Study Protocol Document

Research Official Title:	A Prospective Study on Safety and Efficacy of Stenting for Chronic Middle Cerebral Artery Occlusion With Limb Dysfunction
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A prospective study on the safety and efficacy of stent placement in the treatment of chronic middle cerebral artery occlusion with limb dysfunction

I. Research Background

The middle cerebral artery (MCA) is one of the main blood vessels that supply most areas of the cerebral cortex. When chronic occlusion occurs in MCA, it seriously affects blood flow to multiple important areas of the brain, including areas that control speech, sensation, and motor function. Therefore, MCA occlusion is often associated with severe neurological deficits such as hemiplegia, speech impairment, and cognitive impairment. Chronic MCA occlusion is usually caused by intracranial atherosclerosis, a procession in which the arterial wall gradually accumulates fat and calcium, leading to narrowing of the vessel. When blood vessels narrow to a certain extent, blood flow is reduced to a level that is insufficient to meet the needs of brain tissue, which can result in ischemic brain injury. Studies have shown that hypertension and diabetes are the main risk factors for intracranial stenosis and chronic MCA occlusion. These conditions increase the risk of MCA occlusion by accelerating the process of atherosclerosis, increasing the thickness and stiffness of blood vessel walls. In addition, smoking is another important controllable risk factor, which increases the risk of atherosclerosis by damaging vascular endothelial function and promoting inflammatory reaction.

Although there has been sufficient research on acute MCA occlusion, including vascular recanalization protocols during the acute phase, such as thrombolysis and mechanical thrombectomy, there is limited research on chronic MCA occlusion. Due to the long-term and complex nature of the disease course, the treatment strategies and prognosis evaluation for patients in the chronic phase are not yet clear. In addition, for patients who have not received timely or ineffective acute treatment, how to improve their long-term prognosis through interventional treatment is a major challenge in current research.

Previous case reports and retrospective studies have shown that even after years of MCA

occlusion, vascular reconstruction surgery can still successfully restore blood flow and achieve good therapeutic effects. However, currently, the vascular reconstruction treatment for chronic MCA occlusion is mainly limited to case reports, and there is a lack of systematic prospective studies to verify the safety and effectiveness of these treatments.

Given the above background, this study aims to fill this research gap by systematically evaluating the efficacy and safety of stent placement in patients with chronic MCA occlusion through prospective clinical trials, in order to provide more scientific and standardized treatment guidance for such patients.

II. Research Purpose

The aim of this study is to evaluate the safety and effectiveness of stent placement in patients with chronic MCA occlusion, and to explore its impact on blood flow recovery, reduction of reocclusion rate, and improvement of neurological function recovery.

III. Research Methodology

1. Research Design

This study adopts a prospective, single center, observational clinical trial design. By setting up a stent group and a control group, the therapeutic effects of the two groups of patients were compared to evaluate the safety and effectiveness of stent placement in patients with chronic middle cerebral artery (MCA) occlusion. This study has been approved by the Clinical Ethics Committee of Huishou Central People's Hospital in terms of human research ethics, and strictly adheres to relevant ethical standards and guiding principles.

2. Study Participants

Selection Criteria:

1） Age 18 and above, male and female unlimited.

2） Chronic occlusion of MCAconfirmed by magnetic resonance imaging (MRI) or computed tomography (CT), lasting more than 3 months.

3） Neurological deficits caused by MCA occlusion, such as hemiplegia, speech disorders, etc.

4） Have not received MCA stent revascularization treatment in the past three months.

Exclusion Criteria:

1） Acute stroke occurred within the past three months.

2） Severe heart disease, liver and kidney dysfunction, cerebral hemorrhage, active bleeding, or coagulation dysfunction.

3） Allergy to contrast agents.

4） Serious mental illness or inability to comply with research requirements.

5） Pregnant or lactating women.

6） MCA occlusion was found without any symptoms.

7） Participated in other clinical trials within the past six months.

3. Research Process

Participants first undergo detailed screening to ensure that they meet the inclusion and exclusion

criteria. Afterwards, all patients or their legal representatives are required to sign an informed consent form. Subsequently, patients will be randomly assigned to either the stent group or the control group. The control group received aspirin treatment, while the stent group underwent stent placement surgery on the basis of aspirin treatment.

4. Stenting Method

The patient underwent whole brain angiography in the intervention room, and the Seldinger technique was successfully used to puncture the right femoral artery and insert a 5F sheath. Insert the 5F pigtail catheter and vertebral artery catheter sequentially through the sheath tube for angiography to identify occlusion of left or right MCA. Next, the MCA stent is inserted, and the 0.014-inch microwire and microcatheter are successfully navigated to the left or right MCA occlusion site through the catheter. Then, the microcatheter is exchanged, and an appropriately sized intracranial self expanding stent is placed and released. After surgery, the femoral artery puncture site was sutured using a vascular closure device.

IV. Statistical Analysis

Use R software (version 4.1.2) for statistical processing.Classifieddatais presented in frequency and percentage, while continuous data is represented in mean ± standard deviation or median and interquartile range. Inter group comparisons were conducted using methods such as independent sample t-test, Mann Whitney U test, chi square test, or Fisher's exact test.

V. Research Plan

Preparation phase (March 2021- April 2021): Obtain ethical approval, prepare and review all research documents (including informed consent forms and research protocols), and

establish a data management system.

Recruitment stage (May2021 November 2021): Identify eligible patients through the neurology and interventional radiology departments of collaborating hospitals, screen for inclusion and exclusion criteria, and obtain informed consent from patients.

Treatment stage (December 2021- January 2022): Arrange stent placement surgery or start standard drug treatment for eligible patients.

Follow up stage (February 2022- February 2023): Regular follow-up will beconducted on all participants to evaluate treatment outcomes, including blood flow recovery, reocclusion rate, and neurological function recovery. The follow-up time points is 3 months after surgery.

Data analysis stage (March 2023 September 2023): Collect all data, conduct statistical analysis, compare the differences between the two groups, and write a research report.