found that may add to the thrombotic risk of the jailed right contralateral limb. For instance, there was a higher incidence of contralateral thrombosis in acute versus chronic cases (7 vs. 3; $p = 0.001$). In addition, stopping anticoagulation treatment for initial left lower limb DVT with a previously placed IVC filter was observed in one of the 10 patients who developed contralateral iliac DVT. This finding is similar to the work by Caliste et al.⁹ in which four of 41 patients treated for post-thrombotic disease with the Wallstent (BSCI, Galway, Ireland) had a new contralateral iliac thrombosis; three of them were found to be non-compliant with their anticoagulation regimen ($p = 0.0004$). They concluded that stenting across the ilio caval confluence can be performed safely in the majority of patients with thrombotic obstruction followed by therapeutic anticoagulation.

Contralateral IIV thrombosis is interesting. A significant proportion of patients with acute left IFDVT are shown to have a tight stenosis or occlusion of the left CIV. The left lower extremity venous outflow circulation had probably been via the left IIV for some time. This typically drains into the right IIV; if this latter vein is also thrombosed then subsequent clearance of the left CIV and stenting of the same will significantly diminish the blood flow up the right CIV and together with a stent covering the outflow of the right CIV may lead to thrombosis. This was seen in one patient who had an initially thrombosed right IIV on CTV. This reflects the importance of pre-operative imaging; CTV is superior to DUS as the pelvic veins are not always well visualised by DUS.¹⁰ In addition, these patients may need a tailored follow-up protocol to assess the patency of the iliac veins. Three patients treated for malignancy developed right iliac DVT discovered on follow-up CT. Malignancy has been considered an important factor for developing venous thromboembolism with high mortality rates.¹¹ It may lead to ipsilateral or contralateral DVT through various mechanisms such as direct tumour growth and/or its enlarged lymph nodes or by the associated hypercoagulable state,⁸

so this predictor was considered to be an independent risk that can cause contralateral DVT, but possibly an additional factor to the jailing of the contralateral CIV.

Documented thrombophilia is one of the important factors that may be associated with high risk of ipsilateral, contralateral or recurrent DVT especially in young patients.^{12,13} In this study, one patient at CHU, Nord, had positive homozygous factor V Leiden mutation and a history of old left IFDVT, and developed extensive right IFDVT. Extended or lifelong anticoagulation is critical in the prophylaxis and management of this high risk group. Regular follow-up should be ensured to maintain a therapeutic INR ratio and prevent frequent venous thromboembolism.

In most treated limbs, an extension of the stent into the IVC is required when treating a focal obstruction adjacent at the confluence of the CIVs. This is especially so when using the Wallstent,⁴ which has several performance limitations in this area. The relatively weak radial force at its ends (compared with the stent body) cannot maintain an adequate lumen in the face of the dense fibrotic lesions at the central CIV; the stent may be compressed and cause ipsilateral cranial stent collapse or caudal stent migration with symptom recurrence or ipsilateral DVT.^{14,15} The largest series of Neglen and Raju² was with this stent; they recommended landing the Wallstent several centimeters into the IVC, far enough such that the stent touches the contralateral caval wall. Although the contralateral venous outflow is crossed with increased risk of contralateral DVT, these are bare metals stents and the assumption has always been that flow will pass between the interstices. Nevertheless, they reported contralateral iliac vein thrombosis with an incidence of 1% (absolute rate). In a recent further analysis from the same group by Murphy et al.,³ the absolute rate of contralateral DVT at 5 years in 755 patients treated with Wallstents extending into the IVC by 3–5 cm was (16/755, 2.1%), and of those who had a Gianturco Z-stent extension technique into the IVC it was (3/982, 0.3%). Consequently, the cumulative rate of freedom from contralateral DVT was significantly improved in the Z-stent group at 99% versus 90% (at 5 years) for the Wallstent group in Murphy et al. This was explained by the Z-stent

having significantly larger interstices allowing greater flow between the struts, and that they are therefore less prone to coverage with neointimal growth, and allow interdigitation of stent struts, facilitating bilateral stenting for treatment of contralateral DVT. Of 61 patients treated with nitinol stents, three patients developed contralateral DVT. Two of them had underlying malignancy; a further patient developed a crushed stent during follow-up.

Although it is not possible to position the Wallstent as precisely as more modern laser cut nitinol open cell stents, nevertheless a low risk of contralateral DVT is seen. Also, the Z-stent modification of the iliac stenting technique of Murphy et al.³ appeared to be associated with a significant overall decrease in the contralateral DVT rate by preventing Wallstent encroachment into the IVC.

CONCLUSION

Stent placement across the ilio caval confluence from the left CIV is associated with a low but definite rate of contralateral iliofemoral venous thrombosis. Contralateral IIV thrombosis, pre-existing IVC filters, and anticoagulation non-compliance are significant predictors, and the malignant compression effect can be considered as an associated risk factor. Subsequent right side thrombus removal presents good long-term results. Future stent development may attempt to eliminate the need to cross into a healthy IVC and avoid the risk of secondary contralateral venous thrombosis.

CONFLICT OF INTEREST

G.J.O.S. is a paid medical consultant to Cook Medical, Boston Scientific, Bard, Marvao Medical, Medtronic. O.H. is a paid medical consultant to Boston Scientific. Neither of the other authors reports any conflicts.

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