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Original Research

Central Vein Recanalization and Rehabilitation in Pediatric Patients: Changing the Paradigm for Chronic Occlusions

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ABSTRACT

Background: Chronic total occlusions in the central venous system limit access and increase morbidity in chronically ill pediatric patients. We report the results of transcatheter recanalization of occluded central veins using angioplasty and stenting.

Methods: Patients undergoing successful intervention for venous chronic total occlusions at our institution between April 2013 and December 2019 were retrospectively reviewed.

Results: Sixty-eight occluded central veins in 29 patients underwent recanalization with angioplasty (26 veins) or stenting (42 veins). The indications included limited access for catheterization or central line maintenance (19 patients), limb swelling (4 patients), superior vena cava syndrome (3 patients), and pleural effusion (3 patients). The primary risk factor for occlusion was a history of central venous lines after surgery or extracorporeal membrane oxygenation support in 76% of the patients. The median age and weight at the time of initial intervention were 5.8 years and 14.5 kg, respectively. There were no major complications. Of 10 patients with symptoms of venous congestion, 8 experienced symptomatic improvement. Twenty-two patients (59 veins) underwent 44 recatheterizations during a median follow-up duration of 288 days. Early reintervention was typically planned. The median time to recatheterization was 71 days. Twenty-one veins reoccluded and required repeat recanalization. Reocclusion was associated with persistent upstream collateral vein decompression, as determined using postintervention venography (odds ratio, 14.2; 95% CI, 3.3-62.6; $P < .001$), which was thought to indicate persistently poor venous inflow. Reinterventions were performed on 40 veins. Fifty-two veins that were followed up (88%) remained patent after the most recent intervention.

Conclusions: Invasive transcatheter rehabilitation of occluded central veins has the potential to preserve critical access sites and improve the symptoms of venous congestion in pediatric patients. Reinterventions are common for reocclusion, restenosis, and somatic growth.

Introduction

The incidence of central venous chronic total occlusions (CTOs) has been increasing in pediatric patients as a result of increased use of central venous lines (CVLs) and peripherally inserted central catheter (PICC) lines as well as increased survival of chronically ill patients.[1-3] A multitude of patient groups are impacted by venous thrombosis, including those with thrombophilic syndromes, prematurity, congenital heart disease requiring surgery or catheterization, and other chronic illnesses requiring long-term venous access for therapy or parenteral nutrition.

Chronic total occlusions of the central veins present significant challenges in pediatric patients with chronic access needs for both indwelling lines and cardiac catheterization and can result in a number of congestive sequelae. Occluded access veins are often abandoned as new sites, which can lead to progressive exhaustion of standard central venous access sites. In some patients, the exhaustion of access sites because of venous occlusion can be fatal.[4,5] We present our experience with transcatheter recanalization of chronically occluded central veins in a diverse cohort of pediatric patients using a combination of angioplasty and stent implantation, followed by close surveillance to maintain vein patency and preserve access sites. Currently, we believe that there are no good alternative therapies to recanalization and rehabilitation for problematic central venous CTOs in pediatric patients.

Methods

This was a retrospective cohort study of all patients who underwent successful transcatheter recanalization and angioplasty or stent

Abbreviations: CTO, chronic total occlusion; CVL, central venous line; IFV, iliofemoral vein; IVC, inferior vena cava; SVC, superior vena cava.

Keywords: Chronic pediatric illness; central venous occlusion; vascular access; venous recanalization.

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implantation in occluded central veins at a single institution from 2013 through 2019. Patients were not included if the veins were only stenotic and not completely occluded at the time of initial intervention. Demographic data, clinical and procedural details, and follow-up information were all collected from electronic medical records. The study was approved by the institutional review board.

The indications for recanalization included isolated limitations in central venous access options, either for cardiac catheterization and intervention or for the initiation or maintenance of an indwelling central venous catheter, and central venous occlusion with congestive symptoms. The presence of residual collateral blood flow decompressing veins following initial intervention, referred to as "collateral decompression," is used in the analysis of risk factors for recurrent occlusion after recanalization. For the purpose of this analysis, collateral decompression was considered to be present when a contrast agent was appreciated flowing from the vein proximal to or at the site of intervention back to the central venous circulation via alternative collateral vessels in addition to the recanalized vein. The finding of persistent venous collateral flow is thought to be a result of residual obstruction into the recanalized vessel.

Descriptive baseline characteristics are provided. Means and standard deviations are provided for normally distributed data, and medians and ranges are provided for skewed data. Paired or unpaired *t* tests were used to compare vessel diameters, and the χ^2 test was used to compare categorical variables. Logistic regression was performed for the analysis of risk factors for vein reocclusion with initial intervention (stent or angioplasty alone) and vessel diameter after initial intervention identified a priori as possible risk factors included in the model. STATA 14.2 (StataCorp LLC) was used for all statistical analyses. Statistical significance was set at a *P* value of $<.05$.

Results

Baseline cohort characteristics

Sixty-eight chronically occluded central veins in 29 patients underwent initial transcatheter recanalization with either angioplasty alone or in combination with stenting. The median weight and age at the time of the initial intervention were 14.5 kg and 5.8 years, respectively. Table 1 provides the baseline characteristics of the cohort and veins that underwent intervention. In most patients (76%), a history of chronic postoperative CVL after surgical intervention and/or extracorporeal membrane oxygenation (ECMO) without known underlying thrombophilia were the identified risk factors for central venous CTOs. One patient, listed as having an unknown underlying risk factor, was a previously healthy 3-month-old infant presenting with chylous pleural effusions, superior vena cava (SVC) obstruction, and lymphangiomatosis, as determined using magnetic resonance imaging. At the time of catheterization, his SVC and right iliofemoral vein were occluded.

Nineteen patients (66%) without obvious symptoms of venous congestion required venous recanalization for limited access. Among these patients, 13 underwent recanalization to allow transcatheter evaluation and interventions, whereas 6 underwent recanalization for the initiation or maintenance of a CVL. Five of the 6 asymptomatic patients who underwent recanalization for the placement or maintenance of an indwelling CVL had been treated with unfractionated heparin or enoxaparin prior to intervention, whereas the sixth patient was treated with acetylsalicylic acid (ASA). Ten patients (34%) were symptomatic, with findings of venous congestion. Four patients with a history of postoperative or post-ECMO chronic CVLs had congestive symptoms, 1 with SVC syndrome and pleural effusion, 3 with pleural effusion only, and 1 with severe SVC syndrome and generalized anasarca. There were 2 teenage patients with factor V Leiden mutations who presented as outpatients referred by their hematologists for limb swelling and known deep venous thromboses resistant to medical therapy. There was 1 teenage patient with severe symptoms of SVC syndrome and a history of mediastinal lymphoma in remission who presented with occluded bilateral brachiocephalic veins and SVC. There were 2 patients with parenteral nutrition–dependent intestinal failure, 1 of whom had severe SVC syndrome and the other of whom presented with left-arm swelling and left-sided headaches. Thirty-eight percent of the patients received no maintenance anticoagulation therapy prior to intervention.

Table 1. Preprocedural cohort data

	N = 29
Age	5.8 y (55 d-20.6 y)
Weight, kg	14.5 (2.5-110)
Underlying major thrombosis risk factor	
History of chronic CVL use after surgery or ECMO cannulation	22 (76)
Intestinal failure, PN dependent	3 (10)
Factor V Leiden thrombophilia without current CVL	2 (7)
History of mediastinal lymphoma	1 (3.5)
Unknown	1 (3.5)
Indication for venous recanalization	
Limited central venous access	19 (66)
Superior vena cava syndrome	3 (10)
Persistent pleural effusions	3 (10)
Limb swelling	4 (14)
Most recent prior anticoagulation	
Acetylsalicylic acid	7 (24)
Heparins	5 (17)
Factor Xa inhibitors	1 (3)
Vitamin K antagonists	2 (7)
Combination	3 (10)
None	11 (38)
Occluded central veins	N = 68
Location	
Iliofemoral	32 (47)
Vena cavae	16 (24)
Brachiocephalic	13 (19)
Subclavian or internal jugular	7 (10)

Values are median (range) or n (%).
CVL, central venous line; ECMO, extracorporeal membrane oxygenation; PN, parenteral nutrition.

Initial procedural results

Of the 68 occluded central veins initially recanalized and dilated, 26 underwent balloon angioplasty alone, and a total of 74 bare metal stents were placed in 42 veins. Figure 1 provides a flowchart of interventions by the type and location of intervention as well as follow-up evaluations and reinterventions. The vena cava interventions were more likely to be stent implantations ($P = .003$), and the subclavian or internal jugular vein interventions were all angioplasties without stent implantation. Valeo premounted biliary stents (Bard), Genesis XD (Cordis), Palmaz Genesis (Cordis), and Palmaz Blue (Cordis) stents, all balloon-expandable bare metal stents, were used. Intravascular access was achieved in the femoral and/or internal jugular veins as needed.

The occluded veins were recanalized from the access point using a combination of hydrophilic wires, dilators, and sheaths and were progressively dilated using increasingly larger high-pressure balloons. Stents were implanted if vascular recoil or residual obstruction was significant and there was no contraindication to stent implantation. The mean final vessel diameter was 5.4 ± 2.4 mm after the initial intervention. The final vein diameters were larger in stented vessels (6.6 ± 1.9 mm) than in vessels that underwent angioplasty alone (3.3 ± 1.4 mm; $P < .001$). Figure 2 illustrates the intervention results in 1 patient with extensive bilateral brachiocephalic vein and SVC occlusions.

There were 2 contained wire perforations in the veins and no significant complications. One patient required direct thrombolytic

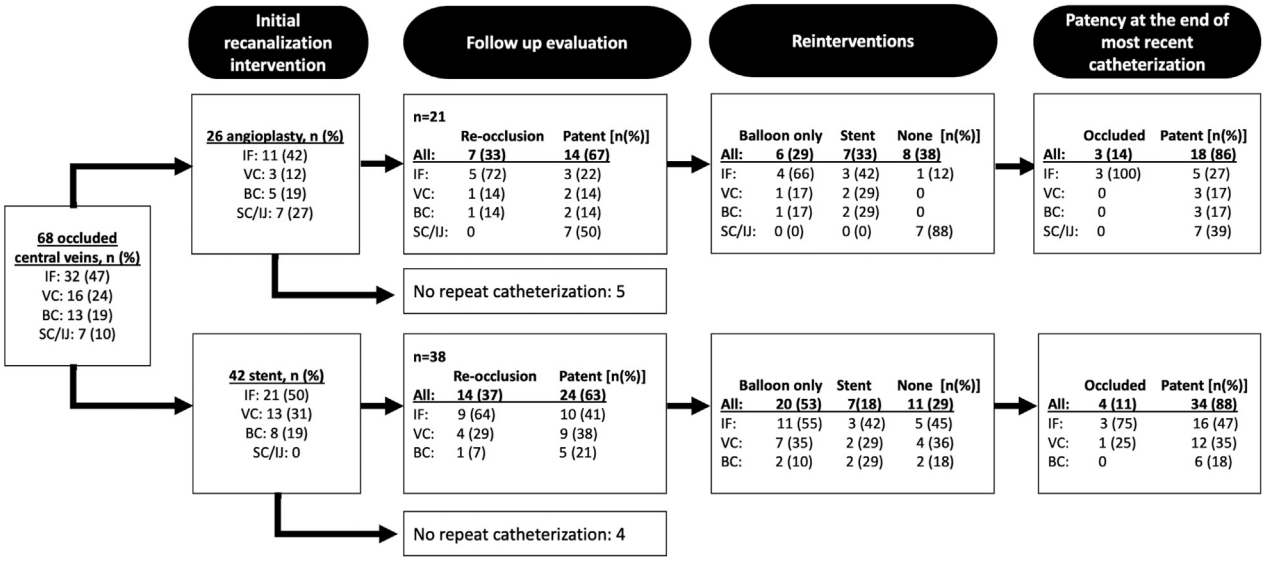


Figure 1.

Flow diagram of initial interventions, available follow-up angiographic evaluations, reinterventions, and patency on most recent evaluation of cohort veins. Data are presented as n (%), and percentages are based on the row totals (between comparison groups) for bolded values and column totals (within group) for nonbolded values. Vein locations are abbreviated. BC, brachiocephalic; IF, iliofemoral; SC/IJ, subclavian or internal jugular; VC, vena cava.

infusion when acute stent thrombosis occurred during catheterization. Of the 10 patients with congestive sequelae, 8 experienced noticeable symptomatic improvement of their swelling or effusion size (Figure 3 and Central Illustration). There were 2 patients who did not experience any notable symptomatic improvement. One was a neonate with congenital diaphragmatic hernia status after 1 week of ECMO for multiple cardiorespiratory arrests as well as progressive and severe generalized edema, which did not improve despite persistent patency of the central veins after intervention. This patient died 9 days after initial catheterization because of underlying progressive disease

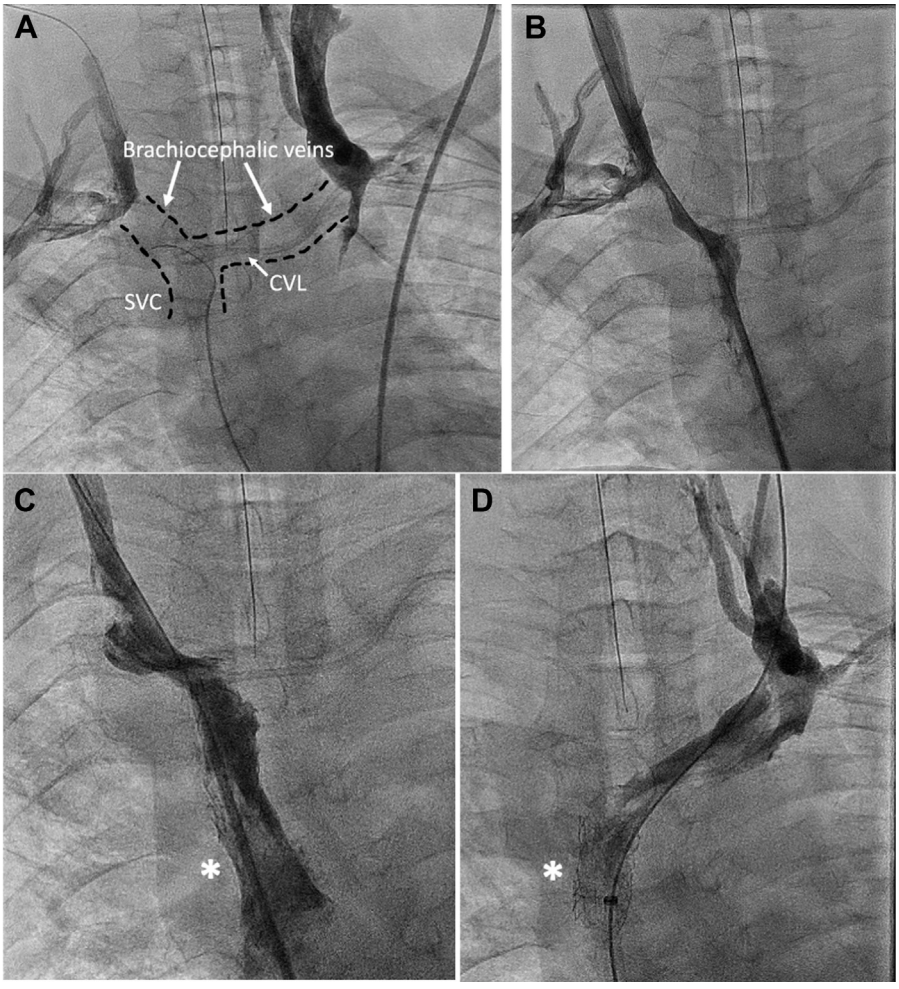


Figure 2.

Recanalization and rehabilitation of the bilateral brachiocephalic veins and superior vena cava. A 14-year-old patient with a central venous line (CVL) for chronic parenteral nutrition presenting with superior vena cava (SVC) syndrome. (**A**) Extensive brachiocephalic vein and SVC occlusions (dotted lines) with an indwelling CVL. (**B**) Recanalization or angioplasty established right brachiocephalic vein and SVC patency followed by (**C**) SVC stenting (*) to improve flow from the right side of the neck to the heart. (**D**) The left brachiocephalic vein was recanalized alongside the CVL, and angioplasty improved flow from the left side of the neck to the heart. SVC syndrome resolved, and the CVL maintained function.

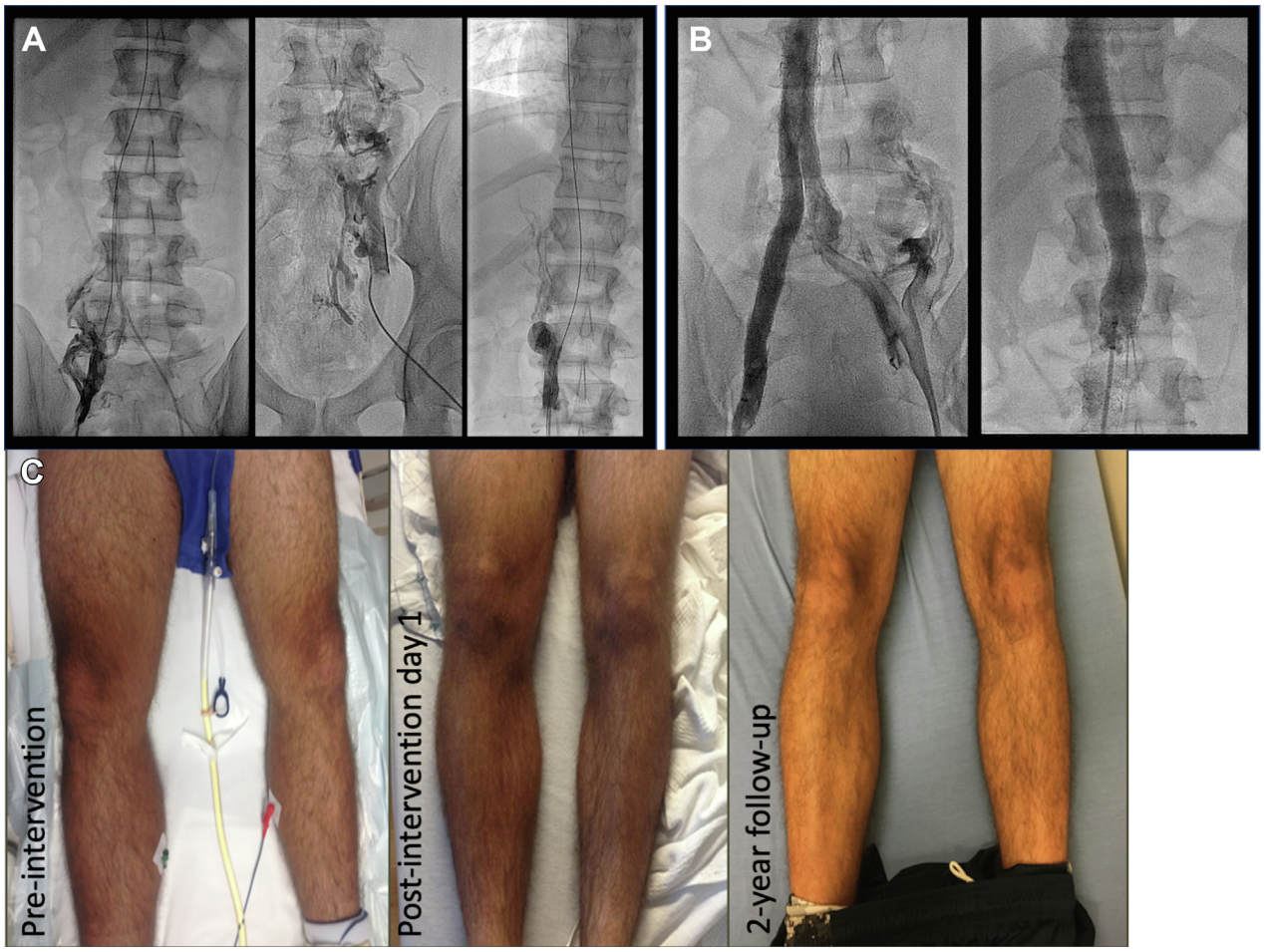


Figure 3.
Recanalization of the bilateral iliofemoral veins and inferior vena cava. A 19-year-old patient presented with chronic swelling of the right leg and chronic occlusion of the (**A**) bilateral iliofemoral veins (left and middle) and inferior vena cava (right). (**B**) After recanalization and stenting from the bilateral iliofemoral veins (left) to the patent hepatic inferior vena cava (right), flow was restored from the legs to the heart. (**C**) Swelling of the right leg before the procedure improved after the intervention and after 2 years.

processes. The other was a teenager with morbid obesity and developmental delay with factor V Leiden thrombophilia and extensive chronic thrombosis in the right lower extremity and inferior vena cava, swelling of the right lower extremity, and poor adherence to medical anticoagulation therapy. He underwent multiple recanalization interventions and stent implantations in the right iliofemoral veins and inferior vena cava but had evidence of reocclusion of the veins at the time of each reintervention.

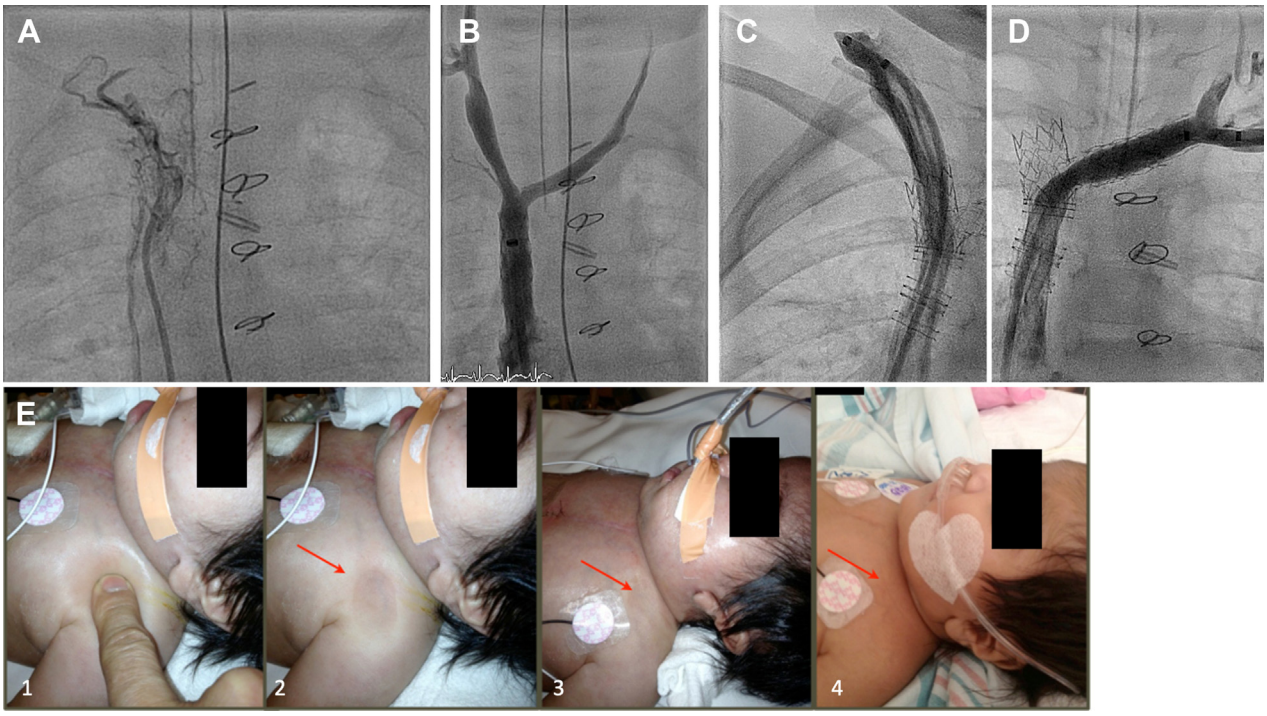
Following the initial intervention, the 2 patients with factor V Leiden thrombophilia were placed on a heparin drip overnight, after which 1 was transitioned to warfarin and the other was transitioned to ASA with rivaroxaban at the discretion of the hematologist comanaging the patients. Thirteen patients were placed on ASA alone, 6 patients were placed on unfractionated heparin or enoxaparin, 2 patients resumed previously prescribed warfarin, 4 patients were placed on a combination of ASA and fondaparinux, 1 patient was placed on a combination of ASA and enoxaparin, and 1 patient was placed on no anticoagulation therapy.

Follow-up and reinterventions

The median follow-up time was 288 days (range, 0-1261 days). Twenty-two patients with 59 initially recanalized veins underwent 44 repeat catheterization procedures (Figure 1 describes the follow-up and reinterventions). Sixteen repeat catheterizations were performed for recurrent or worsening symptoms or for imaging results that raised concerns for restenosis or reocclusion of a recanalized vein. Six of the repeat catheterizations were performed at the time of removal or exchange of a CVL in order to use the line to achieve wire access across an occluded vein for recanalization. The remaining 22 repeat catheterizations were performed for planned surveillance venography because of the anticipated high risk of vein reocclusion. The interventions were performed during repeat catheterizations if necessary. The median time to initial repeat catheterization was 71 days (range, 6-1091 days).

Of the 59 veins that underwent follow-up venography, 21 veins reoccluded at some point during follow-up. Fourteen veins had recurrent stenosis without reocclusion, and 24 remained patent without restenosis. Fourteen of the 21 occluded veins required stent implantation during the initial procedure because of inadequacy of the response to angioplasty alone, and 37% of the initial stents that were followed up became occluded compared with 33% of the vessels that underwent initial angioplasty. No stent fractures were noted at follow-up. The vessel patency at follow-up did not differ based on whether the initial intervention was angioplasty or stent implantation ($P = .81$). The length of the occluded segment, vessel size after the initial intervention, and underlying diagnosis or presence of a thrombophilic disorder were not associated with the risk of vessel reocclusion.

The persistence of residual collateral blood flow decompressing the veins before the intervention, thought to be due to residual obstruction and poor flow at the site of the intervention, was associated with a higher risk of reocclusion at follow-up (Figure 4). Among the 59 veins that underwent follow-up angiography, 19 had evidence of collateral



Central Illustration.

Recanalization of the brachiocephalic veins and superior vena cava. A 2.5-month-old infant presented with superior vena cava (SVC) syndrome and chylous pleural effusions after cardiac surgery. (**A**) The SVC and brachiocephalic veins were occluded. (**B**) Recanalization or angioplasty of the brachiocephalic veins and SVC stenting restored patency. Three years later, after multiple reinterventions, the (**C**) right and (**D**) left brachiocephalic veins and SVC remained patent. (**E**) Improvement of pitting edema (arrows) from preintervention (1, 2) to postintervention day 1 (3) and day 3 (4).

decompression of the vein at the end of the initial intervention and 40 did not. Among the veins that had evidence of collateral decompression, 15 (79%) became reoccluded during follow-up, whereas only 6 veins (15%) without evidence of collateral decompression reoccluded at follow-up ($P < .001$). The presence of collateral decompression was associated with occlusion at follow-up (adjusted odds ratio [OR], 14.2; 95% CI, 3.3-62.6; $P < .001$) while controlling for whether the initial intervention was stent implantation or angioplasty (adjusted OR for initial stent implantation, 3.5; 95% CI, 0.42-28; $P = .3$) and final vessel diameter after the initial intervention (adjusted OR, 0.8; 95% CI, 0.5-1.3; $P = .3$).

Reinterventions were performed on 40 of the 59 veins that underwent follow-up venography. There were 21 new stent implantations in 14 veins during follow-up: 14 were repeat stent implantations for in-stent restenosis or reocclusion, 4 were for restenosis or reocclusion in previously balloon-dilated vessels, and 3 were planned stent implantations after initial angioplasty and a course of antibiotics in a patient with bacteremia and, thus, contraindicated for stent implantation at the time of the initial intervention. There were 72 balloon venoplasties performed in 39 veins during follow-up: 25 venoplasties for restenosis or reocclusion in a previously stented vessel, 10 venoplasties for restenosis or reocclusion in a previously unstented vessel, 33 venoplasties for somatic growth or further expansion of previously stented vessels, and 4 venoplasties for somatic growth or further expansion of unstented vessels. No vessels underwent surgical intervention or required stent removal. Fifty-two of the 59 veins (88%) that underwent follow-up venography were patent at the conclusion of the most recent catheterization and reintervention.

Discussion

Chronic total occlusions of the central veins are becoming increasingly common and impact a wide variety of chronically ill pediatric patients, placing them at the risk of venous congestion syndromes, pulmonary embolism, postthrombotic syndrome, and progressive loss of central access sites. In the last 2 decades, there has been a substantial increase in the reported incidence of venous thrombosis among hospitalized pediatric patients, which is thought to be due to improved survival of the seriously or chronically ill, improved sensitivity of vascular imaging, and increased use of CVLs and PICCs.[1-3,6,7] Although the use of CVLs and PICCs likely contributes to a majority of pediatric venous thromboses, other factors, including infection, surgery, immobility, cancer, chemotherapy, and thrombophilic syndromes, also contribute to the risk.[8-10] Currently, there are no good surgical options to recanalize chronically occluded central veins in infants and children.

We described the use of transcatheter techniques for venous recanalization and rehabilitation in a diverse cohort with various risk factors for, and manifestations of, central venous CTOs. These procedures carried a low risk and were effective in re-establishing critical access sites for catheterization and CVL placement and in relieving congestive symptoms. This cohort did not experience any major complications, uncontained vascular injuries, or thromboembolic events; however, they required repeat catheterizations, reintervention, and medical anticoagulation therapy because of the risk of recurrent occlusion.

Current pediatric guidelines recommend treating CVL-associated thromboses with prompt removal of lines and medical anticoagulation therapy for up to 3 months.[11] In patients with a continuing requirement of a CVL, a new line is typically placed in an alternative vessel, which, in turn, becomes subject to potential thrombosis and occlusion. Anticoagulation therapy has unclear efficacy in the treatment of venous thrombosis after CVL removal in pediatric patients with an ongoing chronic illness,[12-14] and this approach may hasten the progressive exhaustion of available access sites in those requiring chronic or future access across their lifetime. Occlusive thrombi after pediatric cardiac surgery are relatively common and can prompt aggressive anticoagulation therapy, which can result in bleeding complications and

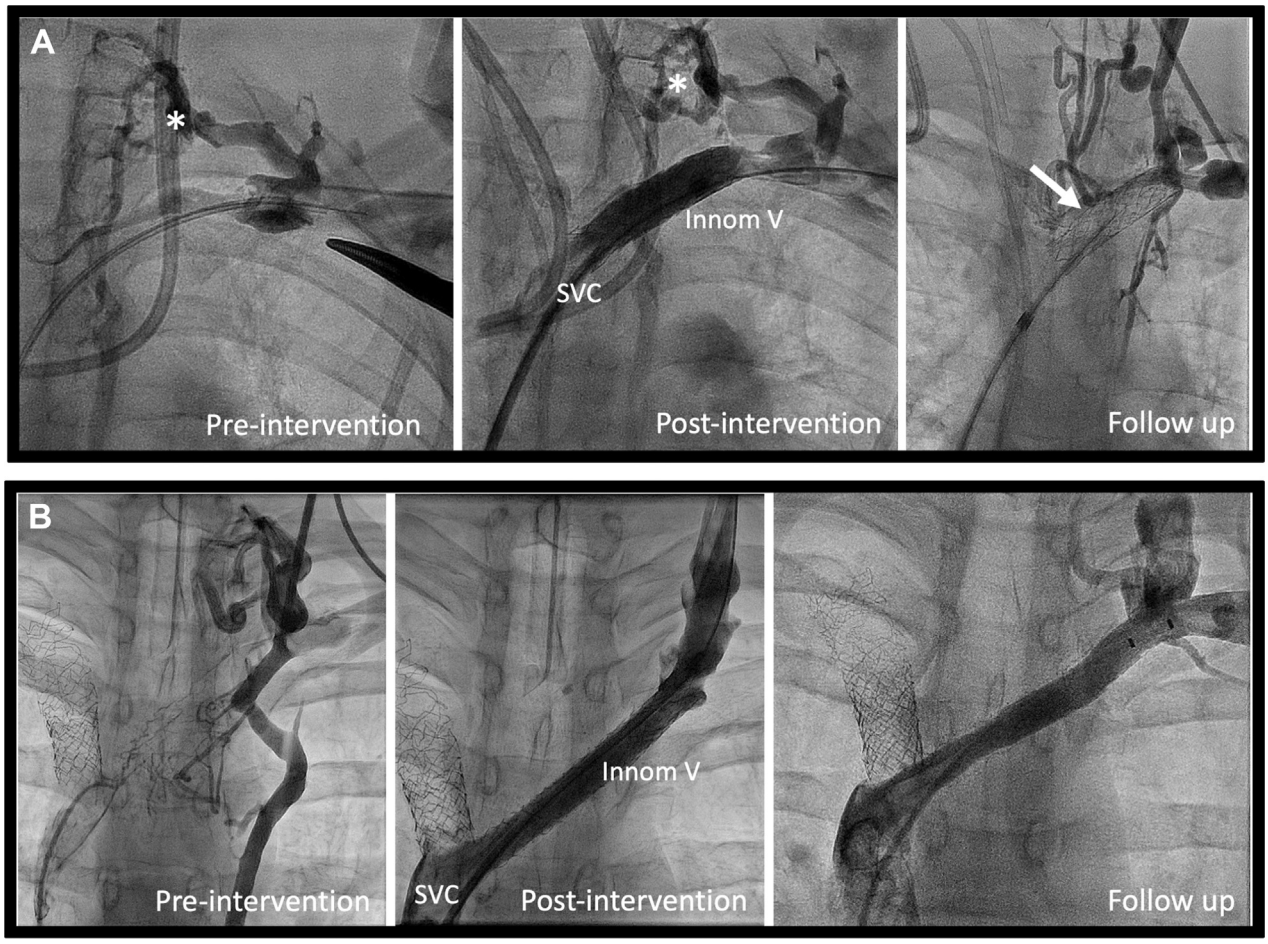


Figure 4.
Presence and absence of residual collateral decompression at the site of recanalization and the risk of reocclusion. Left brachiocephalic vein chronic total occlusions before intervention (left), after intervention (middle), and on follow-up (right) in 2 patients, (**A**) 1 with evidence of postintervention collateral decompression of the vein and (**B**) 1 without decompression. Persistent collateral vein decompression (*) was associated with recurrent occlusion of the stented vessel on follow-up (arrow). SVC, superior vena cava.

still suboptimal rates of vessel patency.[15,16] Furthermore, it is common to develop collateral veins and, therefore, remain relatively asymptomatic in the setting of central venous CTOs. This may delay the diagnosis of central venous CTOs until the time of an attempted central line or PICC placement, at which point the occlusion may have organized into a fibrotic lesion that is impenetrable to anticoagulation medications and increasingly difficult to recanalize using transcatheter techniques.

We present an alternate approach to managing select pediatric patients with chronic occlusive central venous thrombosis who have either not responded adequately to initial anticoagulation therapy or are not expected to adequately respond given the chronicity or extensiveness of the occlusion. This approach involves early percutaneous recanalization of occluded veins using balloon angioplasty and stent implantation if needed. These techniques have been described in addressing access challenges in limited cohorts of patients with congenital heart disease and stenotic or occluded central veins undergoing cardiac catheterization[17-19]; however, reports of patients with other chronic illnesses or underlying risk factors for thrombosis are rare. The pathophysiology of chronic venous occlusions in pediatric patients is different from that of adult atherosclerotic disease, and the techniques and outcomes from the larger amount of literature on adult coronary or other artery recanalizations may not apply to patients like those in our cohort. Venous recanalization can be time consuming, particularly at the time of a patient's initial recanalization procedure. Techniques have been described in some detail in prior publications.[19,20] Because wire recanalization through a venous CTO may not be achievable in every case, it is important to evaluate vessel patency when a previously placed chronic CVL is removed or exchanged for a new site. Lines that are no longer required can be rewired at the time of removal and evaluated for patency using venography. If the veins are occluded or stenotic, rehabilitation can be performed over the wire through the tract of the removed line to salvage the vessel for future access needs.

Asymptomatic venous occlusion is a relatively common incidental finding during transcatheter procedures performed in chronically ill or medically complex infants and children. Wire recanalization may be attempted to varying degrees in many of these cases or may be deferred if there is no visible remnant of the occluded vein or if the goals or acuity of the procedure preclude recanalization attempts. Our cohort included patients who underwent successful recanalization of known venous CTOs and patients in whom venous occlusions were discovered incidentally and successfully recanalized during cardiac catheterizations that were indicated for purposes unrelated to venous occlusion. We did not include patients in whom attempted recanalization of known or incidentally discovered venous occlusions was unsuccessful. Furthermore, recanalization was almost certainly pursued more aggressively in patients who had symptoms of congestion or particularly important and threatened central venous access. Because we were not able to include all patients who underwent attempted but unsuccessful venous CTO recanalization, it is not feasible to comment on the success rate of recanalization using our data. Instead, our purpose was to demonstrate

that invasive reconstruction of chronically occluded central veins can play a role in protecting important access sites and relieving venous congestion and to start to explore the benefits and drawbacks of the approach.

The obvious drawbacks of our approach are the elevated risk of reocclusion and the related need for frequent reinterventions. Following recanalization, nearly all patients were placed on some form of antiplatelet or anticoagulation therapy or a combination of the 2 depending on their underlying risk factors and consultation with a hematologist. Given the retrospective nature of this study and the heterogeneity of the cohort in terms of underlying medical conditions and risk factors for thrombosis, there was variability in the medical anticoagulation strategy and no protocolization of therapy. However, early angiographic re-evaluation of the veins was planned, typically 2 to 6 months after the initial intervention depending on the anatomy, vessel size, and risk factors. Additionally, it was recommended that any patient experiencing the recurrence of symptoms of venous congestion be brought back for reintervention.

The predominant risk factor associated with recurrent venous occlusion in this cohort was residual venous obstruction at or around the site of intervention. Because the anatomy of recanalized veins can be difficult to evaluate using venography and pressure gradients do not often manifest in obstructed veins, we found that the most easily interpretable sign of residual obstruction is that a contrast agent injected upstream from the site of intervention continues to flow through decompressing collateral veins back to the central venous circulation instead of exclusively or nearly exclusively through the recanalized vein (Figure 4). Residual obstruction results in the stasis of flow within the recanalized vein while blood bypasses the vessel in favor of surrounding collaterals, thereby increasing the risk of recurrent thrombosis. In this cohort, ~80% of veins with evidence of residual collateral decompression after the initial intervention went on to reocclude, whereas only 15% of veins without collateral decompression reoccluded. This finding was also independent of whether a stent was implanted, and the absence of residual collateral decompression after angioplasty may be a relatively reliable sign that angioplasty alone is adequate as long as vascular recoil is acceptable. Collateral decompression detected using angiography following venous recanalization with stenting or angioplasty should, however, cause the operator to seriously consider further investigation of and intervention on residual obstructions. Future studies need to assess whether more aggressive treatment of residual obstruction can improve the overall reocclusion rates following initial recanalization procedures.

Collateral decompression is relatively easy to evaluate after intervention. Collateral veins are typically observed to be upstream from the occluded vein prior to intervention using venography, and their persistence after recanalization and rehabilitation suggests that further intervention is needed to completely relieve the obstruction and prevent reocclusion. However, angiography has noted limitations in further characterization of the anatomy and location of residual venous obstructions signaled by collateral decompression. For this reason, additional imaging modalities, such as intravascular ultrasound, which was not available to us during these procedures, may be useful in evaluating and treating these lesions more effectively. Despite the high rates of reocclusion, close follow-up allowed for early detection, and all reoccluded vessels could be accessed and recanalized again. It is important to point out that having an in situ stent visible using fluoroscopy provides a target for recanalization and allows for more aggressive recanalization techniques such as the use of long needles to create tracts through reoccluded stented veins. It is equally important to understand that this technique can be used to perform catheterization or place and secure a CVL via a stented and reoccluded vein in the setting of ongoing access needs and dwindling options.

Conclusion

Transcatheter recanalization of central venous CTOs with angioplasty and stent rehabilitation has the potential to improve congestive symptoms and preserve critical access sites that would otherwise be lost and ultimately exhausted in chronically ill pediatric patients with a variety of underlying disease processes. Reinterventions are common; so, it is important to plan for close follow-up.

Declaration of competing interest

The authors have no financial or personal conflicts of interest to disclose that are relevant to this manuscript.

Peer review statement

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Ethics statement

This manuscript reports patient data; however, all patient data have been deidentified and included into a cohort that does not identify any specific patient. Therefore, this study did not require patient consent.

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