Cardiology in the Young

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Original Article

Cite this article: Eilers LF, Bansal M, Khan A, Webb MK, Qureshi AM, Gowda ST, and Stapleton GE (2024) Hepatic and splenic venous access tract closure using the VASCADE vascular closure system following percutaneous intervention in patients with CHD. *Cardiology in the Young* **34**: 2142–2145. doi: 10.1017/S1047951124025538

Received: 18 December 2023
Revised: 16 February 2024
Accepted: 23 May 2024
First published online: 13 September 2024

Keywords:
cardiac catheterisation; hepatic; splenic; VASCADE Vascular Closure System

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Hepatic and splenic venous access tract closure using the VASCADE vascular closure system following percutaneous intervention in patients with CHD

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Abstract

Background: Hepatic and splenic venous access are specialised techniques used to perform diagnostic and interventional procedures in the cardiac catheterisation laboratory. Bleeding events are the most commonly reported complication following hepatic or splenic venous access. The VASCADE Vascular Closure System (Cardiva Medical Inc. Santa Barbara, CA) is an approved device for closure of femoral vascular access tracts in patients ≥18 years of age. We report our experience using VASCADE to close the hepatic or splenic venous access site in the cardiac catheterisation laboratory. *Methods:* This is a single centre retrospective review of all patients who had percutaneous hepatic or splenic venous access obtained in the cardiac catheterisation laboratory from March 1, 2022 through October 30, 2023 and underwent tract closure with VASCADE. *Results:* Ten patients (six male) underwent 16 procedures (median age and weight 3.5 years and 12.5 kg) with 15 hepatic and two splenic veins accessed. Successful closure of the access tracts with VASCADE was performed in all patients. There were no major adverse events related to closure of the access sites with VASCADE. *Conclusion:* VASCADE can be used following transhepatic and trans-splenic venous access in the cardiac catheterisation laboratory to safely close the access tract and potentially reduce the risk of post-procedural bleeding complications. Further evaluation in a larger cohort of patients is needed to ensure VASCADE is safe for use and provides adequate haemostasis following hepatic or splenic venous access, particularly in children.

Introduction

Hepatic venous access is a specialised technique used to perform cardiac catheterisation in paediatric patients with occlusion of major systemic veins or in whom it facilitates a better trajectory, while splenic venous access may be utilised to access the portal venous system in patients with portosystemic shunts or portal vein occlusion. Bleeding events are a common complication following hepatic or splenic venous access. Several methods of closure of the hepatic or splenic access tract have been utilised including vascular plugs, coils, Gelfoam (Pfizer Inc., New York, NY), and manual compression.[1–9] The VASCADE Vascular Closure System (Cardiva Medical Inc. Santa Barbara, CA) is an approved device for closure of venous and arterial access tracts in adult patients.[10] To date, use of VASCADE has not been described in paediatric patients or for closure of hepatic or splenic venous access tracts. We report our experience using the VASCADE Vascular Closure System for closure of hepatic and splenic venous access tracts in the cardiac catheterisation laboratory.

Methods

This is a single centre retrospective review of all patients who had percutaneous hepatic or splenic venous access obtained in the cardiac catheterisation laboratory from March 1, 2022 through October 30, 2023. All patients who had closure of an access tract using the VASCADE Vascular Closure System were included. Electronic medical records were reviewed and all demographic and procedural data were recorded including diagnosis, access site, sheath size, procedure performed, and patient disposition following the procedure. Post-procedural ultrasound data were also recorded when obtained.

Vascular access in a hepatic or splenic vein was obtained using ultrasound guidance in all procedures. Systemic heparin was administered following access to maintain ACT >250 s in all patients. After completion of the procedure, the VASCADE Vascular Closure System is inserted through the existing sheath, then using ultrasound guidance, the nitinol disc is deployed within

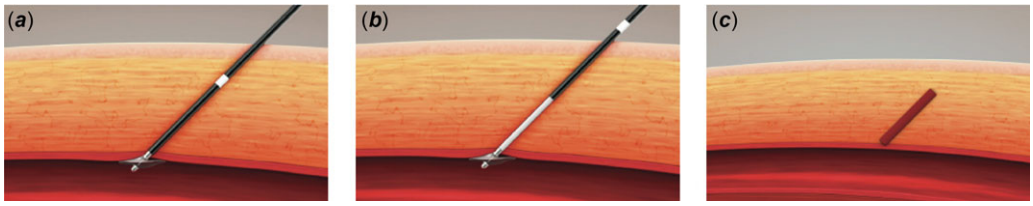

Figure 1. At the completion of the procedure, the VASCADE Vascular Closure System is inserted through the existing introducer sheath. (***a***) The nitinol disc is deployed in the lumen of the vessel. (***b***) The existing sheath is the removed over the device, and the disc is brought against the vessel wall to achieve temporary haemostasis. The collagen patch is exposed in the tissue tract. (***c***) After 30 seconds, the disc is retracted and the device is removed leaving behind only the collagen patch (Figure Source: Cardivamedical.com).

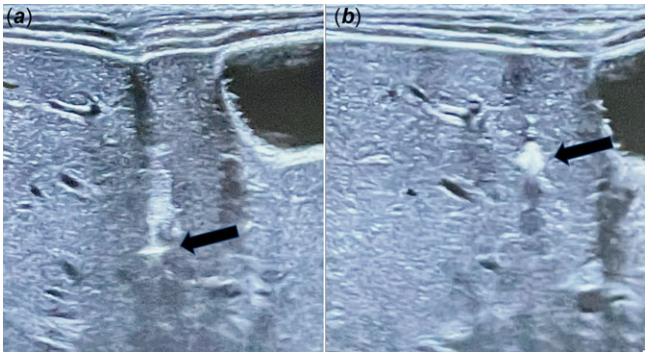

Figure 2. VASCADE Vascular Closure System deployment for patient 1. (***a***) Black arrow indicates nitinol disc deployed in hepatic vein and then pulled against vessel wall. (***b***) Arrow points to collagen patch after removal of VASCADE delivery system.

the lumen of the vessel (Fig. 1). The existing vascular access sheath is removed and the nitinol disc is pulled against the vessel wall. The collagen patch is then exposed within the tissue tract. After 30 s, the disc is retracted and the device is removed leaving behind the collagen patch (Fig. 2). Manual pressure is then applied for an additional 5 to 10 minutes over the puncture site.

Results

Ten patients (6 male) underwent 16 procedures with 15 hepatic and two splenic veins accessed, with closure of the access tract with the VASCADE Vascular Closure System performed at the end of the procedure. The median age was 3.5 years and weight was 12.7 kg at the time of the procedure (Table 1). Three patients had multiple catheterisations (2–4) performed with hepatic venous access. Five patients with pulmonary vein stenosis had a total of 11 catheterisations with hepatic venous access for balloon angioplasty or stenting of pulmonary veins. One patient with cor triatriatum underwent balloon angioplasty of the membrane via transhepatic access. One patient with left atrial isomerism, unbalanced atrioventricular septal defect, and interrupted inferior vena cava status post bilateral bidirectional Glenn who underwent a diagnostic cardiac catheterisation followed by electrophysiology study and ablation for atrial flutter had two hepatic venous sheaths placed with each tract closed with a VASCADE Vascular Closure System at the end of the procedure. One patient with pulmonary atresia, intact ventricular septum, and bilateral femoral vein occlusion underwent implantation of an Alterra Adaptive Prestent and 29 mm Sapien 3 valve (Edwards Lifesciences, Irvine, CA) using right internal jugular venous access. Hepatic venous access was obtained with an 8 French sheath to create a venous wire rail for wire stability, and to perform angiography during valve deployment. Two patients with portosystemic shunts underwent splenic venous access. Following the procedure, seven inpatients were returned to the ICU, one was admitted to the ICU, seven were admitted to the general cardiology floor for overnight observation, and one was discharged home following 6 hours of observation in the recovery area. Two patients received packed red blood cell transfusion following the procedure. One patient had a 2.1 g/dL decrease in haemoglobin during the procedure, prior to sheath withdrawal and received packed red blood cell transfusion before leaving the catheterisation laboratory. This was felt to be secondary to blood loss during procedure and dilution from fluid administration. There was no further drop in haemoglobin over the next 24 hours. An abdominal ultrasound the following morning showed a small retroperitoneal haematoma. The second patient had splenic vein access for portosystemic shunt occlusion. The following morning, she complained of abdominal pain and an abdominal ultrasound showed a retroperitoneal haematoma. Her haemoglobin was unchanged from the last level obtained in catheterisation laboratory 50 minutes before sheath withdrawal. She was given packed red blood cell transfusion by the ICU team. A repeat ultrasound showed a small residual retroperitoneal haematoma that had decreased in size. Abdominal ultrasound was obtained within 24 hours following nine other procedures. One showed a small retroperitoneal haematoma, and one a small hepatic supcapsular haematoma. Neither patient had a decrease in haematocrit or symptoms.

Discussion

Patients with CHD often undergo multiple surgical and trans-catheter procedures and can develop occlusion of major central veins due to repeat cardiac catheterisations or prolonged vascular access with central venous catheters. Transhepatic venous access for cardiac catheterisation and interventions has become a widely used approach for these patients. In addition, in some patients, transhepatic venous access allows for a better trajectory to facilitate interventions. Post-procedure bleeding from the access tract can result in perihepatic capsule haematoma and retroperitoneal bleeding. Qureshi et al reported their experience of 124 cardiac catheterisation procedures performed with transhepatic venous access.[1] Significant bleeding complications occurred in six patients (4.8%), which resulted in one patient's death. The vascular access tracts were closed with vascular coils at the end of the procedure in all patients in their series. Closure of the hepatic access tract has also been performed using Gelfoam, Amplatzer Vascular Plugs (Abbott, Chicago, IL), and Mynxgrip (Cordis, Hialeah, FL) in other series, while some have felt that was not necessary and utilised manual compression only.[2–7]

Trans-splenic access is useful in providing direct access to the portal venous system for diagnostic portography, occlusion of a portosystemic shunt, or recanalization of an occluded portal vein.

https://doi.org/10.1017/S1047951124025538 Published online by Cambridge University Press

Table 1. Demographics

Patient	Sex	Age (yrs)	Wt (kg)	Dx	Access	Sheath	Procedure
1	M	1.2	10.5	PVS	Hepatic	6F	PV intervention
		1.5	11.3	PVS	Hepatic	6F	PV intervention
2	M	3	11.4	PVS	Hepatic	5F	PV intervention
		3	12.8	PVS	Hepatic	6F	PV intervention
		4	14	PVS	Hepatic	6F	PV intervention
		4	15.6	PVS	Hepatic	6F	PV intervention
3	M	2	10.5	PVS	Hepatic	6F	PV intervention
		3	10.4	PVS	Hepatic	6F	PV intervention
		4	12.7	PVS	Hepatic	6F	PV intervention
4	F	1.3	10.4	Cor Triatiatum	Hepatic	7F	BA Cor Triatriatum
5	M	18	85.1	Heterotaxy	Hepatic	8F	Diagnostic cath; Atrial Flutter ablation
						7F	
6	F	6	25.1	PVS	Hepatic	6F	PV intervention
7	F	26	52.6	PS shunt	splenic	6F	PS shunt occlusion
8	F	18	72.9	PS shunt	splenic	5F	Attempted shunt occlusion
9	M	16	74	PA/IVS	Hepatic	8F	TPV
10	M	1.3	10.7	PVS	Hepatic	6F	PV intervention

PVS = pulmonary vein stenosis; PA/IVS = pulmonary atresia with intact ventricular septum; PS = portosystemic shunt; BA = Balloon angioplasty; TPV = transcatheter pulmonary valve.

However, the risk of intraperitoneal bleeding is reported to be 11–20%.[8] Pipalwar et al reported their experience with trans-splenic access in 44 paediatric patients.[9] The access tract was closed with Gelfoam in all patients at the end of the procedure. Twelve patients (27%) had significant bleeding, nine of which required blood transfusions, and three required peritoneal drainage.

The VASCADE Vascular Closure System is an approved device for closure of venous and arterial access tracts in patients 18 years of age and older and is compatible with 5–7 French introducer sheaths. The access tract is closed with a bioresorbable thrombogenic collagen patch. The RESPECT trial demonstrated the VASCADE Vascular Closure System was safe and effective compared with manual compression in adult patients with six or seven French femoral access for diagnostic and interventional cardiac catheterisations.[10] Other series have subsequently reported a 94–99% successful closure rate following femoral venous access for cardiac catheterisation.[11–12]

In this report, we describe a novel technique to close hepatic and splenic venous access tracts in cardiac catheterisation procedures using the VASCADE Vascular Closure System. One of the advantages of this technique is it avoids the implantation of a permanent device, which may make future repetitive venous access procedures in the liver or spleen more challenging. This is an important consideration in patients who will require repeat transcatheter interventions. Five patients with pulmonary vein stenosis underwent 11 procedures with transhepatic venous access in our series. As noted in the results, packed red blood cell transfusion was given following two procedures. The first was for a drop in haemoglobin, which occurred during the procedure prior to sheath removal, while the second was based on ultrasound findings the following day. However, for the latter procedure, there was no further drop in haemoglobin compared to the last value obtained in the catheterisation laboratory. This patient was also receiving Lovenox prior to the procedure. Thus, it is likely that the blood loss for both of these patients occurred during the procedure, and was not related to closure of the access tract by the VASCADE Vascular Closure System. Vigilant monitoring for bleeding or post-procedure complications is needed, especially for smaller or higher-risk patients. The VASCADE Vascular Closure System is approved for closure of five to seven French access tracts. There were two patients (Patient five and nine) in our series who had an eight French sheath placed in a hepatic vein, and the access tracts were successfully closed with the VASCADE Vascular Closure System. The VASCADE MVP System is designed for six to twelve French access sites and could be considered for patients who have hepatic or splenic vein access with larger sheaths, although we are not aware of any reports of this at this time.

Limitations

This is a retrospective review of a small number of patients. This is off-label use of this device as most of the patients in our series were children, and the VASCADE Vascular Closure System was approved for use in femoral vessels. In addition, there was no comparative group in the same time frame to compare efficacy and bleeding complications with.

Conclusion

The VASCADE Vascular Closure System can be used following transhepatic and trans-splenic venous access in the cardiac catheterisation laboratory to safely close the access tract and potentially reduce the risk of post-procedural bleeding complications. Further evaluation in a larger cohort of patients, particularly children is needed to ensure the VASCADE Vascular Closure System is safe for use and provides adequate haemostasis following

https://doi.org/10.1017/S1047951124025538 Published online by Cambridge University Press

hepatic or splenic venous access in paediatric patients. Creation of a standardised post-procedure follow-up protocol would also assist in ensuring safe use of this system for these patients.

Acknowledgements. None.

Financial support. None.

Competing interests. Dr Stapleton is a proctor for Edwards Lifesciences and W.L. Gore, and is a consultant for Medtronic. Dr Qureshi is a consultant for WL Gore, Abiomed, Edwards Lifesciences and Medtronic. All other authors report they have no financial relationships to disclose.

Ethical standard. The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national guidelines on human experimentation and with the Helsinki Declaration of 1975, as revised in 2008.

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