

Study of Safety and Efficacy of Endovascular Management of High-Flow Arteriovenous Malformation

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ABSTRACT

Background: The majority of extratruncular high flow arteries are treated with endovascular therapy, specifically embolization and sclerotherapy.

Objective: This study aimed to evaluate the efficacy as well as safety of endovascular management of high-flow arteriovenous malformation (HFAVM).

Patients and methods: In a clinical trial we conducted this trial on 12 cases with high-flow AVM at Vascular Surgery and Interventional Radiology Department, Zagazig University and International Medical Center. Endovascular intervention was done to all patients.

Results: There was 25% of the cases (3 cases) had complications. One case had a contracture scar, one case had transient ischemia and one case had necrosis, 83.3% of the cases had the complete technique, successful clinical results and very good outcomes while 16.7% were poor. There were no statistically significant differences between cases with poor clinical results and cases with successful clinical results in demographic data, history, clinical data, laboratory findings, or treatment data.

Conclusion: Embolosclerotherapy appears to be a safe and effective intervention for high-flow AVMs.

Keywords: High-Flow Arteriovenous Malformation, Endovascular management.

INTRODUCTION

Vascular malformations provide one of the most pressing challenges in contemporary medicine due to the complexity of both diagnosis and treatment ⁽¹⁾. There are two types of vascular malformations; high-flow and low-flow. Arteriovenous malformations (AVMs), congenital arteriovenous fistulas, arteriovenous fistulas after trauma, and acquired arteriovenous fistulas are all examples of high-flow malformations ⁽²⁾.

It is crucial to diagnose and treat AVMs as soon as possible to prevent complications like ulceration, bleeding, and amputation. After detection and diagnosis, a thorough vascular workup is necessary to assess the severity, blood flow, and area of the lesion ⁽³⁾.

When it comes to post-treatment monitoring, non-invasive techniques like duplex ultrasonography (DUS) are invaluable. Vital physiological data includes documentation of increased arterial flow rates before therapy and decreased arterial flow rates after therapy. Persistent thrombosis documentation can be imaged and correctly assessed in low-flow malformations ⁽⁴⁾.

In terms of diagnostic value, computed tomography (CT) is inferior to magnetic resonance imaging (MRI). Unlike computed tomography (CT), magnetic resonance imaging (MRI) can reliably differentiate between high-flow and low-flow vascular abnormalities. As a result, a full evaluation can be performed by considering the vascular malformation's proximity to nerves, muscles, tendons, solid organs, bone, and subcutaneous fat. Observing patients with MRI is a great noninvasive alternative to repeated arteriography and venography used to assess treatment

outcomes. Intraosseous vascular abnormalities and determining the extent of bone involvement are CT's primary uses ⁽⁴⁾.

It is now widely known that endovascular therapy utilizing embolization and sclerotherapy methods is the treatment of choice for the vast majority of extratruncular high flow AVM lesions ⁽⁵⁾.

The study objective was evaluation of efficacy as well as safety of endovascular managing high-flow arteriovenous malformation (HFAVM).

PATIENTS AND METHODS

In a clinical trial we conducted this trial on 12 cases with high-flow AVM at Vascular Surgery and Interventional Radiology Department, Zagazig University and International Medical Center.

Inclusion criteria: Age from 8 to 60 years, both sexes, and all patients presented with high-flow AVM as assessed by clinical examination, duplex ultrasound and preoperative MRI or CTA.

Exclusion criteria: Intracranial AVM, hypersensitivity for angiographic dye, renal impairment, and young age below age of 8 years old.

All patients were evaluated and performed by the same surgical and radiological team with the standard procedure. History was taken from all participants and physical examinations were done.

Laboratory investigations including: CBC, CRP, PT, PTT, INR and viral markers.

Radiological investigations:

- A definitive diagnosis and evaluation of the extent of the AVMs, including those that extended into the muscles, bones, or joint space were made using non-invasive procedures such as duplex ultrasound imaging, computed tomography (CT), and magnetic resonance imaging (MRI).
- In order to validate the location of the feeding arteries and arteriovenous fistulae and develop a treatment strategy, computed tomography angiography (CTA) was done.

Preoperatively: Antibiotics (usually ceftriaxone 1 gm or Unasyn 1.5 gm) were commenced to prevent infection.

Procedure:

Either local or general anesthesia was performed based on lesion site and embolic agent. Access done either of trans-femoral or trans-brachial approaches was used according to preoperative imaging. Single or double access techniques were used. Double access technique was approached via femoral artery and vein, or femoral artery and internal jugular vein.

Embolosclerotherapy:

Here, the volume of the AVM and the proximity of the microcatheter tip to the nidus determine whether sclerotherapy or embolization will be performed, as well as the type of embolic agent that was used. Direct puncture with or without distal compression were needed in some cases to completely embolize the nidus itself.

Ethanol is used in very small doses, with total dosage caps dependent on body weight (usually no more than 0.5 cc per kg body weight) and the length of time the agent is given. Arrhythmias of the heart, narrowing of the blood vessels in the lungs, and hemolysis are all symptoms linked to the agent's escape into the central circulation. Each compartment of the AVM lesion has its own unique flow and volume characteristics, so the amount of ethanol used in each endovascular operation is customised accordingly. There is no set limit on how much ethanol can be used. Contrast injections can be practiced prior to ethanol embolization. The amount of ethanol needed for the embolization can be estimated by the amount of contrast needed to entirely displace blood without reflux into the proximal artery. In the larger lesions, likes to treat specific compartments serially, gradually achieving entire treatment over time. In order to give the patient time to establish a new baseline before proceeding with lesion therapy, we gave him or her at least four weeks to rest in between operations.

The Onyx copolymer and DMSO were administered into the malformation continually and

slowly over the course of many minutes. The microcatheter was flushed with saline solution before to Onyx embolization, and then the "dead space" was filled with dimethyl sulfoxide (DMSO).

Under fluoroscopic observation, the first Onyx injection was given. A further Onyx injection is carried out while using a negative roadmap injection technique in a serial fashion. Minimized and repeated until full occlusion of feeding arteries and nidus on control DSA or until significant reflux towards the parent artery was observed. Injection was halted and restarted a few seconds later to allow the proximal Onyx cast to harden and distal penetration of Onyx into the nidus to be attained when reflux was detected along the microcatheter in the catheterized feeder (reflux hold-reinjection technique).

Follow-up and Outcome:

Regular physical and radiological investigations with color duplex ultrasonography were used to monitor progress and evaluate primary and secondary outcomes. CTA scan was done for every patient after 6 months after the last session of emboloscclerotherapy for follow-up and measuring radiological improvement. In extensive diffuse lesions, multiple sessions of embolization and sclerotherapy may be needed either transarterial or direct puncture.

Ethical consent:

Criteria of IRB-ZU were applied. Approval was obtained from Institutional Review Board (IRB) number (9071/2-11-2021), Zagazig University Hospitals. Every patient' parent gave his consent for participation in this study. This study was conducted in compliance with the code of ethics of the world medical association (Declaration of Helsinki) for human subjects.

Statistical analysis:

In order to analyze the data acquired, Statistical Package of Social Services version 20 was used to execute it on a computer (SPSS). In order to convey the findings, tables and graphs were employed. The quantitative data were presented in the form of the mean, median, standard deviation, and confidence intervals. The information was presented using qualitative statistics such as frequency and percentage. The student's t test (T) was used to assess the data while dealing with quantitative independent variables. Pearson Chi-Square and Chi-Square for Linear Trend (X^2) were used to assess qualitatively independent data. The significance of a P value of 0.05 or less was determined.

RESULTS

This table showed that age of the studied cases ranged from 10 to 25 years with a mean of 18.67 years. Regarding sex 66.7% were male (Table 1).

Table (1): Demographic data of the studied cases

Variable	(n=12)	
Age: (years)		
Mean ± SD	18.67±4.94	
Range	10-25	
Variable	No	%
Sex:		
Female	4	33.3
Male	8	66.7
Marital status:		
Single	12	100

This table showed that all the studied cases had pain and swelling, 50% had disfigurement and 8.3% had ulcer (Table 2).

Table (2): Symptoms of the studied cases

Variable	(n=12)	
	No	%
Symptoms:		
Pain	12	100
Swelling	12	100
Disfigurement	6	50
Ulcer	1	8.3

Table (3) showed that Hb of the studied cases ranged from 10 to 13 gm/dl with a mean of 11.67 gm/dl. Creatinine level ranged from 0.8 to 1.3 mg/dl with a mean of 1.06 mg/dl. Finally INR ranged from 0.9 to 1.2 with a mean of 1.05.

Table (3): Laboratory findings among the studied cases

Variable	(n=12)
Hb: (gm/dl)	
Mean ± SD	11.67±1.07
Creatinine: (mg/dl)	
Mean ± SD	1.06±0.14
INR:	
Mean ± SD	1.05±0.12

Table (4) showed that most frequently used material was alcohol followed by Onyx (58.4% and 33.3% respectively). Almost 2 thirds of the cases (66.7%) had 1 session.

Table (4): Intervention data among the studied cases

Variable	(n=12)	
	No	%
Type of material:		
Alcohol	7	58.4
Alcohol+Coils	1	8.3
Onyx	4	33.3
Session:		
1	8	66.7
2	3	25
3	1	8.3

This table showed that 25% of the cases (3 cases) had complications. One case had contracture scar, one case had transient ischemia and one case had necrosis (Table 5).

Table (5): Complications among the studied cases:

Variable	(n=12)	
	No	%
Complications:		
No	9	75
Contracture scar	1	8.3
Transient ischemia	1	8.3
Necrosis	1	8.3

This table showed that 83.3% of the cases had complete technique and also 83.3% had successful clinical results (Table 6).

Table (6): Intervention results among the studied cases

Variable	(n=12)	
	No	%
Technical results:		
Incomplete	2	16.7
Complete	10	83.3
Clinical results:		
Poor	2	16.7
Success	10	83.3

Table (7) showed that 83.3% of the cases had very good outcome while 16.7% were poor.

Table (7): Follow up results among the studied cases

Variable	(n=12)	
	No	%
Outcome:		
Poor	2	16.7
Very good	10	83.3

Table (8) showed that there were no statistical significance differences between cases with poor clinical results and cases with successful clinical results in demographic data, history, clinical data, laboratory findings or treatment data.

Table (8): Relation between different parameter and intervention results among the studied cases

Variable	Incomplete (poor) (n=2)		Complete (success) (n=10)		Sig. Test	P
	No	%	No	%		
Age: (years)					0.66 [^]	0.52 NS
<i>Mean ± SD</i>	16.5±4.95		19.1±5.09			
Sex:					1.2 ^{\$}	0.27 NS
<i>Female</i>	0	0	2	100		
<i>Male</i>	4	25	6	75		
Previous intervention:					0.90 ^{\$}	0.64 NS
<i>No</i>	1	33.3	2	66.7		
<i>Embolization</i>	1	12.5	7	87.5		
<i>Surgical+Embolization</i>	0	0	1	100		
Course:					1.92 ^{\$}	0.17 NS
<i>Progressive</i>	1	50	1	50		
<i>Non progressive</i>	1	10	9	90		
Stage:					0.30 ^{\$}	0.58 NS
<i>II</i>	1	12.5	7	87.5		
<i>III</i>	1	25	3	75		
Site:					8.40 ^{\$}	0.40 NS
<i>Head & neck</i>	0	0	2	100		
<i>Left hand</i>	0	0	2	100		
<i>Left foot</i>	0	0	1	100		
<i>Left lower limb</i>	0	0	1	100		
<i>Right upper limb</i>	1	50	1	50		
<i>Right forearm</i>	1	100	0	0		
<i>Right foot</i>	0	0	1	100		
<i>Right lower limb</i>	0	0	1	100		
<i>Right lumber</i>	0	0	1	100		
Symptoms:					2.4 ^{\$}	0.12 NS
<i>Disfigurement</i>	0	0	6	100		
<i>Ulcer</i>	0	0	1	100	0.22 ^{\$}	0.64 NS
Hb:					0.23 [^]	0.82 NS
<i>Mean ± SD</i>	11.5±0.71		11.7±1.16			
Creatinine:					0.09 [^]	0.93 NS
<i>Mean ± SD</i>	1.05±0.07		1.06±0.16			
INR					0.54 [^]	0.60 NS
<i>Mean ± SD</i>	1.1±0.14		1.06±0.12			
Material					2.64 ^{\$}	0.45 NS
<i>Alcohol</i>	2	100	5	50		
<i>Alcohol+Coils</i>	0	0	1	10		
<i>Onyx</i>	0	0	4	40		
Sessions					0.90 ^{\$}	0.64 NS
<i>1</i>		2.5	7	87.5		
<i>2</i>	1	33.3	2	66.7		
<i>3</i>	0	0	1	100		
Complication					5.6 ^{\$}	0.13 NS
<i>No</i>	1	11.1	8	88.9		
<i>Contracture scar</i>	1	100	0	0		
<i>Transient ischemia</i>	0	0	1	100		
<i>Necrosis</i>	0	0	1	100		
Follow up out come:					1.92 ^{\$}	0.17 NS
<i>Poor</i>	1	50	1	50		
<i>Very good</i>	1	10	9	90		

[^]: Independent t test ^{\$}: Chi square test (χ^2)

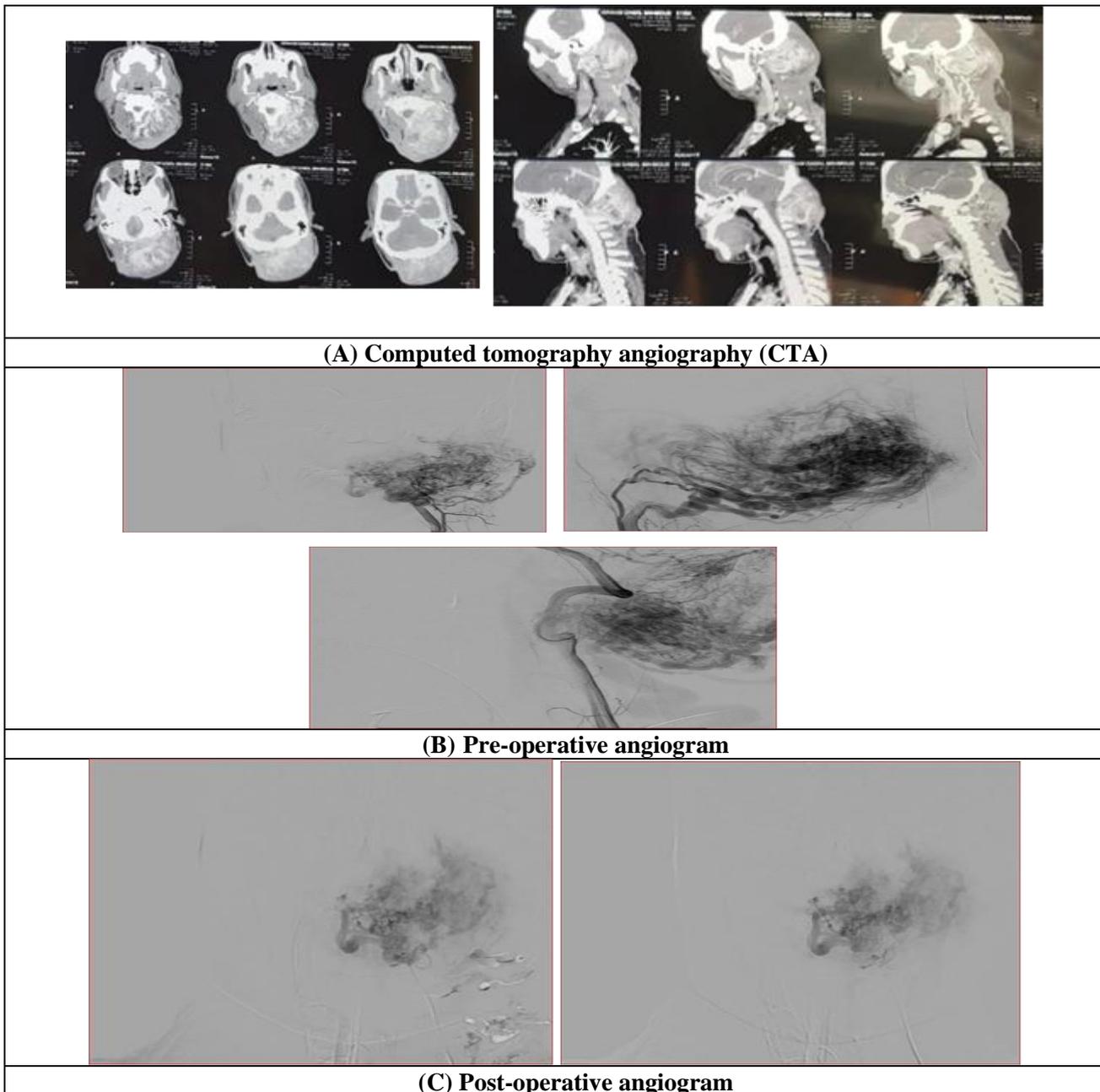


Figure (1): Male patient 23 years old with a large AV malformation in the left posterior aspect of the neck extending to the left occipital region managed by alcohol injection, Transfemoral approach till canulation of posterior auricular artery to inject pure alcohol onto the lesion through the catheter and percutaneous.

DISCUSSION

One of the most sclerosing and profoundly penetrating local embolic agents (LEAs) is alcohol (96% ethanol). Fibrinoid necrosis is induced via cytotoxic damage induction and thrombosis. Alcohol's low viscosity and limited visibility during systemic migration increase the likelihood of non-target embolization and other adverse consequences with a mortality rate reported of 0.6%. To be effective as an embolic liquid agent, a substance must have both sclerotic and embolic properties, without causing systemic toxicity⁽⁶⁾. One of the best-known examples of this is Onyx®⁽⁷⁾. Even if this is not immediately attainable with a microcatheter due to its ability to make a cast through the nidus⁽⁸⁾.

The current study included 12 cases with high-flow AVM. The mean age of the included cases was 18.67 years. Another study handling the same perspective included a total of 16 cases, whose mean age was 38.9 years, and that age was higher than the one reported by our study⁽⁹⁾.

In the current study, males represented 66.7% of these cases, while the remaining patients were females. Similarly, **Kilani et al.**⁽¹⁰⁾ reported that males had a higher prevalence compared to females in their study which included 19 cases of AVM. The authors included 10 males in addition to 9 females.

Regarding symptoms in the current study, all the studied cases had pain and swelling, while, there was 50% had disfigurement and 8.3% had ulcers. These

findings are in agreement with the study of **Rikihisa et al.** ⁽¹¹⁾. In another study, pain and swelling were reported by all cases, whereas bleeding was experienced in 8 (44.44 %) cases. In addition, 10 (55.56 %) cases complained of disfigurement caused by the lesion ⁽¹²⁾.

According to the laboratory findings, the current study revealed that the Hb of the studied cases ranged from 10 to 13 gm/dl with a mean of 11.67 gm/dl. Creatinine levels ranged from 0.8 to 1.3 mg/dl with a mean of 1.06 mg/dl. Finally, INR ranged from 0.9 to 1.2 with a mean of 1.05. These results are going with the laboratory findings in a study of **Li et al.** ⁽¹³⁾.

Regarding the type of material used in intervention embolization, the current study observed most frequent used material was alcohol followed by Onyx ampoules (Type 18-1.5 ml) (58.4% and 33.3% respectively). These findings agree with that of **Zheng et al.** ⁽¹⁴⁾ and **Saad et al.** ⁽¹²⁾.

A study of **Hyun et al.** ⁽¹⁵⁾ conducted 29 patients underwent ethanol embolotherapy. In 29 patients, ethanol embolization was performed a total of 61 times (range: 1-10; median: 1). Of the 29 patients, 17 received only one treatment. Six patients underwent the transarterial technique, while the remaining 11 underwent direct puncture. Twelve patients needed a transarterial technique in addition to a straight puncture. The same patient was treated with both transarterial ethanol embolotherapy and coil embolization through direct puncture. Seventeen out of the 29 patients showed signs of improvement, or 59%. No progression of the lesion was seen in three cases (10%). Out of the 29 patients, two (7%) did not respond to treatment. Only 24% (7/29) of the issues were considered to be major, while 52% were considered to be minor. The most common mild consequence was skin necrosis (35%; 10/29). Their research led them to the conclusion that Ethanol embolotherapy for foot AVMs is feasible and safe. It has also been found in the past that Onyx is not a very curative agent. In preliminary work by **Hoss et al.** ⁽¹⁶⁾ there was evidence of recanalization in 13 of 18 samples taken after Onyx embolization. Evidence from the past suggests that ethanol sclerotherapy is a successful long-term treatment with low rates of recanalization, angiogenic recruitment, and disease progression. A sclerotic agent, ethanol ablates the nidus by inducing inflammation of the nidus endothelium and subsequent severe thrombosis ⁽¹⁷⁾. **Han et al.** ⁽¹⁸⁾ reported that in the treatment of scalp AVMs, ethanol embolization offers the possibility of cure while carrying a tolerable risk of both mild and significant consequences. After AVMs have been surgically devascularized, aesthetic outcomes can be enhanced through resection.

In the current study, 8 cases (66.7%) had only one embolization session, whereas the remaining three cases had two sessions (25%). No complications were documented in any of the sessions. It is frequent that multiple embolization sessions are necessary ^(19, 20).

Another study done in 2017 found that in 14 of the instances, 73.68%, just one embolization session was performed; in three cases, 15.78%; in one case, 5.26%; and in one case, 5.68 sessions were performed (5.26%) ⁽¹⁰⁾.

As regards the encountered complications, the current study observed that 25% of cases had complications that were encountered in 3 cases, one case (8.3%) had contracture scar, one case (8.3%) transient ischemia, and one case (8.3%) had skin necrosis. On the other hand, a study of **Saad et al.** ⁽¹²⁾ transient ischemia was encountered in 2 cases (11.11%). Other complications included ulceration (5.56%), foot gangrene (5.56%), hand ischemia with amputation (5.56%), contracture scar (5.56%) and necrosis with transient PE (6.7%). The two cases that had finger and foot amputation had previous brachial and posterior tibial ligation respectively. Also, histoacryl was used in these cases, and it was associated with reflux, that exaggerated the ischemic condition.

Regarding the intervention results and outcome in the current study, complete embolization was achieved in 10 cases (83.3%), while only 2 cases had incomplete embolization. As regards the clinical results, success was achieved in 10 cases (83.3%). While two cases had poor clinical result (16.7%). In line with our results, **Saad et al.** ⁽¹²⁾ revealed that complete embolization was achieved in most cases (88.89%), while only one case had partial embolization. As regards the clinical result, success was achieved in 16 cases (61.11%). Only two cases had poor clinical result (11.11%). Other studies have reported varying degrees of success; for example, in 2004, **Numan et al.** ⁽²¹⁾ published a case series describing 15 procedures on 9 patients with upper or lower extremity AVM. They reported complete embolization in 2 patients and significantly reduced flow in the other 4 cases, but overall, the clinical success rate was low (33.3%). The low success rate may have been due to the lack of experience with onyx® a property at the time, but with the knowledge that has been gained through neurovascular procedures, the substance is currently being handled more effectively.

No statistically significant differences were found between instances with poor clinical results and those with successful clinical results in terms of demographic data, history, clinical data, laboratory findings, or follow-up duration, all of which are potential predictors of intervention effectiveness. These findings are in accordance with the results of **Kilani et al.** ⁽¹⁰⁾, **Park et al.** ⁽²²⁾ and **Saad et al.** ⁽¹²⁾ studies.

CONCLUSION

Most of our patients with advanced AVMs showed positive therapeutic results when treated with ethanol. Embolization procedures for AVMs should not exceed 1 mL per kg of body weight due to the potential for serious side effects. AVMs that are tiny and localized in

the tongue may only require a single ethanol embolization surgery for treatment. In conclusion, embolosclerotherapy appears to be a safe and effective intervention for high-flow AVMs.

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