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Clinical Review of Arteriovenous Malformation in the Brain: a Theoretical Study Explaining the Behavior of LAVA Liquid Embolic System during Endovascular Treatment

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Summary

A comprehensive clinical assessment is conducted by Neurosafe Medical Co., Ltd.to thoroughly document the clinical safety, clinical performance, and clinical benefits of LAVA liquid embolic system. This meticulous review adheres to the guidelines outlined in the New Medical Device Regulation (MDR) 2017/745/EC, Medical Device Directive (MDD) 93/42/EEC, and the latest version of BS EN ISO 14155:2020. The review was done based on the following intended purpose of this product.

Abstract

There is no theoretical study on blood flow in brain arteriovenous malformation (AVM). We present a numerical theory on AVM and LAVA liquid embolic system AVM embolization. Darcy's law was used to compute flow relations for brain AVMs. Maag's formula was used to explain the diffuse patterns of N-butyl-2-cyanoacrylate (NBCA) and ethylene-vinyl alcohol copolymer (EVOH) in brain AVMs. According to Darcy's law, the instantaneous blood flow rate through an AVM is directly proportional to the pressure drop between two places in the AVM and indirectly proportional to the distance between them. The greater the pressure gradient (through the AVM), the greater the discharge rate, and the discharge rate of blood will often differ through different AVM (or even through the same AVM, in a different direction) even if the same pressure gradient exists in both cases. Subsequent to Darcy's initial discovery, Maag found that the radius of NBCA or EVOH diffusion is inversely proportional to their viscosity. Darcy's Law and Maag's formula could be used to analyze flow patterns of brain AVM and LAVA liquid embolic system behavior in AVM near ideal.

The article addresses a notable gap in theoretical studies concerning blood flow in brain arteriovenous malformations (AVMs), a condition characterized by abnormal connections between arteries and veins in the brain. Arteriovenous malformations can lead to serious medical complications, including hemorrhages and neurological deficits.

Understanding the hemodynamics of blood flow within these malformations is crucial for devising effective treatment strategies.

1. Lack of Theoretical Studies on Blood Flow in Brain AVMs:
   - The article begins by highlighting the absence of theoretical studies on blood flow within brain arteriovenous malformations. This gap underscores the need for comprehensive research to elucidate the complex dynamics of blood circulation in these abnormal vascular structures.

2. Introduction of Numerical Theory on AVM and LAVA Liquid Embolic System:
   - It presents a numerical theory focused on both brain AVMs and the LAVA (Liquid Embolization of Arterial Hemorrhages) liquid embolic system used in AVM embolization procedures. This theoretical framework aims to provide insights into the hemodynamic aspects of blood flow within AVMs and the behavior of embolic substances during treatment.

3. Utilization of Darcy's Law:
   - Darcy's law, a fundamental principle in fluid dynamics, is employed to compute flow relations specific to brain AVMs. According to Darcy's law, the instantaneous blood flow rate through an AVM is directly proportional to the pressure drop within the malformation and inversely proportional to the distance between two points within the AVM.

4. Pressure Gradient and Discharge Rate Correlation:
   - The article emphasizes the relationship between pressure gradients within the AVM and the resulting discharge rate of blood. Higher pressure gradients lead to increased blood discharge rates. Importantly, it notes that even with similar pressure gradients, the discharge rate may vary across different AVMs or within the same AVM in different directions.

5. Application of Maag's Formula:
   - Maag's formula is introduced to explain the diffuse patterns of embolic substances, specifically N-butyl-2-cyanoacrylate (NBCA) and ethylene-vinyl alcohol copolymer (EVOH), within brain AVMs. Maag's formula establishes an inverse relationship between the radius of substance diffusion and its viscosity.

6. Analyzing Flow Patterns and System Behavior:
   - The combination of Darcy's law and Maag's formula is proposed as a method to analyze the flow patterns within brain AVMs and the behavior of the LAVA liquid embolic system during AVM embolization. This theoretical framework is suggested to be applicable under near-ideal conditions.

Keywords: brain AVM, LAVA liquid embolic system, Darcy's law, AVM embolization, EVOH

Introduction

Intracranial arteriovenous malformations (AVMs) have been described as lesions of the cerebral vasculature for 160 years since Luschka and Virchow [1]. Brain AVM is a con- glomeration of abnormal arteriovenous shunts that may be connected to each other by one or more fistulas, with feeding arteries and drain- ing veins within brain parenchyma [2,3]. This di- rect connection of arteries and veins (a lack of a capillary bed) causes pulsatile low resistance and turbulent high-velocity blood flow, high- pressure vascular channels, which can often lead to rupture of vessels [2,3] (Figure 1). Under- standing AVM embolization is very emotional and only based on our experiences, such as the fact that NBCA diffuses in AVM in a blood flow direction and lava could diffuse inversing the pressure gradient in AVM. There is a lack of rational understanding of the factors affecting embolic agent diffusion in AVM. Embolic agents diffuse well in some AVM but not in others. This theoretical study will explain the behavior of liquid embolic agents during endovas- cular AVM embolization. We hope to present this as a breakthrough to open the gateway for a liquid embolic agent diffusion theory in AVM.

Intracranial arteriovenous malformations (AVMs) have been recognized as intricate anomalies within the cerebral vasculature for over a century and a half, dating back to seminal observations by Luschka and Virchow in the mid- 19th century (1). Described as conglomerates of abnormal arteriovenous shunts connected by one or more fistulas, brain AVMs present a unique vascular architecture, featuring feeding arteries and draining veins embedded within the brain parenchyma [(2,3)]. This distinctive anatomy, characterized by a direct connection between arteries and veins without an intervening capillary bed, results in pulsatile, low-resistance, and turbulent high-velocity blood flow, leading to the development of high-pressure vascular channels. Unfortunately, the consequence of this aberrant blood flow often manifests in the rupture of vessels, posing a significant risk to patients [(2,3)] (see Figure 1).

Despite the longstanding recognition of AVMs, the understanding of AVM embolization remains a challenge, often relying on empirical knowledge and experiential insights. For instance, the diffusion of N-butyl-2-cyanoacrylate (NBCA) in AVMs follows the blood flow direction, while the behavior of LAVA (Liquid Embolization of Arterial Hemorrhages) suggests diffusion in the inverse direction to the pressure gradient within the AVM. The complexities of AVM embolization evoke emotional considerations and necessitate a more profound comprehension of the factors influencing this intricate medical intervention.

This literature seeks to bridge the existing gaps in rational understanding related to AVM embolization, delving into the nuanced dynamics of blood flow, embolic substance diffusion, and the underlying factors that influence treatment outcomes. By exploring the historical context and acknowledging the empirical nature of current knowledge, this literature aims to contribute to a more comprehensive and rational foundation for AVM embolization practices.

Methods

Darcy's Law

The cornerstone of fluid dynamics in porous media, Darcy's law, was first formulated by the pioneering French civil engineer Henry Darcy in 1856. Darcy's groundbreaking insights emerged from meticulous experiments involving vertical water filtration through sand beds, as illustrated in Figure 2 [(4)].

In his experimental endeavors focused on unidirectional flow within a uniform medium, Henry Darcy unearthed a fundamental principle that has since shaped our understanding of fluid dynamics. Darcy's law establishes a linear proportionality between the flow velocity of a fluid through porous media and the factors influencing this flow. It serves as a foundational framework for comprehending fluid behavior in diverse porous environments, including those encountered in the intricate vascular structures of the human body.

As we embark on an exploration of the methodologies employed in this study, Darcy's law stands as a pivotal tool, providing a mathematical foundation to analyze and interpret fluid dynamics within the context of arteriovenous malformations (AVMs). The application of this venerable principle contributes to a systematic and quantitative understanding of blood flow within AVMs, offering valuable insights that inform our broader comprehension of vascular anomalies and, by extension, guide advancements in medical interventions and treatments.

Conclusion

In conclusion, the clinical article introduces a numerical theory aimed at addressing the lack of theoretical studies on blood flow in brain arteriovenous malformations. By applying principles such as Darcy's law and Maag's formula, the authors seek to enhance the understanding of hemodynamic patterns within AVMs and the dynamics of liquid embolic systems during treatment. This research contributes to the broader objective of refining therapeutic approaches for patients with brain arteriovenous malformations.

The comprehensive clinical review conducted by Neurosafe Medical Co., Ltd. represents a meticulous examination of the clinical safety, clinical performance, and clinical benefits associated with the LAVA liquid embolic system. This thorough evaluation adheres rigorously to established guidelines, including the New Medical Device Regulation (MDR) 2017/745/EC, the Medical Device Directive (MDD) 93/42/EEC, and the latest iteration of BS EN ISO 14155:2020.

The review process has been executed with a commitment to ensuring compliance with regulatory standards and best practices in the field of medical devices. By systematically evaluating the LAVA liquid embolic system against these criteria, Neurosafe Medical Co., Ltd. has sought to provide a robust and evidence based understanding of the product's safety, performance, and overall benefits in clinical applications.

This scrutiny has been conducted with a clear focus on the intended purpose of the LAVA liquid embolic system. Through a methodical assessment aligned with regulatory frameworks, the review aims to offer valuable insights into the product's capabilities in embolization procedures and its potential impact on patient outcomes.

By adhering to the highest standards set forth in regulatory directives and international norms, the clinical review by Neurosafe Medical Co., Ltd. contributes to the broader goal of ensuring the reliability, efficacy, and safety of the LAVA liquid embolic system in clinical practice. This diligent evaluation serves as a cornerstone for healthcare practitioners, regulatory authorities, and stakeholders seeking a comprehensive understanding of the product's clinical profile.

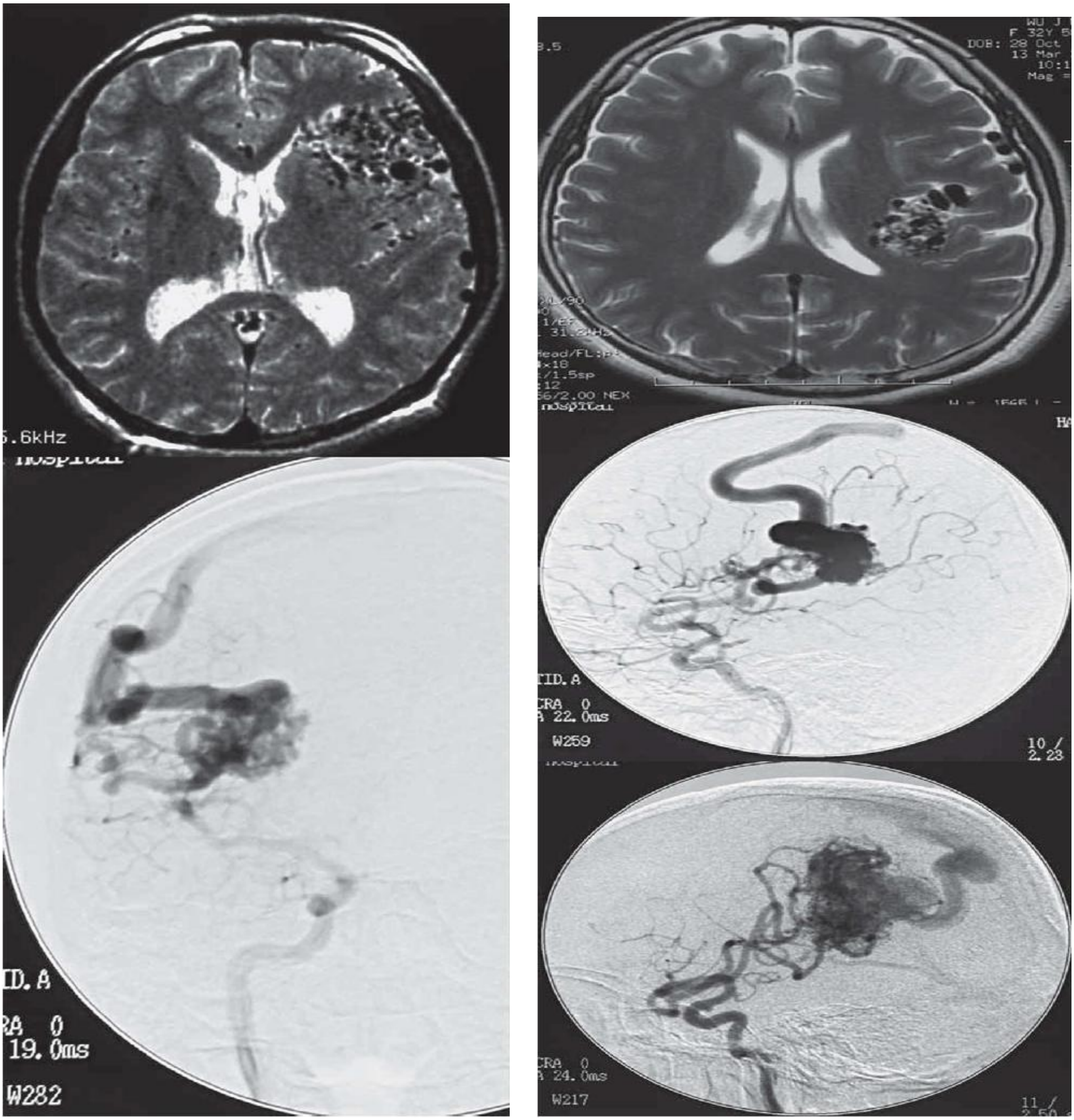

Figure 1 A,B) T2-weighted MR images of AVM. C-E) Angi- ograms of brain AVMs.

and the applied pressure difference. When the outflow is stable, Q is the flow volume through the
sample content over time t. Darcy's law is:

$$Q=\frac{kA\Delta pt}{\mu L} \quad (1)$$

where: Δp = pressure [cmH2O], L = length of sample [cm], Q = volumetric flow [cm3], A = cross-sectional area of sample [cm2], k = permeability (cm/s), μ = incompressible fluid of vis- cosity (cp or mPa•s), t = time [s].

Since its discovery, Darcy's law has been found valid for any linear flow of Newtonian fluid in consistent units. Likewise, while it was established under saturated flow conditions, it may be adjusted to account for unsaturated and multiphase flow.

The flow rate is q=Q/t, according to Eqn. (1), the flow rate is related to other factors by

$$q=\frac{kA\Delta p}{\mu L} \quad (2)$$

The superficial velocity is $v=\frac{q}{A}$. Also, we recognize that the limit of the quotient of the pressure difference and the length of flow is minus the pressure gradient (or its derivative with respect to length, $\lim_{\Delta x\to 0}=\frac{p(x+\Delta x)-p(x)}{\Delta x}=\frac{dp}{dx}$ For transient processes in which the flux varies from point to point, we need a differential form of Darcy's law. The differential form of Darcy's law for one dimensional, horizontal flow is:

$$u=v_{\sup}=-\frac{k}{\mu}\frac{dp}{dx} \quad (3)$$

The change in sign is necessary because the direction of flow is opposite to the direction of pressure change. Eqn. (3) can be integrated to compute forms of Darcy's law for various flow geometries and fluid types. A generalization of Darcy's law for anisotropic permeability should be considered first because the blood flow in AVM is a turbulent flow. In AVMs, the permeability is assumed to be a horizontal permeability.

The permeability may vary horizontally because of compact or diffuse AVM type; plexiform, fistulous, or mixed shunts. The result is that we must consider different permeabilities for blood flows in these different directions. In a three dimensional system, the components of velocity are

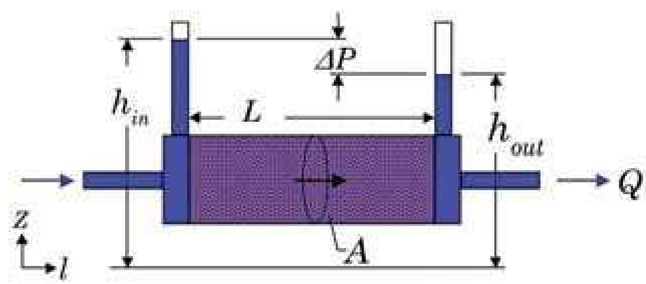

Figure 2 Simple column.

$$\begin{aligned} u_x&=-\frac{1}{\mu}\left(k_{xx}\frac{\partial p}{\partial x}+k_{xy}\frac{\partial p}{\partial y}+k_{xz}\frac{\partial p}{\partial z}\right)\\ u_y&=-\frac{1}{\mu}\left(k_{yx}\frac{\partial p}{\partial x}+k_{yy}\frac{\partial p}{\partial y}+k_{yz}\frac{\partial p}{\partial z}\right)\\ u_z&=-\frac{1}{\mu}\left(k_{zx}\frac{\partial p}{\partial x}+k_{zy}\frac{\partial p}{\partial y}+k_{zz}\frac{\partial p}{\partial z}\right) \end{aligned} \quad (4)$$

In anisotropic systems, permeability is a tensor. Physically, elements like kxy give the flow that occurs in the x-direction due to pressure gradients in the y-direction. Anisotropic porous media can act like “louvers”, with flow being “shunted” toward the direction of highest permeability (parallel to the louvers) even if the pressure gradient is not in that direction. For porous media, kij = kji, and one can always define a coordinate system in which the off- diagonal terms are zero. This is the principal coordinate space, which is defined in exactly the same way the principal stress space was defined in statics.

In the principal coordinate space (X, Y, Z), $u_X=-\frac{k_X}{\mu}\frac{\partial p}{\partial X}$, and so on. The negative sign is needed because fluid flows from high pressure to low pressure. If the change in pressure is negative, then the flow will be in the positive ‘x’ direction.

Permeation Grouting Theory

N-butyl-2-cyanoacrylate (NBCA) and ethylenevinyl alcohol copolymer (EVOH) have been used frequently in the endovascular treatment of intracranial AVMs 5,6. If the mixture comes into contact with aqueous solutions, precipitation of the polymer is initiated by diffusion of DMSO. This process begins on the surface while the core is still liquid, resulting in a soft non- adherent mass.

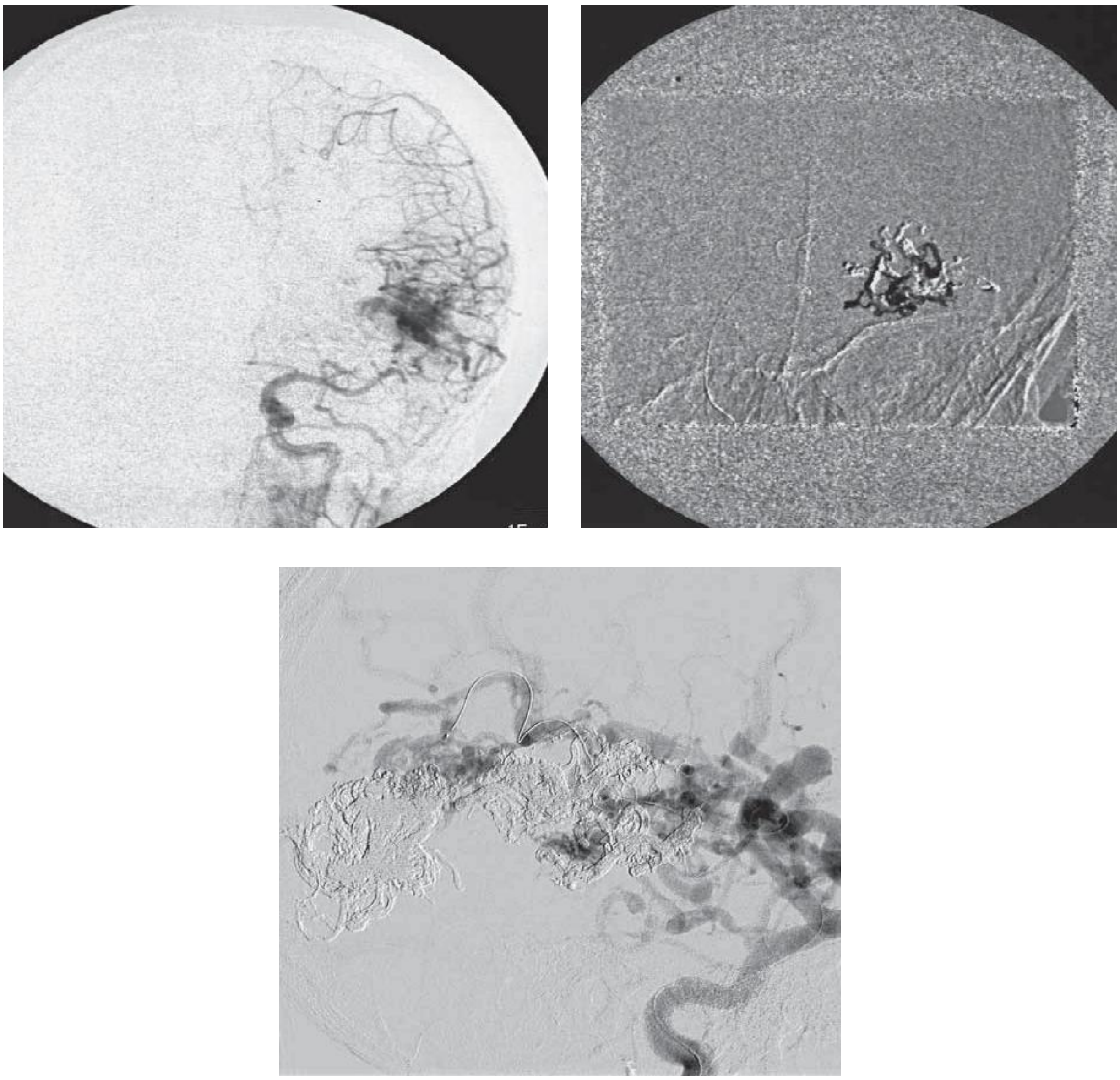

Figure 3 A) Left carotid artery angiogram showing an AVM of the left frontal lobe. B) Lava 18 permeation patterns in the AVM. C) A Marathon microcatheter was accessed to a previously embolized AVM.

Therefore, Lava has a lava like flow pattern within blood vessels without any fragmentation during its injection. Due to these properties and because Lava is not absorbable, it is capable of producing permanent vascular occlusion. (Figure 3). Figure 4 shows the Lava dispersion pattern in AVM. The spherical diffusion formula is the most widely used, Maag's formula, to explain the penetrating grouting calculation formula 7. Based on the generalized Darcy's law and theory for spherical diffusion model, Maag's formula was used for calculating the effective diffusion radius of Newton fluid injected into homogeneous sandy stratum. Maag's slurry penetration formula 7, derived from Darcy's law, is as follows:

$$R = \sqrt[3]{\frac{3kpr_0 t}{n\beta}} \quad (5)$$

where: R = Diffusion radius (cm), k = permeability (cm/s), β = viscosity (cp or mPa•s), p = pressure (cmH_2O), $r0$= the grouting pipe radius (cm), n = porosity, t = time (s).

Results

Darcy's law is a simple mathematical statement which neatly summarizes several properties of blood flow in AVMs. If there is no pressure gradient over a distance, no flow occurs (these are hydrostatic conditions). If there is a pressure gradient, flow will occur from high pressure towards low pressure (opposite the direction of increasing gradient, hence the negative sign in Darcy's law). The greater the pressure gradient (through the same formation material), the greater the discharge rate, and the discharge rate of fluid will often be different through different formation materials (or even through the same material, in a different direction) even if the same pressure gradient exists in both cases.

Subsequent to Darcy's initial discovery, Maag found that, all other factors being equal, R is inversely proportional to the fluid viscosity [β (cp or mPa•s)] and AVM porosity (n). The viscosity of NBCA in centipoise (cp or mPa•s) is 2~5 (25°C). EVOH is now commercially available as Compact or plexiform AVMs should be embolized with NBCA or Lava 18 (with lower viscosity) for easy penetration to obtain a better penetration into the nidus.

Table 1 The radius of currently used DMSO-compatible microcatheters

Catheters	*Distal I.D. (in)*	r_0 *(mm)*
UltraFlow™ HPC	0.012	0.15
Marathon™	0.013	0.17
Rebar™ 10	0.015	0.19
Headway Duo	0.0165	0.21
Rebar™14	0.017	0.22
Echelon™	0.017	0.22
Rebar™ 18	0.021	0.27
Rebar™ 27	0.027	0.34

Although higher pressure is associated with a larger diffusion radius, the embolization procedure should be stopped immediately when the injection resistance increases significantly to prevent rupture of the microcatheter or vessels. This phenomenon may be an indicator of the complete filling of the embolized nidus compartment.

Discussion

Darcy's law and Maag's formula were initially used for theoretical research on industrial permeation grouting. We think that the model of dynamic principle of AVM and its embolization is consistent with Darcy's law. The fluid mechanics of blood seepage in AVM and diffusion of LAVA liquid embolic system permeation in AVM are consistent sets of units that can be used in Darcy's law. Darcy's law is mathematically analogous to incompressible linear phenomenological transport laws. Applications of Darcy's model to blood flow in an AVM nidus where u, P, L and k are the Darcy velocity (the average of the blood flow velocity over the AVM cross section), blood pressure, dynamic viscosity of the blood and the permeability of the AVM porous medium, respectively. Our work has applied this law in the field of the mechanics of blood perfusion through soft tissues.

At low pressure, flow of Lava liquid embolic system in AVM is much like laminar flow of liquids — the flow rate is proportional to the difference in pressure. The Lava injection started at a rate of 0.1 mL/min. The embolic agent released the tip of the microcatheter under free-flow

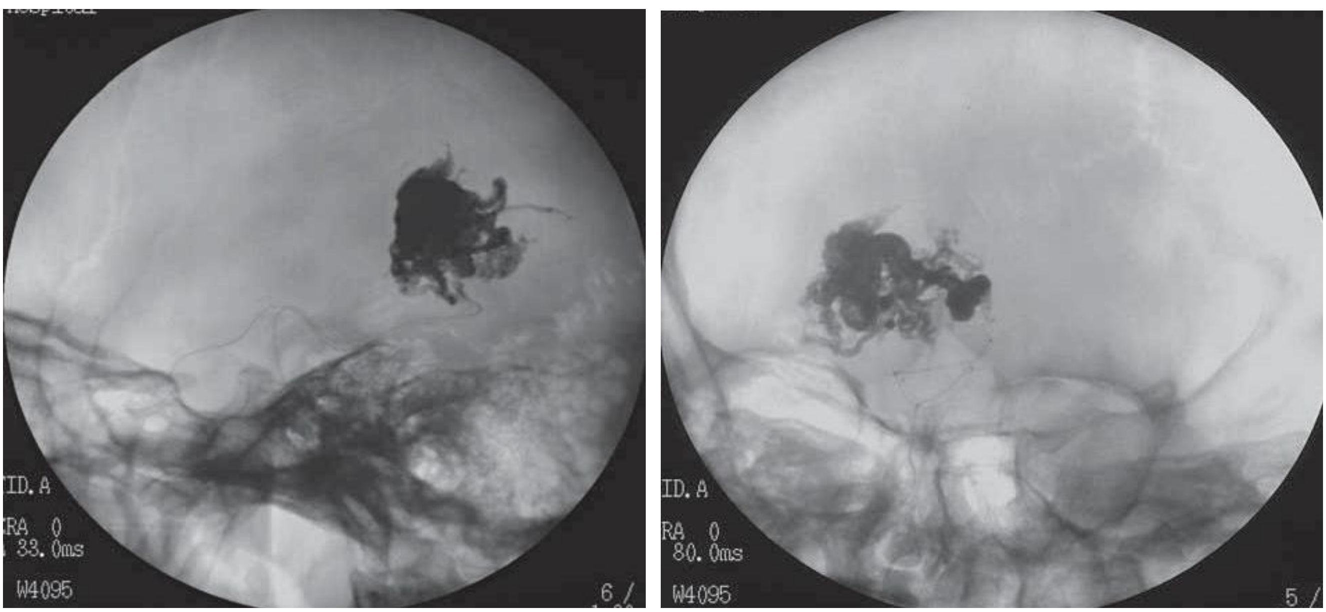

Figure 4 A,B) Lava dispersion pattern in AVM.

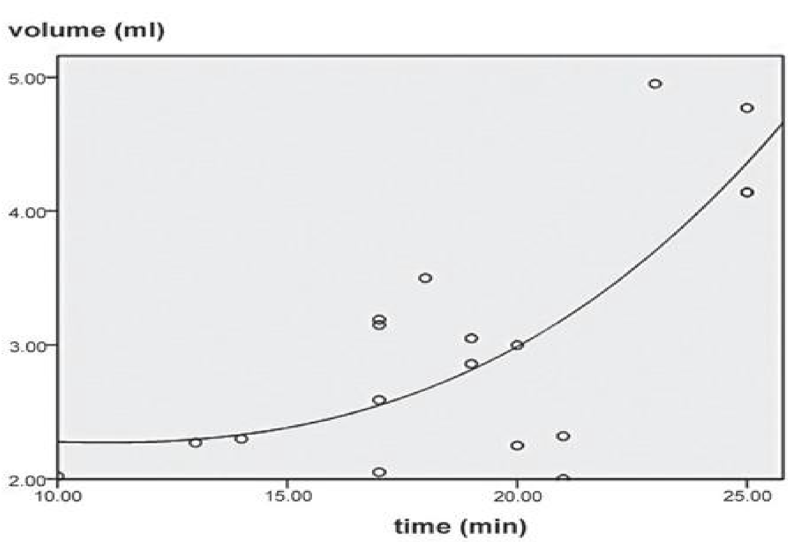

Figure 5 Non-linear regression resulted in a cubic curve (R2=0.572).

conditions and filled the directly dependent nidus compartment antegradely and later retrogradely until it flowed to the tip of the micro- catheter. Thus, Eqn. (4) could be used for accurate analysis of L a v a liquid embolic system behavior in AVM near ideal.

The Darcy model has been utilized success- fully in several biomedical applications leading to a number of developments in the areas[9]. Huyghe and van Campen[5] presented a constitutive formulation for finite deformation of porous solids in order to model flow through different hierarchical arrangements. They developed an extended Darcy model utilizing an averaging method which transformed the net- work of pores into a continuum. They considered the pores a network of cylindrical vessels in which Poiseuille-type pressure-flow relation- ships are valid.

In three dimensions, Eq. (3) can be generalized to

$$v = \frac{k}{\mu} \nabla p \qquad (6)$$

where the permeability k is a general second-order tensor. The terms v and ∇p are Darcy velocity and pressure gradient vector. For isotropic porous medium, the permeability is scalar and Eq. (6) reduces to

$$\nabla p = -\frac{k}{\mu} v \qquad (7)$$

Later, Vankan et al.[11] compared a hierarchical mixture model of blood perfusion in bio- logical tissue that utilizes an extended Darcy equation for blood flow with a network analysis of the biological tissue. A good correspondence is achieved between both methods if the hierarchical quantification is based on the network fluid pressure. Vankan et al.[12] also performed a simulation for blood flow through a contracting muscle, with a hierarchical structure of pores (the hierarchy corresponds to the tree-like vascular structure). The fluid flow was described by a Darcy model for deformable porous media with a second-order permeability tensor while fluid pressure and hydrostatic solid pressures were related through an elastic fluid solid interface.

The state of the fluid, the Darcy permeability tensor and the elastic interface were taken to be functions of space as well as the hierarchical level. They found that their calculated blood pressures approximately corresponded to blood pressures measured in skeletal muscles. Butler et al.[13] studied interstitial fluid flow in axisymmetric soft connective tissues such as ligaments or tendons (fibrous tissue connecting bones and cartilage and connective tissue that connects muscle to bone, respectively) when they are in tension. The flow in these tissues were modeled as Darcian flow through a porous medium having the pressure and velocity of the interstitial fluid as the un- known variables. A parametric study was con- ducted by varying the fluid viscosity and the permeability of the solid matrix where they were found to strongly affect the resulting fluid flow behavior. Baish et al.[14] considered a simple network model to model the important features of flow through a network of permeable and compliant vessels embedded in an isotropic porous medium. They used the Darcy model to represent the flow through the porous medium. Weber et al. [15] reported their experiences in the treatment of intracranial AVMs with Lava embolization focusing on the embolization technique with Lava. Non-linear regression for Lava volume and injection time was performed and resulted in a cubic curve (R2=0.572) (Figure 5), which is consistent with Maag's formula. In this non-linear regression analysis, the relationship between the perfusion radius (R) and injection time (t) was only considered, besides the factors of Lava viscosity (18 and 20), pushing pressure (p) and AVM type, which is associated with k and n.

Limitations

Darcy's law and Maag's formula may be too simple to elucidate the natural state of properties of blood flowing in AVMs and liquid embolic agent AVM embolization. In this theoretical consideration only a steady flow is taken into account, but in the brain the pulsatile low resistance flow still prevails in many AVMs. And there is a major difference between industrial permeation grouting and the biological tissue. But we think that this may provide a simple and understandable method for explanation of AVM and AVM embolization. This theory needs further investigation to make it more precise.

Conclusions

Darcy's Law and Maag's formula could be used to analyze flow patterns of brain AVM and Lava liquid embolic system behavior in AVM near ideal. This theory needs further investigation to make it more precise.

The comprehensive clinical review conducted by Neurosafe Medical Co., Ltd. represents a meticulous examination of the clinical safety, clinical performance, and clinical benefits associated with the LAVA liquid embolic system. This thorough evaluation adheres rigorously to established guidelines, including the New Medical Device Regulation (MDR) 2017/745/EC, the Medical Device Directive (MDD) 93/42/EEC, and the latest iteration of BS EN ISO 14155:2020.

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