STUDY OF PHIL EMBOLIC SYSTEM IN THE TREATMENT OF INTRACRANIAL DURAL ARTERIOVENOUS FISTULAS

Status: Recruiting

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

- 22 to 80 years old - diagnosis of intracranial arteriovenous dural fistula (dAVF)

Exclusion Criteria:

- multiple dAVFs to be treated - history of life threatening allergy to contrast media (unless treatment for allergy is tolerated) - women who are pregnant

Conditions & Interventions

Conditions:
Brain & Nervous System
Keywords:
Arteriovenous Dural Fistula, dAVF

More Information

Description: Arteriovenous fistulas are a type of arteriovenous malformation whereby blood is shunted directly from the arterial system to the venous system, bypassing the capillary bed. Dural arteriovenous fistulas (dAVFs) are a rare type of acquired intracranial vascular malformation consisting of a pathologic shunt located within the dura mater of the brain. 1 These lesions have been categorized by Awad et al 2, Borden et al 3, and Cognard et al 4 according to their locations and patterns of venous drainage. Dural arteriovenous fistulas (dAVFs) can be observed anywhere on the dural layer meninges of the cranium and spine. This condition accounts for 10-15% of all intracranial arteriovenous malformations diagnosed. 5 These fistulas can be congenital or acquired diseases. When observed as acquired diseases, they are most often encountered in males between the age of 50 and 60 years old. DAVFs present with a wide spectrum of symptoms or none at all, and come with varying range of risk of clinical sequalae. A thorough evaluation of the anatomy and venous drainage is crucial to determining the best treatment strategy. Acute presentation with intracranial hemorrhage occurs in up to 65% of patients, and patients with a previous intracranial hemorrhage may have up to a 35% risk of another neurologic event within 2 weeks. 6 Endovascular embolization has become the primary treatment approach for DAVFs. The goal of endovascular therapy is to achieve complete obliteration of the fistulous point between the feeding arteries and the draining veins. This can be safely accomplished by occluding the draining veins, which often results in complete closure of the lesion, unlike in cerebral arteriovenous malformations. The PHIL® device is a non-adhesive liquid embolic agent comprised of a Triiodophenol-(lactide-co-glycolide) acrylate and hydroxyethyl methacrylate (HEMA) co-polymer dissolved in DMSO (dimethyl sulfoxide). An iodine component is chemically bonded to the co-polymer to provide a radiopacifier element during fluoroscopic visualization. The PHIL® Liquid Embolic System consists of a sterile, pre-filled, 1.0 mL syringe of PHIL® liquid embolic, a sterile, prefilled 1.0 mL syringe of DMSO, and microcatheter hub adaptors. Intracranial dAVFs may produce a wide variety of symptoms. Individual risk is evaluated by a precise analysis of the venous drainage. The decision to treat is based on this analysis. Treatment strategy is decided by a multidisciplinary neurovascular team and must consider the individual risk of each dAVF. Embolization is, in most cases, proposed as the first treatment option and often succeeds to obtain a complete and definitive cure of the dAVF. Surgery may be required in some locations or in the case of embolization failure. Radiosurgery is rarely indicated because it is not always efficient and because of the time required for shunt obliteration and the risk of bleeding in this period. Liquid embolics have distinct characteristics that make them a principle treatment option in the obliteration of dAVFs. They can flow through complex vascular structures so that the surgeon does not need to target the catheter to every single vessel. 10 There is little choice available in the US market for the liquid embolic treatment of dAVF. Currently, nBCA (TRUFILL n-Butyl Cyanoacrylate, Cordis) and Onyx (Medtronic) are the only liquid embolic agents available. Both are approved by FDA for presurgical embolization of cerebral arteriovenous malformations. However, they have been used off-label for dAVFs. This use demonstrates the unmet medical need for the patients suffering with dAVFs. The aim of this study is to evaluate the use of PHIL in the management of intracranial dural AVFs.

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