Inferior Vena Cava Reconstruction in Symptomatic Patients Using Palmaz Stents: A Retrospective Single-Center Experience

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Background: The use of stents for treating central venous occlusion is well described. Limited evidence exists related to Palmaz balloon-expandable stent use in inferior vena cava (IVC) reconstruction. We analyzed patency and complication rates after IVC reconstruction using Palmaz stents.

Methods: From 2002 to 2019, 37 patients (mean age: 51 year) underwent IVC reconstruction with 68 Palmaz stents. Indications were symptomatic chronic venous obstruction in the infrarenal ($n = 25$) and intrahepatic ($n = 12$) IVC. Demographic, operative, and imaging data were evaluated. Clinical data, abdominal CT, and/or duplex ultrasound were used to determine patency at follow-up.

Results: Restoration of caval patency was achieved in all patients, with complications in 2/37 (5.4%) patients (thrombus formation within the stent; stent embolization eight days after placement). Follow-up data were available for 27 patients. Primary patency was maintained through last follow-up in 19/27 (70%) patients (mean: 1.1 year), with successful stent redilation performed in 6 patients. Mean duration of primary-assisted patency ($n = 5$) was 1.2 year. Late lumen loss was ($n = 13$) was 40% during a mean time to follow-up of 2.0 years. Primary patency in patients with occlusion secondary to malignancy was 109 day (range: 1 day−1.0 year), whereas primary patency in patients with occlusion from other etiologies was 1.1 year (range: 2 day−5.9 year). The Kaplan-Meier analysis demonstrated primary and primary-assisted patency of 66% and 84%, respectively, at 24 and 48 months.

Conclusions: Palmaz balloon-expandable stents for IVC reconstruction is feasible and effective for symptomatic IVC occlusion. Risk of stent migration was low.

INTRODUCTION

A range of pathologic entities, both thrombotic and compressive, may cause occlusion of the inferior vena cava (IVC). These include extrinsic compression by neoplasm or other structures, prior catheterization, trauma, hypercoagulability, infection, and idiopathic thrombophlebitis.[1−5] Thrombosis of indwelling IVC filters may also lead to IVC obstruction.[5,6] Chronic IVC obstruction can cause debilitating lower extremity pain and edema, ascites, and venous ulceration, as well as impaired hepatic or renal function if left untreated (IVC syndrome or post-thrombotic syndrome).[1−6]

Percutaneous stenting is the method of choice for treatment for central venous obstruction, including

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in the IVC; stenting has been shown to be technically effective and superior to surgical alternatives or percutaneous transluminal angioplasty (PTA) alone in a variety of pathologic contexts.[3–28] Evidence comparing the long-term efficacy of different methods for stent-based reconstruction of the IVC is more limited and has generally focused on self-expanding stents (SESs) during recanalization of the iliocaval system.[3–10,12–16]

Data regarding experience with balloon expandable stents (BES) in treating central venous obstruction are sparse, and lower still in iliocaval applications.[6,12,29,30] The increased radial strength, higher potential accuracy of placement, and lower flexibility of Palmaz BES relative to SES could allow for long patency and efficacy in relieving symptoms of IVC syndrome.[31,32] However, there exists a strong relative contraindication to using BES when extrinsic compression is the etiology, as BES are more susceptible to crush deformation.[1–6,33] This study presents retrospective, single-center experience treating chronic IVC occlusion resulting from a spectrum of disease entities with BES and to assess the technical feasibility, safety, and efficacy of this intervention.

MATERIALS AND METHODS

A retrospective analysis was performed using continuous, single-center data ranging from May 2002 to July 2019. Thirty-seven patients undergoing IVC reconstruction with Palmaz BES were identified from a quality assurance database (Hi-IQ, Conexsys, Lincoln, RI) and a radiology informatics system (Montage, Nuance Communications, Burlington, MA). Patient demographic and operative data were accessed and protected according to institutional IRB protocol for retrospective clinical studies. Study inclusion criteria were defined by IVC stenting using BES after chronic, symptomatic occlusion as determined by interventional radiology attending physicians. Operators included 9 attending interventional radiologists working at a single academic institution. Patients were initially evaluated based on symptomatology and past medical history, noninvasive hemodynamic studies, and CT or MR angiography. Follow-up imaging modalities used to assess IVC stent patency were duplex ultrasound and/or CT/MR angiography, as well as clinical information regarding patient symptoms.

Patient demographic data (age, sex, BMI) were recorded for all patients undergoing IVC recanalization and stenting. From operative notes, the heparin dose, sheath size, stent quantity and stent dimension used, and final expanded stent diameter (based on deployment balloon size) were recorded. Indications for IVC reconstruction were symptomatic IVC syndrome including lower extremity edema, pain, or nonhealing ulceration with evidence of IVC occlusion or stenosis. Heparin dosing was determined by interventional radiology attending physicians based on specific patient characteristics and indications. For each patient, intraoperative complications related to stent placement were recorded, as well as all available follow-up data related to stent patency and reintervention. Intra-operative complications were documented in the electronic medical record and a prospectively maintained quality assurance database. Primary and primary-assisted patency (defined as duration from intervention to last available reintervention maintaining stent patency) was determined using the Kaplan-Meier analysis. Patients lost to follow-up or patients who died before follow-up ($n = 10$) were excluded from this patency analysis. Patency was not assumed in patients lacking follow-up data.

Follow-up CT angiograms obtained within the period of primary patency were analyzed for 13 patients. From these imaging studies, two perpendicular inner diameters of the stented segment at the inlet and outlet were measured (as the stents had maintained a circular configuration or were compressed into approximately elliptical cross section). Mean cross-sectional area reduction from initial stented area to final calculated area was then determined. Corresponding estimated reductions in flow were calculated based on the Boussinesq flow equation for elliptical cross-sections (assuming no change in pressure gradient across the stented segment because of restenosis).[34]

RESULTS

The 37 patients underwent IVC recanalization, and stenting during the period analyzed underwent placement of a total of 68 Palmaz stents, with 25 patients undergoing infrarenal IVC stent placement and 12 patients undergoing intrahepatic IVC stent placement. 14 patients had IVC thrombosis in the setting of malignancy. BES placed during recanalization ranged from 1 to 4 stents based on the length of the obstructed segment, with a median of 2 stents used. Technical success (restored caval patency after successful stent deployment) was achieved in 37/37 patients (100%) at initial operation.

Patient and operative characteristics are tabulated in Table I. Clinical and/or imaging follow-up data were available for 27/37 (73%) patients. For the 10 patients without clinical or imaging follow-

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Table I. Patient demographic and operative data

Characteristic	
Age, mean (SD), year	51.0 (16.0)
BMI, mean (SD), kg/m^2	30.1 (6.7)
Operative time, mean (SD), min	238 (86)
Heparin, median (25th–75th), units	5,000 (0–7,000)
Sheath size, median (25th–75th), French	14 (14–16)
Balloon diameter, median (25th–75th), mm	18 (18–20)

up data, 6 died and 4 were lost to follow-up. These patients were censored from the Kaplan-Meier analysis at the time of last follow-up data. Patients lost to follow-up who did not die in the period analyzed ($n = 4$) were also censored from the Kaplan-Meier analysis.

Figures 1 and 2 show images from IVC stenting of patient 6 and patient 17. Thrombosis of the stented segment of the IVC occurred in one patient intraoperatively (patient 10), a complication resolved with pharmacomechanical thrombectomy and anticoagulation. Stent migration was noted in patient 21 postoperatively, with one of two Palmaz stents initially placed embolizing to the left pulmonary artery 8 days after implantation; further IVC stenting was later performed in this patient, but reintervention related to stent embolization was not required (Fig. 3). Reintervention was performed in 8/37 (22%) of cases: six patients required stent redilation via balloon angioplasty because of symptom reemergence (16%), and two patients required additional stent implantation because of symptom reemergence (5%). Primary-assisted patency was documented in the charts of 5/8 (63%) of patients requiring reintervention. Table II shows primary patency for all patients, patients with occlusion due to thrombosis or malignancy, or patients who died during the period analyzed. Primary patency was maintained until last follow-up in 19/27 (70%) patients, with a mean duration of 1.1 years. No statistically significant difference was seen in primary patency between patients with occlusion in the setting of malignancy versus those without malignancy ($P = 0.1$; Student's t-test).

Stents were mounted on balloons ranging from 16 mm to 24 mm, with a median expanded luminal diameter of 18 mm. Stent lengths used ranged from 39 to 50 mm, with the Palmaz 4,010 (Cordis, Miami Lakes, FL) most commonly used (38/68, 56%). 13/37 patients (35%) died during the time analyzed (11/13 in the setting of malignancy, 2/13 from unrelated etiology), with studies establishing primary patency clearly documented in the medical record of 7 of these patients (mean: 111 day; range: 1 day–1.0 year). Primary patency failure was documented in 8 of 37 patients (22%). This was determined by symptom re-emergence requiring further intervention (angioplasty and placement of new stents). The Kaplan-Meier survival analysis demonstrates that at 12, 24, and 48 months' postintervention, primary patency was 66% in patients at risk, and primary-assisted patency was 84% (Fig. 4).

Follow-up surveillance CT angiograms were available for 13/24 (54%) patients, with time to follow-up imaging ranging from 1 day to 5.9 year (mean time to follow-up: 2.0 year). CT angiograms were used to estimate reductions in cross-sectional area due to compression and stenosis of implanted BES (Fig. 5). Average area reduction was 40% (range: 13–72%). Assuming no reduction in blood viscosity and change in pressure gradient across the stented segment at follow-up, estimated flow reductions ranged from 20 to 95% with an average reduction of 63%.

DISCUSSION

Chronic IVC obstruction resulting from thrombosis or compression is under-recognized and incompletely understood.[1–7,24–28] Endovascular stenting and PTA for venous occlusions have surpassed surgical management as the preferred approach.[3–28] Stenting for treatment of nonmalignant central venous occlusions is superior to anticoagulation or PTA alone and provides symptom relief in a higher proportion of patients with malignant superior vena cava obstruction than steroids, radiotherapy, or chemotherapy.[18–20,35,36] A series presented by Chick et al. confirmed preserved renal function in patients with venous stent placement across the renal inflow, further supporting SES safety in the IVC.[17] Yet, there remains a relative paucity of evidence regarding treatment modalities available for IVC stenting (e.g. SES versus BES).[3–10,12–17]

Literature describing the use of BES stents for IVC reconstruction has been limited to smaller patient series, case reports, and safety and feasibility studies in animal models.[12,29–31,37] This may be due to the relative contraindication of using BES where compression is the occlusive etiology. Yet, bench studies have shown that BES exert higher radial force of 5.3 N at a strain of 0.5 and have lower flexibility (148×10^{-2} N of force required to produce 10° of stent flexion) compared with SES (3.9 N radial force, 3×10^{-2} N required).[31] Although this may limit the use of BES in vessels with significant

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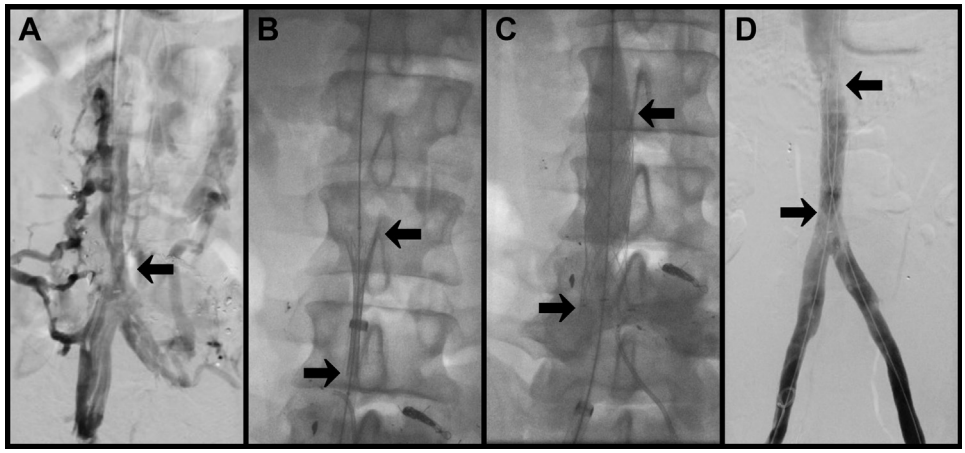


Fig. 1. Patient 6: 36-year-old male developed chronic IVC occlusion after a gunshot wound. **(A)**. Venogram showing near complete occlusion of the infrarenal IVC (arrow). **(B)**. IVC reconstruction during deployment of initial, predilated Palmaz 5,010 stent (chosen based on length of lesion) **(C)**. IVC stent construct after balloon dilation to 18 mm **(D)**. Completion venogram after IVC stenting.

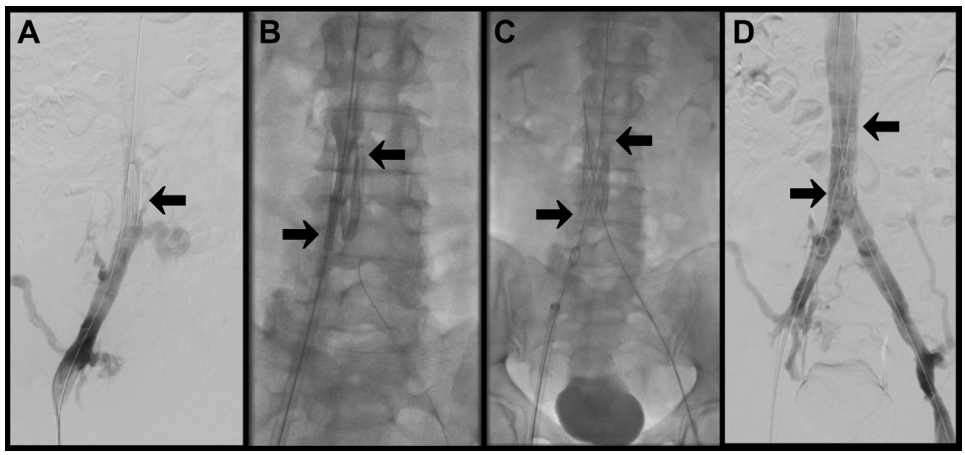


Fig. 2. Patient 17: 57-year-old female developed chronic IVC occlusion after permanent indwelling IVC filter thrombosis. **(A)**. Venogram showing complete occlusion of the infrarenal IVC and VenaTech LGM (B. Braun, Bethlehem, PA) IVC filter (arrow). **(B)**. IVC reconstruction during deployment of initial Palmaz 5,010 stent. **(C)**. Final position of the Palmaz 5,010 stent. **(D)**. Completion venogram after IVC stenting.

tortuosity, the high radial force and low flexibility suggest that these stents may play a role in IVC reconstruction. Furthermore, BES may be safely redilated after stenosis.[37,38]

In a series of 982 chronic nonmalignant femoroiliocaval venous obstructions treated using SES by Neglén et al., primary and secondary cumulative patency rates of 67% and 93%, respectively, at 72 months were shown.[11] A series of 69 non-IVC filter–related recanalization procedures presented by McDevitt et al. demonstrated 6-, 12-, and 24-month primary patency rates of 91%, 88%, and 62%, respectively, and secondary patency rates of 100%. Patients were treated with a variety of SES combinations, with two total BES used; 9 complications (13%) were seen in this series.[6] Six- and 12-month primary patency rates were lower in our BES study, whereas 24-month primary patency rates were comparable. Erben et al. documented a series of 66 patients undergoing IVC reconstruction using 164 SES, with primary patency and secondary patency rates of 78% and 91%, respectively, at

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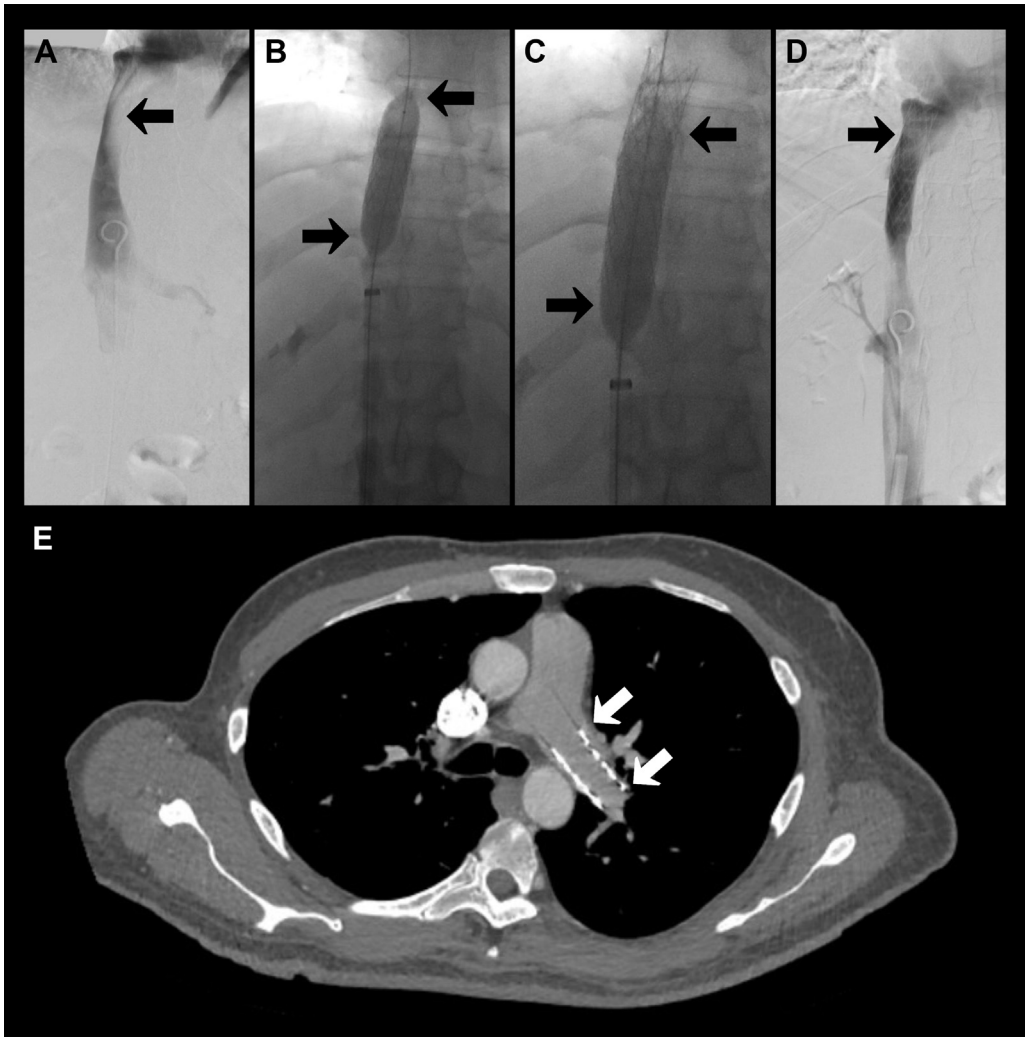


Fig. 3. Patient 21: 49-year-old male developed chronic IVC occlusion after metastasis of a neuroendocrine tumor to the liver. **(A)**. CT image showing occlusion of the intrahepatic IVC (arrow). **(B)**. IVC reconstruction during deployment of initial Palmaz 4,010 stent. **(C)**. Balloon dilatation of IVC stent construct of 2 overlapping Palmaz 4,010 stents. **(D)**. Completion venogram after IVC stenting. **(E)**. Contrast-enhanced CT after embolization of one Palmaz 4,010 stent to the left pulmonary artery. The patient remained asymptomatic, and therefore, no efforts were undertaken to retrieve the embolized stent.

Table II. Complications, stent patency, and dimension analysis based on follow-up imaging

Characteristic	Patient no.	
Primary patency (all), mean (range)	27	293 day (1 day−5.9 year)
Secondary patency (all), mean (range)	5	1.2 year (50 day−3.7 year)
Primary patency (subgroup: malignancy), mean (range)	9	109 day (1 day−1 year)
Primary patency (subgroup: deceased), mean (range)	7	111 day (1 day−1 year)
Complications	2	1. Intraoperative stent thrombosis 2. Stent migration (L pulmonary artery)
Reintervention	8	1. Additional stent placement (2) 2. Angioplasty of the existing stent (6)
Late lumen loss, mean (SD)	$n = 13$	40% (14%)
Flow reduction, mean (SD)	$n = 13$	63% (19%)

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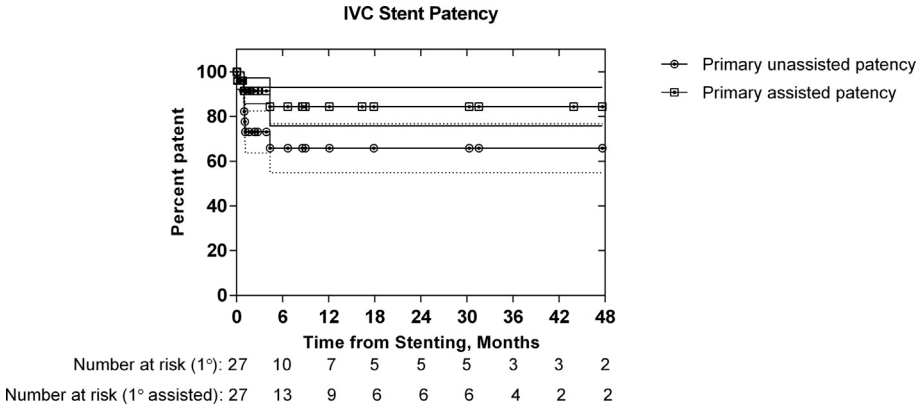


Fig. 4. Stent patency estimated with the Kaplan-Meier analysis. Primary-unassisted (with dotted standard error lines) and primary-assisted patency (with solid standard error lines) among 27 patients with clinical follow-up.



Fig. 5. Cross-sectional area measurement and flow reduction estimation (patient no. 7). **(A)** Contrast-enhanced CT image showing transverse dimensions of Palmaz stent within infrarenal IVC. **(B)** Magnified view showing measurement of stent dimensions with electronic calipers.

36 months; 5 periprocedural complications (8%) were documented.[7] Randomized trials for stenting in vena cava syndrome (IVC and superior vena cava) remain limited to SES use, with technical success rates of 96.4% and 100% and an adverse event rate of 14.3%.[9]

This series of 37 patients showed 100% technical success in stent placement and a low complication rate related to stenting (5%). The Kaplan-Meier analysis demonstrates 66% primary patency from 6 to 48 months in patients at risk. Although primary patency at shorter follow-up times (i.e. < 6 months) was lower than historical SES controls, primary patency was maintained at a consistent level for 3.5 years, approaching patency levels seen in historical SES controls at later time points.[6,7,11] Primary-assisted patency follow-up data were only recorded in 5/37 patients (14%), with primary-assisted patency maintained in 84% of patients who failed primary patency. Only 8/37 patients (22%) required reintervention from stent occlusion. A risk of stent migration and stent collapse within the central venous system has been noted in the literature with BES and SES.[27,31] No complete stent collapse was seen in this patient series, and all patients who underwent reintervention had successful dilation of the BES. A single instance of late stent migration was observed in a patient with malignant obstruction of the suprarenal IVC because of prolapse into the right atrium with subsequent migration into the left pulmonary artery.

Although the exact degree of venous occlusion in the iliocaval system associated with symptom emergence is not known, stenting of obstructions $>50\%$ of the vessel area have been reported as leading to sustained symptom relief.[5,39–41] In this series, symptom re-emergence was not seen despite a 40% mean late lumen loss on follow-up CT. The higher radial strength of BES may account for this low reduction in area over time and contributes to BES utility as a solution for IVC obstruction. Accurate placement afforded by balloon expansion and

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the ability for coaxial tandem stent placement may increase BES utility.[32] No statistically significant differences in primary patency were noted based on indication for stenting (malignancy versus thrombosis, IVC filter thrombosis versus other), suggesting BES feasibility for a range of indications.

Study limitations are related to the retrospective method of data collection; 10/37 patients (27%) were lost to follow-up or dying before follow-up. Although more recently treated patients were known to have received antiplatelet therapy and/or systemic anticoagulation after stent placement, these data were not available in all patients and were therefore not analyzed. The small sample size also limits this study's external validity. Assumptions made in area and flow estimations may limit the accuracy of these data.

CONCLUSION

No difference in primary patency duration based on etiology was found in patients undergoing short segmental occlusion IVC stenting with Palmaz stents. Complications related to stent placement were infrequent, and most patients did not require reintervention after stent placement. Long-term primary patency was comparable to historical SES patency data. Using BES may be an effective and durable approach to treating chronic IVC obstruction.

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