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Hand acceleration time (HAT) as a diagnostic tool in the assessment of haemodialysis access-induced distal ischaemia (HAIDI): study protocol for a prospective cohort study in the Barcelona south metropolitan area

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ABSTRACT

Introduction Chronic hand ischaemia may affect some haemodialysis patients with an arteriovenous fistula (AVF) or graft (AVG), a condition known as haemodialysis access-induced distal ischaemia (HAIDI). Duplex ultrasonography (DUS) can provide comprehensive insights into anatomical and perfusion properties, and measuring the hand acceleration time (HAT) has been demonstrated to be sensitive within the framework of chronic upper limb ischaemia.

Methods and analysis This single-centre, prospective cohort study will involve adult end-stage renal disease (ESRD) patients requiring either AVF or AVG for haemodialysis. The primary outcome will be HAT values (measured at the radial, ulnar and four hand arteries) before and after surgery. Secondary outcomes will include the incidence of HAIDI, vascular access patency, and the incidence of complications. A sample size of 126 subjects will be required to estimate HAIDI incidence with a 95% CI and ±5% precision. Statistical analyses will involve paired t-tests to compare preoperative and postoperative HAT values and determine optimal HAT cut-off values for diagnosing HAIDI.

Ethics and dissemination This study was approved by the Bellvitge University Hospital Institutional Review Board (PR 201/23). Written informed consent will be obtained from all study participants before any study-related procedure is performed. Results will be published in peer-reviewed journals.

Trial registration number ClinicalTrial.gov: NCT06187207. Pre Results.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Duplex ultrasonography (DUS) will be used to measure the hand acceleration time (HAT), a non-invasive, low-cost technique for quantifying blood flow.
⇒ Systematic and stepwise HAT assessments will enhance diagnostic accuracy while accounting for anatomical variability.
⇒ The observational design limits causal inferences but offers robust data on associations between HAT and haemodialysis access-induced distal ischaemia.
⇒ The examiner-dependent nature of DUS introduces an inherent risk of information bias, which will be minimised by having the procedure performed exclusively by expert professionals.

BACKGROUND

Vascular accesses (VAs) for haemodialysis are a lifeline for end-stage renal disease (ESRD) patients.[1] Although arteriovenous fistulae (AVF) and grafts (AVG) do not usually compromise hand perfusion in haemodialysis patients, around 5–7% may suffer from clinically overt hand ischaemia.[1–3] Provided that haemodialysis is the most common form of kidney replacement therapy in Europe and the USA[4 5] and ESRD incidence and prevalence are on the rise,[5] VA-related ischaemic complications are likely to gain more relevance in the near future.

An AVF represents a non-anatomic communication between a high-pressure (arterial) system and a low-pressure (venous) system, resulting in a deranged blood flow to the distal limb and hypoperfusion. This pressure gradient can also generate a reversal of blood flow in the inflow artery, referred to as vascular 'steal phenomenon'.[6] The arterial tree can often accommodate the resulting hypoperfusion by remodelling and creating a robust compensatory collateral network; hence, most patients remain asymptomatic. Nevertheless, in some cases, remodelling and compensatory collateral flow fail to maint ain the distal arterial pressure, or a previously somewhat asymptomatic arterial stenosis

Table 1 Haemodialysis access-induced distal ischaemia severity classification

Grade	Description
I	► No clear symptoms, but mild signs of ischaemia may be observed.* ► Conservative treatment may be indicated.
IIa	► Complaints during dialysis sessions or intense use of the hand, such as tolerable pain, cramps, paraesthesia, numbness, or disturbing coldness in fingers or hand. ► Conservative treatment is indicated.
IIb	► Similar complaints to Grade 2a but intolerable, requiring combined conservative and invasive treatment (endovascular or surgical).
III	► Rest pain or motor dysfunction of fingers or hand, necessitating urgent invasive treatment supported by conservative measures.
IVa	► Limited tissue loss (ulceration, necrosis). ► Reversing ischaemia may preserve clinically significant hand function. ► Urgent invasive treatment supported by conservative measures is indicated.
IVb	► Irreversible tissue loss of the hand or proximal parts of the extremity, resulting in the inability to preserve clinically significant hand function. ► Amputation is required.

Adapted from Scheltinga *et al*[3 11]
*Mild signs of ischaemia include slight cyanosis of nail beds, mild coldness of the hand skin, reduced arterial pulsations at the wrist, and reduced systolic finger pressures.

becomes clinically significant, and patients develop the so-called haemodialysis access-induced distal ischaemia (HAIDI).[6]

Despite its not fully elucidated pathophysiology, atherosclerosis of the arm's arterial tree, recurrent intradialytic hypotension and ongoing AVF maturation may determine the clinical picture of HAIDI.[7 8] HAIDI is predominantly a clinical diagnosis but sometimes can be difficult to ascertain.[9] Although signs and symptoms are sometimes non-specific (eg, pain, paleness, coldness, paraesthesia),[10] they are used for establishing the clinical severity—as proposed by Scheltinga *et al* (table 1).[3 11] Diagnostic workup may also include non-invasive procedures, such as digital pressures (at baseline and during VA compression), the digital-brachial index (DBI), plethysmography and digital oxygen saturation. Indeed, current guidelines recommend performing such procedures to aid diagnosis, these procedures lack standardisation of their diagnostic thresholds, and no reference cut-off values have been established for HAIDI.[12 13] For instance, some authors reported an association between a DBI <0.4 or digital pressures <60 mm Hg and HAIDI,[14] while others suggested higher thresholds.[15 16] Conversely, other studies failed to find a consistent relationship between DBI and HAIDI.[17] Not rarely, these patients undergo invasive procedures, such as arteriography, underscoring an unmet medical need.

Given that around 5% of all haemodialysis patients with an AVF receive treatment for HAIDI at some point of their lives,[8 18] and haemodialysis requirements are likely to rise driven by the growing incidence and prevalence of ESRD and diabetes,[5 19] a low-cost, non-invasive, and widely available diagnostic tool would be certainly most welcome. In this scenario, duplex ultrasonography (DUS) assessment can be very useful to provide comprehensive anatomic and perfusion data,[20] particularly through the acceleration time, a straightforward sonographic perfusion measurement that quantifies the time elapsed from the beginning of the systole in the arterial DUS waveform until reaching its systolic peak. Of note, the acceleration time is more extensively studied for the foot's arterial territory (pedal acceleration time), where it has been proven useful for perfusion assessment,[21–23] but recent reports have also described potential applications in other territories,[9 24–29] the hand arterial tree being one of them.[9 28 29] For instance, Gruber *et al* found promising results using the hand acceleration time (HAT) to diagnose HAIDI and assess reperfusion therapy response.[9] In a recently published exploratory cross-sectional study, we have found the HAT to be a sensitive diagnostic tool for chronic upper limb ischaemia (regardless of the cause), given the significantly different HAT values between patients and healthy volunteers.[30] Thus, it is not unreasonable to think that the HAT may also be sensitive for diagnosing HAIDI.

The present manuscript describes a study protocol designed to assess whether the HAT is a sensitive method to detect HAIDI among haemodialysis patients with a VA (either AVF or AVG). We expect to find an association between postoperative HAT values and HAIDI (diagnosed under standard clinical practice procedures), while putting them into perspective with what was previously reported by Gruber *et al*.[9] The preoperative HAT values or the change in HAT values (ΔHAT) may serve as a starting point for future studies aiming to predict the risk of developing HAIDI.

Objectives

Our primary objectives are to quantify the HAT in ESRD patients before and after surgery for creating an VA for

haemodialysis and to evaluate whether differences in preoperative and postoperative HAT values associate with the incidence of HAIDI.

Our secondary objectives are (1) to determine the number of new HAIDI diagnoses during the study period, (2) to assess the 6 month VA patency and (3) to study the VA-related complications during the study period.

METHODS AND ANALYSIS

Study design

This will be a single-centre prospective cohort study. Individual participant duration will last approximately 24 weeks. The study started on May 2023, and we expect it to end by February 2025.

Study setting and population

The study will be carried out at the Bellvitge University Hospital, a fully equipped tertiary hospital with a service area covering over two million people in the Barcelona south metropolitan area. The study population will consist of ESRD who require a VA (either AVF or AVG) for haemodialysis and under follow-up at the outpatient clinic by the Angiology and Vascular Surgery Department.

Eligibility criteria

Adult (≥18 years of age) patients of either sex, with a known ESRD diagnosis, candidates for an AVF or AVG creation surgery, and who sign the written informed consent will be included. On the other hand, all patients deemed unable to understand or comply with any study-related procedure/requirement (and those unwilling to participate), those with a previous vascular access in the ipsilateral limb, and those with existing upper limb peripheral arterial disease will be excluded. Furthermore, patients with fistulae failing to mature properly and those requiring additional treatment to improve fistulae maturation or patency will also be excluded.

Follow-up and retention strategy

No retention issues are expected since these patients already undergo DUS assessment and are followed by vascular surgeons in our setting, the only difference being the measurement of an additional parameter (ie, the HAT), which takes approximately 15 min. Nonetheless, patients will be reminded of their scheduled study visit by phone.

Participant timeline

Table 2 summarises the participant timeline during the study. As mentioned, no study-related procedures will be performed before participants sign the written informed consent. Study visits and their planned assessments will be performed as follows.

On visit 1 (V1), the study staff will make sure that potential participants meet all the inclusion criteria and none of the exclusion criteria; will provide a detailed explanation of the study objectives, procedures, and potential risks and benefits; and will provide a detailed explanation of the study, handing the participant an information sheet. We will underscore that their participation is voluntary and unpaid for. Those who decide to participate will be asked to sign the written informed consent.

Table 2 Participant timeline

	V1	V2	V3
Timepoint	Day 1 (preop.)	Week 6–8 (postop.)	Week 24 (postop.)
Written informed consent	✓		
Eligibility criteria	✓		
Baseline and sociodemographic data	✓		
Previous medical history	✓		
Medical interview	✓	✓	✓
Vascular physical examination	✓	✓	✓
VA-related data		✓	
VA physical evaluation*		✓	✓
DUS assessment†	✓	✓	✓
Adverse events	✓	✓	✓

*VA physical evaluation will include inspection, palpation and auscultation.
†HAT measurements will be performed in every study visit.
DUS assessment at V1 will include a preoperative mapping that consists of measuring the diameter of the arm's arteries and veins and conducting a perfusion assessment through the arterial waveforms. Clearly, DUS assessment of the VA will be performed only at V2 and V3.
DUS, duplex ultrasonography; post-op, post-operative; preop, preoperative; V, visit; VA, vascular access.

Thereafter, baseline and sociodemographic data—age, sex, cardiovascular risk factors (eg, smoking habits, hypertension, diabetes mellitus, dyslipidaemia)—and previous medical history—cardiovascular diseases (eg, ischaemic heart disease, congestive heart failure), pulmonary disease and ESRD characteristics (date of diagnosis, history of prior haemodialysis via a catheter)—will be collected. Information regarding anticoagulant/antiplatelet therapy will also be gathered.

The vascular physical examination will include the evaluation of distal pulses and the Allen test. Subsequently, a DUS assessment (including HAT measurement) will be carried out following the procedures detailed in the *DUS assessment* section.

Visit 2 (V2) will take place 6–8 weeks after performing the VA surgical procedure. In addition to the vascular physical examination and DUS assessment described for V1, a specific VA physical evaluation (inspection, palpation and auscultation) and DUS assessment will be performed: VA type (AVG/AVF), location (wrist/elbow), which vein (cephalic, basilic, perforating or axillary) and artery (radial or ulnar) were used, and the type of anastomosis (end-to-side, side-to-side). VA maturation and functionality will be then assessed, like the presence of

HAIDI—which will be classified as proposed by Scheltinga *et al* (table 1).[3] As outlined in the exclusion criteria, patients with fistulae failing to mature properly and those requiring additional treatment to improve fistulae maturation or patency will be excluded, as non-functional AVF/AVG do not impact hand perfusion considerably and would generate a distinct subset of patients and undermine homogeneity within the study population. Importantly, two-stage brachiobasilic fistulae are the standard procedure in our centre, while single-stage fistulae are rarely performed and typically reserved for reanastomosis cases where superficialisation and transposition are completed simultaneously. Since transposition and superficialisation are unlikely to significantly affect fistula flow or hand perfusion, these patients will be included in the analysis along with the rest of the cohort.

Visit 3 (V3) will take place 24 weeks after VA creation and will follow the same steps described for V2. Adverse events will be monitored throughout the study from the moment participants sign the written informed consent until their participation ends (online supplemental file 1).

DUS assessment

Participants will be asked to lie on the examination table in a supine position. Room temperature will be kept at approximately 24°C. Before conducting the DUS assessment, we will check for distal pulses on the upper extremities and perform the Allen test. The DUS assessment will be performed with the Philips EPIQ Elite System (Philips Healthcare, Koninklijke Philips NV, Amsterdam, the Netherlands). For HAT evaluation, a high-frequency linear array (22 MHz) will be used. At V1, we will obtain sonographic images and calculate the arterial and vein diameters in the preoperative mapping, as well as the HATs.

Notably, the technique for the HAT assessment in different hand arteries has been detailed elsewhere.[30] In brief, we will increase the colour gain and decrease the pulse repetition frequency for a proper evaluation of the hand arteries. Once the artery is located, the Doppler spectrum waveform will be analysed by freezing the image. The HAT will be measured at the radial (HAT-R) and ulnar (HAT-U) arteries and, due to possible anatomical variability in the hand's vascularisation, at four hand arteries: (1) *Princeps Pollicis* artery (HAT1), (2) *Radialis Indicis* artery (HAT2), (3) first common palmar digital artery (HAT3) and (4) third common palmar digital artery (HAT4).

The DUS assessment at V2 and V3 will focus on the VA and HAT measurements. We will perform a sonographic quantification of the blood flow through VA measured in the brachial artery, evaluate the anastomosis, and venous outflow, measuring its diameter, depth and anatomy. We will also assess the distal radial artery spectral waveform.

Diagnosis of HAIDI as per standard clinical practice

In our current standard clinical practice, a multidisciplinary committee diagnoses HAIDI by combining data from the physical examination, DUS assessment, plethysmography and DBI. A HAIDI diagnosis is established if a patient meets any of the criteria set by Scheltinga *et al*.[3] If a patient is deemed to be in a grey area (ie, does not have a straightforward diagnosis of HAIDI), the multidisciplinary committee indicates an arteriography, as recommended by the Spanish Society of Vascular Access and the European Society of Vascular Surgery.[12 13]

Outcomes

Table 3 shows the study outcomes for each study objective mentioned above.

Of note, possible types of venous outflow routes include (1) one vein, (2) two anterograde veins, (3) one anterograde and one retrograde vein and (4) two anterograde veins and one retrograde vein. Furthermore, VA patency assessment will include collecting primary patency,

Table 3 Study outcomes

	Objectives	Outcomes
Primary	To quantify the HAT in ESRD patients before and after VA surgery and whether they associate with HAIDI	► HAT values (in ms).
Secondary	To determine the number of new HAIDI diagnoses during the study period.	► The cumulative incidence of HAIDI at V3.
	To assess the 6-month VA patency	► The presence of distal pulses at V1, V2 and V3.
		► VA blood flow (in mL/min)
		► Type of venous outflow (1, 2 or 3 outflow veins, presence of retrograde vein)
		► Vein diameter (in mm)
		► Distal radial artery spectral waveform.
	To study the VA-related complications within 6 months of the procedure	► The cumulative incidence of VA-related complications at V3.

ESRD, end-stage renal disease; HAIDI, haemodialysis access-induced distal ischaemia; HAT, hand acceleration time; V1, visit 1; V2, visit 2; V3, visit 3; VA, vascular access.

primary adjusted patency and secondary patency data. Incorporating these additional patency metrics into the study will allow correlating them with HAT measurements to explore potential associations.

Data sources, data collection and quality control

Our data sources will be the clinical interviews, individual medical histories and sonographic examinations performed on all study participants. All study-related information will be registered in the participant's medical history and in an ad hoc-created database. This database will be made up of anonymised data, and only the principal investigator and authorised study team members will have access to it. Confidentiality will be ensured according to the current Spanish (LOPD 3/2018) and European (EU Regulation 2016/679 of the European Parliament and Council of 27 April 2016) legislations. All data will be dissociated, and participants will be assigned a number (code) on enrolment.

To ensure data accuracy, the principal investigator will review all individual medical histories as a quality control measure. Nonetheless, this study may have limitations. The observational design can only assess associations between predictor and outcome and does not allow for establishing cause-and-effect relationships. Furthermore, the present study might incur in information bias since sonographic measurements are examiner-dependent. Nonetheless, DUS assessments will be performed only by three examiners, who have been validated for the measurement of HATs.

Sample size and statistical analysis

A sample size of 126 randomly selected subjects will suffice to estimate—with a 95% CI and a ±5 unit precision—a population percentage of HAIDI considered around 7%.[18 31 32] A 20% substitution rate has been anticipated.

Descriptive analysis will be performed for all study variables. Categoric variables will be expressed as absolute and relative frequencies. Quantitative variables will be expressed as means (SD), whenever they meet the assumption of normality, or as medians (quartile 1; quartile 3, Q1; Q3), if they do not. Presurgery and postsurgery (at 6 weeks and 6 months) HAT values in ESRD patients will be compared with paired Student's t-tests. Additionally, Cohen's d for paired samples will be reported. The cumulative incidences and their respective 95% CIs will be estimated. The assessment of optimal HAT cut-off values for HAIDI at 6 weeks and 6 months after surgery will be based on minimising an overall cost function in two-state and three-state settings.

A receiver operating characteristic (ROC) curve will be used to evaluate HAT's ability for classifying disease status,[33] and the Youden index (J) will be used as a summary measure of the ROC curve to determine the maximum potential effectiveness of ΔHAT, alongside preoperative and postoperative HAT values. Appropriate correction methods will be applied for mean estimation and testing. Marginal generalised linear models will be applied to analyse classification probabilities, with a focus on sensitivity, specificity, and their dependence on cut-off values derived from the ROC curve and Youden index.[33]

Statistical analyses will be performed with R 4.3 software or higher (R Foundation for Statistical Computing, Vienna, Austria) for Windows.

Ethics and dissemination

The study protocol was prospectively registered (ClinicalTrial.gov: NCT06187207) and has been approved by the Bellvitge University Hospital Institutional Review Board (PR 201/23). Written informed consent will be obtained from all study participants before any study-related procedure is performed, in accordance with the updated Declaration of Helsinki, Good Clinical Practice guidelines, and applicable Spanish and European regulatory requirements. Confidentiality will be ensured according to the current Spanish (LOPD 3/2018) and European (EU Regulation 2016/679 of the European Parliament and Council of 27 April 2016) legislations.

The results will be published after study conclusion, regardless of being positive or negative. Results will also be sent for publication on (preferably) English-language peer-reviewed medical journals and medical congresses. Publishing decisions will be taken jointly between the sponsor and the investigators.

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