MynxGrip vascular closure device use in pediatric neurointerventional procedures

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OBJECTIVE The aim of this paper was assess the efficacy and safety of using the MynxGrip arterial closure device in pediatric neuroendovascular procedures where the use of closure devices remains off-label despite their validation and widespread use in adults.

METHODS A retrospective review of all pediatric patients who underwent diagnostic or interventional neuroendovascular procedures at the authors' institution was performed. MynxGrip use was predicated by an adequate depth of subcutaneous tissue and common femoral artery (CFA) diameter. Patients remained on supine bedrest for 2 hours after diagnostic procedures and for 3 hours after therapeutic procedures. Patient demographics, procedural details, hemostasis status, and complications were recorded.

RESULTS Over 36 months, 83 MynxGrip devices were deployed in 53 patients (23 male and 30 female patients; mean age 14 years) who underwent neuroendovascular procedures. The right-side CFA was the main point of access for most procedures. The mean CFA diameter was 6.24 mm and ranged from 4 mm to 8.5 mm. Diagnostic angiography comprised 46% of the procedures. A single device failure occurred without any sequelae; the device was extracted, and hemostasis was achieved by manual compression with the placement of a Safeguard compression device. No other immediate or delayed major complications were recorded.

CONCLUSIONS MynxGrip can be used safely in the pediatric population for effective hemostasis and has the advantage of earlier mobilization.

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KEY WORDS vascular closure device; MynxGrip; endovascular procedures; interventional procedures; common femoral artery; vascular disorders

ACHIEVING fast and effective hemostasis after cerebrovascular procedures with minimal discomfort confers particular benefits in the pediatric population where patients are less cooperative and may need prolonged sedation to ensure immobilization after manual compression.

The application of vascular closure devices has been broadly investigated and previously approved in adults, but their efficacy and safety have not been approved for pediatric patients, and any application of such devices in children is considered off-label.^{2,9} In general, vascular closure devices are being used in adults for several reasons,

such as overall lower risk of bleeding and faster hemostasis, earlier mobilization, and to take into account underlying coagulopathies, concurrent anticoagulant medications, obesity, high blood pressure, and the patient's mental status and level of cooperation. The same reasons apply to the use of vascular closure devices in pediatric patients. There is no study in children that addresses the risk of bleeding with manual compression; however, there is no reason to assume that the risk would be less in children than in adults with the same risk factors.

The frequencies and patterns of using vascular closure devices are often practitioner dependent, and intervention-

ABBREVIATIONS CFA = common femoral artery; PEG = polyethylene glycol.

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alists choose to use the device based on patient status and risk factors.

The technical challenges of pediatric arterial access differ from those in adults. On the positive side, the vessels are more superficial and straighter with little or no intrinsic disease. However, a smaller arterial diameter, larger catheter-to-vessel ratio, and a greater risk of spasm and dissection confer a higher risk of iatrogenic arterial occlusion compared with adults. Moreover, children are less likely to conform to postprocedural instructions for immobilization, which may put them at higher risk of rebleeding compared with adults. Multiple studies have concluded that common femoral artery (CFA) access should be standard for pediatric angiographic procedures.^{1,9,12}

Among the closure devices approved for adult use, pertinent disadvantages may include an incompatible device size relative to the small CFA diameter in children, a mural or transmural attachment with a cicatricial action, and retained intraluminal biomaterial after completion of the procedure.¹² The MynxGrip device (AccessClosure Inc.) achieves hemostasis through the delivery of an extravascular, nonadhesive, expansile, water-soluble foam plug that fully resorbs over 1 month. There are no known contraindications for MynxGrip except a known allergy to polyethylene glycol (PEG) according to the manufacturer's suggested protocol. The main reason for the use of MynxGrip in our practice is the low rate of reported complications in adults and the fact that MynxGrip does not leave any biomaterials inside the vessel after the procedure.

Methods

The current study on the use of the MynxGrip in pediatric patients was approved by our institutional review board. Between October 2013 and November 2016, a retrospective review of our database and medical records was performed for all pediatric patients (age < 18 years) who underwent diagnostic or interventional neurovascular procedures. The children's demographic parameters of age, sex, body mass index (BMI), and their status as either an inpatient or outpatient were recorded.

The use of MynxGrip was confined to pediatric patients who fulfilled standard safety criteria, which consisted of an adequate subcutaneous tissue space (assessed visually and by ultrasonography) and a CFA diameter greater than 4 mm; these criteria are based on those of previous studies, guidelines, and the manufacturer's instructions-for-use protocols.^{4,14} The MynxGrip deployment technique in children was identical to the technique used in adults if the child met our criteria for the utilization of the device as outlined above. All punctures were performed using micropuncture set under ultrasonographic guidance to place a 5-Fr sheath, and at the end of the procedure a roadmap image of the puncture site was acquired using an injection through the sheath to confirm the adequacy of the anatomy and puncture site. A 5-Fr sheath was used in all procedures, and all were conducted under general anesthesia. MynxGrip deployment was performed according to the manufacturer's suggested protocol.

The delivery device comes in 2 sizes, 5-Fr and 6- to

7-Fr sheaths, and consists of a single lumen balloon catheter without an end hole that was designed to be advanced to a calibrated marker through a short sheath. The balloon is then inflated intravascularly and pulled back until it meets the resistance of the vessel wall. The extraluminal positioning of the more proximal delivery site is confirmed by observing the lack of back bleeding through the sheath. The foam plug is extruded by calibrated advancement of the pushing catheter. PEG is the main part of the sealant, which expands when in contact with the subcutaneous fluid and seals the arteriotomy site. After 2 minutes the balloon is deflated, the delivery device is removed with the sheath, and light manual compression is performed for 3 minutes. The groin site and distal pulses were assessed every 15 minutes for 1 hour, every 1 hour for 4 hours, and then every 4 hours until same-day discharge or overnight for inpatients.

All patients had the sheaths and catheters irrigated by microdrip infusions of heparinized saline (3 units per 1000 ml), and intravenous bolus heparin was administered to select interventional cases (50–75 unit/kg loading dose and 20–30 units/kg/hr maintenance dose).

Results

Over 36 months, there were 302 diagnostic or interventional neuroendovascular procedures performed on 192 patients that were conducted through CFA access. The closure device was not used in 139 patients (72.4%), including 89 patients younger than 6 years, 14 patients older than 6 years without adequate subcutaneous soft tissue for safe deployment, and 36 patients in whom only a 4-Fr catheter was used without a sheath. In the 53 patients (27.6%) who underwent 83 procedures, the MynxGrip device was deployed. Most of these patients (57%) were between 12 and 15 years of age, although the youngest patient was 6 years (Table 1). The mean age-adjusted BMI was 23.5, with a range from 15.9 to 39.3. The CFA diameter ranged between 4 mm and 8.5 mm with a mean $\pm$ SD of 6.24 ± 1.16 mm. Subcutaneous fat tissue thickness was between 9 mm and 29 mm with a mean $\pm$ SD of 15.54 ± 5.74 mm. Demographic and procedural information are presented in Table 1.

Two patients required an additional dose of heparin due to the prolonged procedural time. Patients left the extended recovery area 3 hours after interventional procedures and 2 hours after diagnostic procedures.

Forty-six percent of our procedures consisted of diagnostic neuroangiography, and 54% consisted of embolization of spinal or cerebral arteriovenous malformations. The list of neurovascular conditions indicated for neuroangiography or intervention is shown in Table 2.

Of the 38 patients who underwent diagnostic angiography, 29 (76%) returned for a subsequent angiographic procedure after a mean of 21 days; in all but 1 of these cases the sheath was placed through the same CFA immediately above the previous puncture site. MynxGrip deployment was successful in 82 procedures (98.8%). The 1 (1.2%) device failure occurred in a young teenage patient in which the device balloon failed to inflate. The device was extracted, and hemostasis achieved by manual compression

TABLE 1. Patient demographic and procedural characteristics

Variable	Value
Mean age, yrs	14.07 ± 2.87
Age category*	
Children (6–11 yrs)	9 (17)
Young teenagers (12–14 yrs)	20 (38)
Teenagers (15–17 yrs)	24 (45)
Sex	
Male	23 (43.3)
Female	30 (56.7)
Mean age-adjusted BMI	23.48 ± 4.95
Age-adjusted BMI category	
Underweight (BMI <18.5)	3 (5.7)
Normal (18.5 ≤ BMI < 25)	32 (60.4)
Overweight (25 ≤ BMI < 30)	13 (24.5)
Obese (BMI ≥30)	5 (9.4)
Status†	
Inpatient	40 (48.2)
Outpatient	43 (51.8)
Mean CFA diameter, mm	6.24 ± 1.16
Side of arteriotomy†	
Rt	82 (98.7)
Lt	1 (1.3)
Type of interventional procedure†	
Diagnostic angiography	38 (45.7)
Angiography & embolization	45 (54.4)
Mean time btwn initial & subsequent procedure, days	21 ± 16.97

BMI = body mass index.

Values are shown as the number of patients (%) or mean ± SD unless stated otherwise.

* Age categories are based on those of the Division of Human Development and Disabilities of the Centers for Disease Control and Prevention (<https://www.cdc.gov/ncbddd/childdevelopment/positiveparenting/>).

† Values are shown as the number of procedures (%).

with the placement of a Safeguard external compression device (Merit Medical Systems, Inc.).

No major complications such as uncontrolled access site hemorrhage, hematoma, pseudoaneurysm, or fistula were detected immediately or during the follow-up period, which ranged from 1 to 8 weeks (mean 3 weeks).

A list of the relevant comorbidities can be found in Table 3.

Discussion

Currently, there are 2 possible ways to achieve hemostasis at the CFA puncture site: manual compression or the use of a vascular closure device. Manual compression requires a longer time of arterial compression, which can also be affected by multiple factors including catheter or sheath size, blood pressure, body habitus, and coagulation status, in comparison with almost immediate hemostasis with the use of closure devices. The total time for deployment of the MynxGrip device, including 3 minutes of manual compression, is less than 5 minutes. Manual com-

TABLE 2. List of neurovascular conditions treated using neuroangiography

Type	No. of Patients (%)
Intracranial AVM/AVF	28 (52.8)
Intracerebral hemorrhage	7 (13.2)
Hypervascular lesion	4 (7.5)
Spinal AVM/AVF	4 (7.5)
Extracranial AVM/AVF	3 (5.6)
Aneurysm	2 (3.8)
Other vascular abnormalities (including vasculitis)	5 (9.4)

AVF = arteriovenous fistula; AVM = arteriovenous malformation.

pression in our practice is performed for a minimum of 12 minutes, with a range of 12–45 minutes reported in other studies,^{13,14} and is usually performed while the patient is still under general anesthesia. Therefore, using a vascular closure device can decrease the general anesthesia time by up to 40 minutes (range 7–40 minutes). In addition to the higher risk of subsequent bleeding from the puncture site with manual compression, compliance with immobilization is generally more difficult in the pediatric population, which adds to the risk of rebleeding.^{17,18}

After hemostasis is achieved, manual compression requires a longer period of immobilization of the patient (4–6 hours) compared with the use of the MynxGrip device (2 hours). Dauerman et al. reported a significant decrease in the mean time to ambulation after both diagnostic and interventional catheterization (162 minutes) with the use of a vascular closure device in comparison with manual compression (270 minutes).⁵

In a recent study, Walter et al. compared complications, length of hospital stay, and resulting costs of manual compression with femoral vascular closure devices in adults. They reported a significant cost reduction with the use of a vascular closure device against manual compression in diagnostic (€275 [approximately \$328 USD]) and interventional (€373 [approximately \$445 USD]) catheterizations. They concluded that vascular closure devices significantly reduce complication rates and subsequent length of hospital stay and associated costs.¹⁷ This also has been shown in another study by Kerré et al. who compared the costs of vascular closure device use with manual compression in interventional procedures and found a significant reduction (€498 [approximately \$594 USD]) in total costs with the use of a vascular closure device.¹¹ Although the general conclusion regarding the economic effects of vascular closure device use versus manual compression might not be accurate due to different accounting systems in oth-

TABLE 3. Patient comorbidities

Comorbidities	No. of Patients (%)
Hypertension	2 (3.7)
BMI >25	18 (33.9)
Attention-deficit/hyperactivity disorder	3 (5.7)
Thrombocytopenia	2 (3.7)

er countries, to the best of our knowledge all previously published studies in the English-language literature have shown the significant lower costs of interventional procedures with the use of a vascular closure device. Similarly, in our practice, the typical time spent in the postanesthesia care unit is 2–4 hours, and by simply looking at the cost savings due to the shorter stay gives us a potential minimum cost saving of \$150.

Previous studies have also shown the safety and efficacy of the MynxGrip vascular closure device in adults,^{8,10,16} but there is no evidence for the safety and efficacy of MynxGrip in the pediatric population where manual compression is the standard of care.

An ideal closure device should have a simple design, be easy to use, be more effective than manual compression in achieving hemostasis, and enable earlier ambulation, while having a low rate of complications such as infection, bleeding, or thrombosis.

Commercially available vascular closure devices commonly used by neurointerventionists can be categorized into 4 main groups¹⁴: 1) suture-based devices such as Perclose (Perclose Inc.), ProStar (Abbott Vascular), and ProGlide (Abbott Vascular); 2) plug-based devices such as AngioSeal (St. Jude Medical) and MynxGrip; 3) metal clip-based devices such as StarClose (Abbott Vascular) and Angiolink (Angiolink Corp.); and 4) disc-based devices such as Catalyst (Cardiva Medical, Inc.).

Prabhu et al. reviewed AngioSeal (6-Fr Angio-Seal Evolution) use in 38 children (range 4–17 years old) after percutaneous femoral arterial puncture. They reported 37 of 38 successful deployments of the device and 1 access site hematoma as a minor complication.¹³ However, they were concerned about the potential compromise posed by the presence of an intraluminal anchor, which takes about 2 months to resorb.

Given the smaller arteries in children, it is desirable to use an entirely extraluminal implant, and given their young age it should be fully resorbable. Among alternative devices, StarClose and Vascade (Cardiva Medical, Inc.) are purely extraluminal, although the former is a larger device with a permanent implant. Vascade is a newly developed device that is similar to MynxGrip in that it deposits an expansile implant, which in this case consists of collagen rather than PEG, and uses a nitinol disc as a temporary intraluminal anchor during deployment instead of the balloon used by MynxGrip. Although similar in design, Vascade is a less established device for adults, and a potential concern is the tolerance of the pediatric arteries for the disc-anchor design rather than the balloon used by MynxGrip. MynxGrip is a more established device in adults and was designed to achieve immediate hemostasis of a common femoral arteriotomy with the application of a water-soluble PEG sealant to the outside of the vessel. Hence, our decision to use MynxGrip as the main vascular closure device in our practice was based on 2 facts: 1) low reports of complications in previous studies conducted on adults; and 2) no remaining intra- or extraluminal element after the procedure and complete resorption of the extraluminal plug over 30 days.

Prior adult studies on the complications of the MynxGrip device have reported a complication rate of 0%–

4.2%. Differences between the reported rates are based on the quality of follow-up and definition of complications.^{3,6,7} In a salient study, Grandhi et al. reported a total complication rate of 2.45% (13 major and 10 minor) with the application of MynxGrip in 937 neurovascular procedures. Major complications consisted of 7 patients who required surgical intervention and 6 patients who required blood transfusion for groin hematoma. Minor complications included 4 minor hematomas, 3 infections, 1 case of puncture site pain, and 1 femoral artery dissection (which was managed nonsurgically). They confirmed that lower BMI and larger sheath size are independent predictors of device failure in their practice.⁸

To the best of our knowledge, the current study is the first report of the use of the MynxGrip vascular closure device in the pediatric population. We found MynxGrip to be safe and effective in achieving hemostasis at the CFA arteriotomy site in children undergoing diagnostic or neurointerventional procedures. The low rate of complications in our practice is consistent with previous studies conducted in the adult population.^{3,8,15}

In addition to all relevant benefits, the application of MynxGrip, like any other vascular closure device, carries certain limitations. Having an insufficient amount of subcutaneous fat tissue and an inadequate diameter of the common femoral artery (< 4 mm) may limit the use of vascular closure devices in children. We should point out that in our practice, only 27% of all pediatric neurointerventional procedures included the use of the MynxGrip device, which was mainly due to the requirement of a sufficient CFA diameter and, as a result, all patients were older than 6 years. The other limitation of our study is that we only used 5-Fr sheaths in our procedures, whereas Grandhi et al. reported higher rates of device failure with larger sheaths.⁸

We endorse performing a future pediatric study to compare MynxGrip to manual compression in terms of procedure times, length of anesthesia, complication rates, and subsequent length of hospital stay.

Conclusions

We conclude that the MynxGrip can be safely and effectively used after the performance of diagnostic or neurointerventional procedures in children who have the appropriate anatomical criteria for device use.

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Disclosures

The authors report no conflict of interest concerning the materials or methods used in this study or the findings specified in this paper.

Author Contributions

Conception and design: Shaibani, Shokuhfar, Hurley. Acquisition of data: all authors. Analysis and interpretation of data: all authors. Drafting the article: Shaibani, Shokuhfar, Hurley, Al-Smadi, Ansari. Critically revising the article: all authors. Reviewed submitted version of manuscript: all authors. Approved the final version of the manuscript on behalf of all authors: Shaibani. Statistical analysis: Alden. Administrative/technical/material support: Shaibani, Shokuhfar, Hurley, Ansari, Potts, Jahromi, Alden. Study supervision: Shaibani, Shokuhfar.

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