Final Results of the ELANA FDA-IDE Study on High Flow Cerebral Bypasses for Surgical Treatment of Anterior Circulation Aneurysms

David J. Langer; Peter Vajkoczy; Shamik Chakraborty; Michael Tymianski; Sepideh Amin-Hanjani; Fady T. Charbel; Babu Guai Welch; Duke S. Samson; Leena Kivipelto; Jacques J. Morcos; Ricardo A. Hanel; Michael Reinert; Ali F. Krisht; Luca Regli; Martin Lehecka; Ulf Schneider; Marcus Czabanka; Lars Kihlstrom; Tristan Van Doomaal; Cornelius Tulleken; Bart Van

Introduction

Complex intracranial aneurysms and tumors may require high flow cerebral bypasses for safe treatment. All previous studies on such high flow bypasses have been retrospective single institution case series with complication rates and outcomes that may be inherently biased. Here we present results from the first prospective, multicenter international trial on high flow bypasses using the Excimer Laser Assisted Nonocclusive Anastomosis (ELANA) system.

Methods

A total of 8 centers in the US, Canada, and Europe participated in an FDA - IDE trial. All patients required flow replacement or protective bypass for safe treatment of giant/complex aneurysms or tumors; and additionally in Europe, for flow augmentation for bilateral carotid occlusion.

Results

A total of 46 patients were enrolled, with a mean age of 54.2 (R: 17 - 76 yrs); 15 males, and 31 females. A subgroup of 35 patients who received a permanent ELANA bypass for anterior circulation aneurysms were analyzed. Bypass patency was 94% immediately postoperatively, and 85% at 7 days. 14% of patients suffered a stroke with neurologic deficits at 30 days post op. Mortality was 6%, with 86% of patients having a modified Rankin score of 2 or better. ELANA related complication rate was 6%.

Conclusions

The ELANA bypass system can consistently create a saphenous vein EC-IC bypass with no occlusion time, minimizing the risk of ischemia and the need for intraoperative neuro-protective medications. These grafts appear to have an acceptable patency rate in the early postoperative period and can safely be performed in patients with complex intracranial lesions of the anterior cerebral circulation.

Learning Objectives

1. High flow bypasses - what are they, how do they work, their role in treatment of cerebrovascular disease

2. The ELANA system and its efficacy in helping treat complex cerebrovascular disease

[DEFAULT POSTER]