Chapter 36
In Patients with Chronic Venous Stenosis, Does Placement of a Stent Improve Patency Compared to Recurrent Angioplasty?

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Abstract The endovascular treatment of chronic venous stenosis or occlusion in both the upper and lower extremities are increasing in frequency. Chronic venous stenoses in the upper extremity are primarily related to dialysis access, indwelling catheters, and pacemakers. In the lower extremity, they are primarily related to chronic deep vein thrombosis, surgical complications, and iliac vein compression syndrome. Many resources are expended to maintain appropriate dialysis access in the end-stage renal failure population. Treating patients with post thrombotic syndrome secondary to venous stenoses in the femoroiliocaval segments can alleviate debilitating symptoms, improve quality of life, and help heal ulcerations. In treating the upper central veins in a patient with end-stage renal disease on dialysis it seems that stenting does not convey an advantage in patency or longevity of the dialysis access over multiple angioplasties. In treating the lower central veins angioplasty followed by primary stenting seems to be the overwhelming modality of choice, combining the benefits of a low complication rate and high long-term patency rates.

Keywords Chronic venous stenosis • Angioplasty • Stent • Dialysis

Introduction

Percutaneous endovascular procedures have emerged over the last decade as the preferred method of treatment for venous diseases. The low rates of morbidity and mortality associated with endovenous procedures are likely to have influenced their popularity. In the upper extremities most chronic venous stenoses or occlusions are related to

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Table 36.1 PICO table for treatment of chronic venous stenosis

P (Patients)	I (Intervention)	C (Comparator group)	O (Outcomes measured)
Patients with upper and lower extremity chronic venous stenosis	Endovascular treatment with angioplasty alone	Angioplasty with placement of stent	Patency

dialysis access, long-term central venous access, or pacemaker/defibrillator placement [1–3]. In the lower extremities chronic venous occlusions are more commonly related to iliac vein compression syndrome, history of deep vein thrombosis, or injury to the vein [4, 5]. There are two primary areas of concern for the vascular specialist. The first is the treatment of chronic venous stenosis in the dialysis access patient. The other is the treatment of chronic venous stenosis in the femoroiliocaval segment.

The dialysis population survival is dependent on their ability to obtain dialysis. Their ability to obtain dialysis is dependent on the patency of the dialysis access which in turn is greatly affected by the patency and the obstructive status of the central veins [1, 6]. The patency of the central veins affects both patients with fistulas and grafts as well as patients who are reliant on central catheters. In this subset of patients central venous stenosis and occlusions are common conditions which reduce long-term patency of upper extremity arteriovenous access as they are a common cause for acute thrombosis or obstruction [6, 7]. While it is reasonable to employ angioplasty and or stenting to relieve the stenosis to maintain patency. It is still undecided whether multiple balloon angioplasties or primary stenting is more appropriate in the treatment of central venous stenosis.

Post thrombotic syndrome affects a large number of patients in the United States where there are 6–7 million patients who have venous stasis changes and 500,000 patients with leg ulcers yearly. 47 % of patients with femoroiliocaval DVT and thrombosis will go on to develop post thrombotic syndrome and 33 % with post thrombotic syndrome will go on to develop ulceration [8, 9]. May Thurner's also affects a large number of patients, although the exact number is unknown. Reports range from 18 to 59 % of patients who have left lower extremity deep vein thrombosis can be attributed to May Thurner's [10]. Proper evaluation and endovascular treatment of chronic venous stenosis in the femoroiliocaval segment can lead to the reduction in post thrombotic syndrome symptoms [11]. Although in the literature reviewed there was not a direct head-to-head comparison of angioplasty versus stenting when treating femoroiliocaval obstructions. There was a strong tendency towards stenting in the femoroiliocaval venous segment when there was a symptomatic stenosis or occlusion.

Search Strategy

A literature search of English language publications was used to identity published data on endovascular treatment of chronic venous stenosis using the PICO outline (Table 36.1). The Google Scholar and MEDLINE databases were searched as well as the Cochrane Central Register of Controlled Trials using the following search

terms: “Chronic venous stenosis” AND/OR “Angioplasty”, “Stent”, “Pacemaker”, “May Thurner”, “Iliac compression syndrome”, “dialysis”, “indwelling catheter”, “balloon dilation”, and “recurrent angioplasty versus stent placement”.

Articles were excluded if they were related to: Multiple Sclerosis; chronic cerebrospinal venous insufficiency; thrombecomy; Malignancy; Kidney, liver, lung or heart transplant; Pulmonary vein stenosis; Saphenous vein bypass in either periphery or cardiac; foreign language articles, or articles were case reports involving less than ten patients. No restrictions were made on date or type of publication.

Results

There were 46 articles included in the analysis. The articles were required to include data on either angioplasty or stenting of chronic venous stenosis to be included in the analysis. There were two small prospective randomized controlled study comparing PTA to stent in dialysis patients (Table 36.2) and none in the femoroiliocaval group (Table 36.3). The remainder were retrospective studies In the femoroiliocaval vein group there were no articles with greater than ten patients that were treated with balloon angioplasty as a single modality.

Venous Stenosis in Dialysis Patients

Endovascular percutaneous transluminal angioplasty (PTA) is an accepted alternative to surgical revision for hemodialysis related stenoses or occlusions [31]. However, PTA alone is complicated by restenosis or occlusion. For this reason, it has been proposed that PTA with concomitant stent placement will increase patency. In the treatment of venous stenosis in dialysis patients, Quinn reported one small prospective randomized trial which included 87 consecutive patients who had venous stenosis and were undergoing hemodialysis; 47 patients were randomized to percutaneous angioplasty (PTA) alone and 40 were randomized to PTA and stent placement. Ninety-nine percent of the patients (n = 86) had polytetrafluoroethylene (PTFE) access grafts while one percent (n = 1) had an arteriovenous fistula. The locations of the stenosis (n = 85) and occlusions were both peripheral (n = 59), central (n = 20), or both (n = 8). Peripheral sites included axillary, basilic, cephalic, and saphenous veins and venous anastomoses. Central locations included the subclavian, brachiocephalic, and iliac veins. Anticoagulation was not given after the procedure. Outcomes were primary and secondary patency at 60, 180 and 360 days post intervention and determined by venography. A stenosis or restenosis of 60 % or greater was classified as hemodynamically significant. For peripheral sites, the primary patency rates were 55 %, 31 %, and 10 %, respectively, and for stents were 36 %, 27 %, and 11 %, respectively (P = .6528). The secondary patency rates for PTA were 94 %, 80 %, and 71 %, respectively, and for PTA and stents were 73 %, 64 %, and 64 %, respectively (P = .1677). For central sites, the primary patency rates for PTA were 81 %, 23 %, and 12 %, respectively, and for stents were 67 %, 11 %, and 11 %, respectively (P = .4595).

Table 36.2 Studies performed for Venous stenosis in dialysis patients

Author	Year	Number of patients	Location	Angioplsty or Stent better	Quality of evidence
Quinn -RCT	1995	87-Dialysis patients	Central and peripheral	No difference	Moderate
Hoffer-RCT	1997	34-Dialysis patients	Peripheral venous	No difference	Moderate
Bakken		24 Dialysis patients	Central	No difference	Very low
Lumsden- retrospective review of central stent	1992	25 –central venous stenosis treated with stent	Central	N/A	Very low
Beathard	1992	285 patients-vascular access stenosis treated with angioplasty	Central and peripheral	N/A	Very low
Vorwek	1995	65 Dialysis patients-vascular access stenosis treated with angioplasty and stent	Central and peripheral	N/A	Very low
Mickley	1997	14 Dialysis patients-vascular access stenosis treated with angioplasty and stent	Central	N/A	Very low
Turmel-Rodrigues	1993	59 Dialysis patients- vascular access stenosis treated with angioplasty	Central and peripheral	N/A	Very low
Aytekin	2004	14 Dialysis patients- vascular access stenosis treated with angioplasty and stent	Central	N/A	Very low
Gray	1995	52 Dialysis patients- vascular access stenosis treated with angioplasty and stent	Central and peripheral	N/A	Very low
Jones	2011	52 Dialysis patients- vascular access stenosis treated with angioplasty and covered stent	Central	N/A	Very low
Vesely	1997	20 Dialysis patients- vascular access stenosis treated with angioplasty and covered stent	Central	N/A	Very low

RCT randomized control trial, *RRT* retrospective review trial

The secondary patency rates for PTA were 100 % at each interval, and for stents were 100 %, 89 %, and 78 %, respectively (P = .5408) [32]. They concluded at one year there was no difference and primary secondary patency between dialysis patients who have been treated with PTA or PTA and stent placement.

In a similar prospective randomized study by Hoffer and reported in 1997, 37 grafts in 34 patients were treated with either PTA alone (n = 20) or PTA with stent (n = 17). Inclusion criteria for this study were: (1) that the access was a dysfunctional upper extremity PTFE loop graft, (2) the stenosis was in a vein peripheral to the subclavian, (3) the lesion had recurred within 6 months of a previous angioplasty. Patients differed somewhat in that the stent group had more prior interventions. The 30, 60, 180, and 360 day primary and secondary patency for the different groups did not differ significantly, but the adjunctive stent placement increased the cost of the procedure by 90 % [33].

Bakken reported in 2007 in a retrospective fashion the only other head to head comparison of angioplasty versus stenting to treat upper central venous stenosis in the dialysis patient. Primary stenting (PTS) was used to treat 26 patients (35 % male; average age, 57 ± 15 years) with 26 central venous stenoses, and primary angioplasty (PTA) was used to treat 47 patients (45 % male; average age, 57 ± 18 years) with 49 central venous stenoses. Primary and primary assisted patency were one of the endpoints. Primary patency was equivalent between groups, with 30-day rates of 76 % for both groups and 12-month rates of 29 % for PTA and 21 % for PTS (P = .48). Assisted primary patency was also equivalent (P = .08), with a 30-day patency rate of 81 % and 12-month rate of 73 % for the PTA group, vs PTS assisted patency rates of 84 % at 30 days, and 46 % at 12 months. Ipsilateral hemodialysis access survival was equivalent between groups. The PTS group underwent 71 percutaneous interventions per stenosis (average, 2.7 ± 2.4 interventions), and the PTA group underwent 98 interventions per stenosis (average, 2.0 ± 1.6 interventions). The PTS group hemodialysis access site was an average of 1.0 ± 1.3 years old at the time of the initial intervention, and the hemodialysis access in the PTA group was an average of 1.1 ± 1.2 years old [1]. The authors concluded that endovascular therapy with PTA or PTS for central venous stenosis is safe; however, neither offers durable outcomes and PTS does not improve on the patency rates versus angioplasty and does not add longevity to the hemodialysis access site.

Multiple other retrospective and a few prospective studies have reported similar results to the prior studies [34–40]. Although some studies report higher patency rates early on for stenting, patency past one year is similar to the previous reports [41, 42]. The other studies however do not directly compare balloon angioplasty to primary stenting. It is clear that there is a lack of substantial randomized controlled trials in this area. Furthermore, the studies presented have inherent biases including selection bias and attrition bias which weakens the evidence.

Symptomatic Femoroiliocaval Venous Stenosis

Lower extremity venous outflow obstruction plays an important role in the pathophysiology of chronic venous insufficiency [17, 43]. Etiologies include post-thrombotic occlusion or stenosis [44], and the presence of external iliac vein compression and

Table 36.3 Studies performed for venous stenosis or occlusion in the femoroiliocaval veins

Author	Year	Number of patients	Primary patency	Primary assisted	Secondary patency	Quality of evidence
Neglén [12]	2000	137	52 %		90 %	Very low
O'Sullivan [13]	2000	39	79 % (1 year)			Very low
Abu Rahma [14]	2001	18	83 %, 69 %, 69 % (1, 3, and 5 years)			Very low
Hurst [15]	2001	18	89, 79 % (6, 12 months)			Very low
Lamont [16]	2002	15	93, 87 % (6, 16 months)	100 % (6,16 months)		Very low
Raju [11]	2002	38	49 % (2 years)	62 % (2 years)	76 % (2 years)	
Neglen [17]	2003	429	92.8 % (13 months)	95.1 % (13 months)		Very low
Neglen [18]	2004	316	75 % (3 years)	92 % (3 years)	93 % (3 years)	Very low
Neglen [5]	2007	870	67 % 72 (months)	89 % (72 months)	93 % (72 months)	Low
Neglen [19]	2008	177 Limbs with stents crossing inguinal ligament	52 % (42 months)	80 % (42 months)	86 % (42 months)	Very Low
Hartung [20]	2009	89	83 % (38 months)	89 % (38 months)	93 % (38 months)	Very low
Kölbel [21]	2009	59	67 %	75 %	79 % (25 months)	Very low
Raju [22]	2009	131	32 %	58 %	66 %	Very low
Rosales [23]	2010	34	67 % (2 years)	76 % (2 years)	90 % (2 years)	Very low
Ye [24]	2012	205	98.7 (4 years)	100 % (4 years)	N/A	Very low
Raju [25]	2014	217 limbs	69 % (24 months)	93 % (24 months)	N/A	Very low
Sang [26]	2014	67	70.7 % (36 months)	N/A	82.8 % (36 months)	Very low
Blanch Alerany [27]	2014	36	74 % (33 months)	87 % (33 months)	89 % (33 months)	Very low
Catarinella [28]	2015	153	65 % (24 months)	78 % (24 months)	89 % (24 months)	Very low
Liu [29]	2014	48	93 % (12 months)	N/A	N/A	Very low
Ye [30]	2014	110	70 %	90 %	94 %	Very low

N/A not applicable

intraluminal webs [45]. Despite clinical success of the fem-femoral bypass (Palma procedure) [46], percutaneous intervention has replaced bypass surgery as the primary treatment in part to the studies listed below. In patients who have symptomatic chronic femoroiliocaval stenosis the largest experience have been reported by Raju and Neglen. In 2000 they reported their experience of 139 consecutive lower extremities with chronic iliac venous obstruction (61 limbs with primary disease and 78 with post-thrombotic disease) that were treated by balloon dilation and stenting. Overall, the results were very promising with no mortality and primary, primary-assisted and secondary cumulative patency rates of the stented area at 2 years were 52%, 88% and 90%, respectively, in the post-thrombotic group 60%, 100% and 100% in the May-Thurner syndrome group. Clinical improvement in pain and swelling and ulceration were demonstrated in both groups [12]. They concluded that chronic iliac vein obstruction that appears to be a symptomatic lesion can be treated safely and effectively by endovascular surgery regardless of etiology, and that stenting after balloon dilation is advised in all venoplasties. They went on to report several increasingly larger studies including a report on 304 limbs in 2001 with a demonstration of actuarial primary and secondary stent patency rates at 24 months of 71 and 90% [11]; of and an even larger series of 938 limbs in 2006 [6]. They also demonstrated excellent secondary patency rates in stent placed across the inguinal crease [19]. In multiple small series patency rates ranged from 32 to 98.7% for primary patency and 66 to 100% for secondary patency for femoroiliocaval stents [5, 11–30] (Table 36.3).

Recommendations

Upper extremity venous stenosis in dialysis patients

1. For the treatment of venous stenosis in dialysis patients, endovenous treatment may be performed with patency outcomes of percutaneous angioplasty equivalent to angioplasty and stent for both peripheral and central stenoses. (**Quality of evidence: Moderate; Recommendation: Moderate**)
2. If there is a residual obstructive lesion after angioplasty stenting should be performed (**Quality of evidence: Low; Recommendation: Moderate**)
3. If there is no residual obstruction after angioplasty, primary stenting does not provide benefit in terms of long-term patency nor does it increase the longevity of the hemodialysis access (**Quality of evidence: Low; Recommendation: Moderate**)

Femoroiliocaval Venous stenosis/occlusion

1. When the diagnosis of iliac vein compression syndrome has been made primary stenting is recommended (**Quality of evidence: Very Low; Recommendation: Strong**)
2. Stenting below the inguinal ligament should be done with caution (**Quality of evidence: Very Low; Recommendation: Moderate**)
3. When the diagnosis of ileo-caval occlusion or stenosis has been made primary stenting is recommended (**Quality of evidence: Very Low; Recommendation: Strong**)

Personal View of the Data

Overall, the data for treatment venous stenoses/occlusion in both the upper and lower extremity is weak data with studies that are biased by: selection, detection, and reporting. There is a significant lack of randomized controlled trials in the treatment of these lesions. In the upper extremity, there were some very small randomized controlled trials early on; however, in the femoroileocaval venous obstruction/occlusion group there was no significant data on primary balloon angioplasty. My suspicion is that at the time of procedure there were a large number of lesions that had significant recoil after angioplasty or had significant flow limitations after angioplasty which then subsequently required stenting. Also in the case of iliac vein compression syndrome the pathophysiology dictates that to alleviate the compression, stenting will be required. Stenting below the inguinal ligament subjects the stents to the same forces that any stent placed across the hip joint would encounter. That being said there was a significant patency difference in favor of the ileo-caval group for patency of the primarily placed stents over that of the dialysis access group. In the dialysis group there was no benefit in terms of patency or longevity of the dialysis access when comparing multiple balloon angioplasties versus primary stenting. In the studies that were reviewed, stenting of the central vein was performed if balloon angioplasty yielded a suboptimal result. Stenting across the clavicular first rib junction subjected the stent to the force of the clavicle compressing the subclavian vein on the first rib. In a comparison of dialysis access catheters placed in the internal jugular vein as compared to the subclavian vein it was noted that there was a much higher incidence of subclavian stenosis as compared to the internal jugular vein stenosis [15, 17, 47].

In conclusion for patients with femoroileocaval venous obstruction, primary stenting after angioplasty seems to be the accepted strategy for treatment of these lesions. Recommendations have also been made for the liberal use of IVUS when treating these types of lesions. Stenting into the inferior vena cava does not seem to have significant consequences in terms of patency. However stenting below the inguinal ligament does seem to impact patency rates of stents. For patients with upper central vein stenosis secondary to dialysis access, there seems to be little to no difference between recurrent angioplasty versus primary stenting. However most studies did include the use of bailout stenting.

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