3D Time-of-Flight Magnetic Resonance Angiography in Hemodialysis Patients With Arteriovenous Fistula

Clinical trial No: NCT04312731

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Study Design and Patient Population

From June 2018 to March 2021, maintenance dialysis patients in the nephrology department at our hospital with suspected dysfunctional AVFs were considered candidates for this study. The inclusion criteria of the dysfunctional hemodialysis access patients were as follows. 1) Physical examination showed swelling of the extremities, a reduction of pulsation and a tremor at the anastomotic site, and reduction of the murmur. 2) The venous pressure and arterial negative pressure were increased, and the blood flow of the fistula was decreased (< 500 mL/min). 3) The hemodialysis site was difficult to puncture during dialysis; the cannulation coagulated easily; and the bleeding time was prolonged after needle extraction. The exclusion criteria were as follows: 1) a previous history of stent or artificial blood vessel implantation; 2) contraindications to magnetic resonance; 3) a platelet (PLT) level < 60×10^9/L or an international normalized ratio (INR) > 1.5; 4), pregnancy or lactation; and 5) a functional failure of other important organs or other serious diseases except for renal failure (Clinical trial No. NCT04312731). A detailed flowchart of the patient selection process is provided in Figure 1.

Imaging protocol

Color Doppler ultrasonography: Ultrasonography studies were independently performed in the Department of Ultrasonography by two sonographers (L.X.Y. and Y.J.X. with 12 and 8 years of experience, respectively). The entire hemodialysis access fistula was evaluated by means of 5- and 7-mHz linear array scanners (Aspen Advanced; Siemens, Erlangen, Germany), from the feeding artery from the level of the axillary

artery and draining vein to the level of the subclavian vein. The examinations were performed in both longitudinal and transverse planes. Spectral waveforms were obtained at each examination level, and color Doppler interrogation was used throughout the studies. Peak systolic velocity (PSV) and the location of any narrowed areas were calculated and recorded. The PSV criteria were the same for the inflow, shunt proper (e.g., anastomotic sites), and outflow tract. All measurements were obtained from waveforms with an insonating angle of less than 60° when possible. The stenosis was considered significant if the PSV was greater than 375 cm/s or if there was narrowing of 50% or more on the grayscale imaging. All data were recorded on a form on which the localizations of the stenoses were drawn.

Magnetic resonance angiography: MRIs were undertaken on a 3-T system (Skyra, Siemens Healthcare, Erlangen, Germany) using a superficial body array matrix coil. The imaging was performed with the patient lying supine, with the target arm containing the fistula as close to the midline of the examination bed as possible. A TOF-MRA acquisition, covering a transverse slab from the elbow joint to 5 cm below the anastomosis, had acquisition parameters of a 23 ms/3.5 ms repetition time/echo time; a 70° flip angle; a 200*200 *200 mm^3 volume of interest; a 2 mm section thickness; a 1024*1024 acquisition matrix; 180 slices and an appropriately 5 minutes scan duration. Based on the TOF images, two radiologists, with extensive experience in AVF diagnosis, preliminarily determined the position of the stenosis. Finally, through an automatic subtraction method, maximum-intensity projection (MIP) images of each of the four stations were reconstructed in the coronal orientation and were fused to form a single

image using MR MobiView software (Philips Medical Systems).

The *DSAs* were carried out by interventional radiologists (Y.Q.Z. and H.T.L., who have 17 and 15 years of experience in vascular imaging, respectively) on the digital angiography unit (Artis zee; Siemens Medical Solutions), within a mean of 10 (range: 1-14) days after the ultrasonography and MRA. An access approach on the brachial artery was used. An iodine-based contrast agent (Imeron 350; Bracco Imaging, Shanghai, China) was injected through a 5-French catheter positioned in the feeding artery. The anteroposterior views were chosen at the discretion of the interventional radiologist. Images of the feeding artery, fistula and distal venous outflow were obtained. After the angiogram, percutaneous transluminal angioplasty (PTA) was performed for the areas that had >50% stenoses or that had a total occlusion.

Image analysis

Two radiologists (L.M.W. and Y.Q.Z. with 10 and 15 years of experience in evaluating vascular images, respectively) independently evaluated the MRA and DSA images while blinded to the patient's identity, medical history, and symptoms. In case of disagreement, consensus was reached after mutual consultation. The MRA datasets were evaluated on dedicated workstations (Syngo® MR B17, Siemens), and the DSA images were also analyzed on a workstation (SyngoXWP; Siemens Healthcare).

The image quality and diagnostic performance of TOF-MRA were evaluated in all regions. For all participants, the architecture of the AVF was divided into three regions: arterial inflow, anastomosis (including 1 cm of vessel length on both sides of the anastomosis), and venous outflow. The most central part of the venous outflow,

comprising the proximal half of the brachiocephalic vein and superior caval vein, was excluded from the analysis because these venous structures were not depicted by the TOF-MRA in this study.

The diagnostic quality of the images obtained at each of the three regions was graded (0-4) using the Likert scale: 0 for a “nondiagnostic” image; 1 for a “poor” quality, with the observer not confident due to severe image artifacts, significant venous contamination and/or poor vascular signals; 2 for a “fair” quality, with the observer marginally confident due to minor artifacts, mild-to-moderate venous contamination and/or a moderately homogenous vascular signal; 3 for a “good” quality, with the observer being confident; or 4 for an “excellent” quality, with no or minimal venous contamination, without artifacts and homogenous vascular signals, thereby enabling the observer to be highly confident.

The grading of lesion stenosis on CDUS, MRA, and DSA was performed by using an electronic caliper. The sonographer or radiologist determined whether stenosis or occlusion was present in all regions (Figure 2-4). The degree of stenosis was assessed according to a visual grading system: 0 = a completely smooth vessel wall; 1 = < 50% stenosis; 2 = 50–75% stenosis; 3 = 75–99% stenosis; 4 = occlusion (segmental and complete). For analysis purposes, only the most severe stenosis per region was evaluated. Stenoses with a luminal narrowing exceeding 50% were considered to be hemodynamically significant. The stenosis severity of TOF-MRA and CDUS was considered overestimated if the score of stenosis was higher than that found on DSA; otherwise, it was considered underestimated.

Statistical analysis

The Likert scores for the diagnostic image quality are reported as the mean ± standard deviation and were compared using the paired t test. DSA was considered to be the standard of reference. The whole-region and per-region sensitivities, specificities, positive predictive values (PPVs) and negative predictive values (NPVs) for the detection of significant (50–100%) stenosis are shown as proportions, with corresponding 95% confidence intervals (CIs) and were provided for each estimate. The interobserver agreement with regard to the determination of significant stenosis was evaluated by calculating the k statistic. Cohen's kappa coefficient (κ) was calculated, with $\kappa > 0.80$ regarded as "almost perfect", between 0.61 and 0.80 regarded as "substantial", and between 0.41 and 0.60 regarded as "moderate". $P < 0.05$ (two-sided) were regarded significant. The statistical analyses were undertaken using SPSS v19.0 (IBM, Armonk, NY, USA).