Clinical study protocol for the ARCH project
Computational modeling for improvement of outcome after vascular access creation

Aron Bode[1], Anna Caroli[2], Wouter Huberts[3], Nils Planken[4], Luca Antiga[2], Marielle Bosboom[3], Andrea Remuzzi[2,5], Jan Tordoir[1], on behalf of the ARCH project consortium[*]

[1]Department of Surgery, Maastricht University Medical Center, Maastricht - The Netherlands
[2]Department of Biomedical Engineering, Mario Negri Institute, Bergamo - Italy
[3]Department of Biomedical Engineering, Eindhoven University of Technology, Eindhoven - The Netherlands
[4]Department of Radiology, Academic Medical Center, Amsterdam - The Netherlands
[5]Department of Industrial Engineering, University of Bergamo - Italy

[*]A complete list of the members of the ARCH consortium can be found in the Appendix

ABSTRACT
Despite clinical guidelines and the possibility of diagnostic vascular imaging, creation and maintenance of a vascular access (VA) remains problematic: avoiding short- and long-term VA dysfunction is challenging. Although prognostic factors for VA dysfunction have been identified in previous studies, their potential interplay at a systemic level is disregarded. Consideration of multiple prognostic patient specific factors and their complex interaction using dedicated computational modeling tools might improve outcome after VA creation by enabling a better selection of VA configuration. These computational modeling tools are developed and validated in the ARCH project: a joint initiative of four medical centers and three industrial partners (FP7-ICT-224390). This paper reports the rationale behind computational modeling and presents the clinical study protocol designed for calibrating and validating these modeling tools. The clinical study is based on the pre-operative collection of structural and functional data at a vascular level, as well as a VA functional evaluation during the follow-up period. The strategy adopted to perform the study and for data collection is also described here.

Key words: Arteriovenous fistula, Clinical protocols, Computer simulation, Hemodynamics

INTRODUCTION

End-stage renal disease (ESRD) is a major and growing public and social healthcare problem associated with substantial costs (1, 2). It is expected that by the end of 2010 the global patient population requiring chronic renal replacement therapy will exceed 2 million of which approximately 90% will depend on hemodialysis (HD) therapy (3, 4). To facilitate adequate HD therapy a reliable vascular access (VA) is mandatory and can be provided by either creation of an autogenous arteriovenous fistula (AVF), a prosthetic arteriovenous graft (AVG) or a central venous catheter (CVC). Guidelines by the National Kidney Foundation (NKF K-DOQI Guidelines), the Vascular Access Society (Good Nephrologic Practice Guidelines), and the European Dialysis and Transplant Association (European Best Practice Guidelines on HD) advocate the implementation of an all-autogenous policy to maximize the use of AVFs over AVGs and CVCs because AVFs have the best long-term patency, fewer complications, and require less interventions once fully maturated (5).

Although the implementation of a pre-operative duplex ultrasound (DUS) examination reduced the total number of early AVF failure by improved selection of the most suitable site for AVF creation, short-term and long-term AVF dysfunction remains the major cause of morbidity and hospitalization in HD patients and is therefore the major limitation of HD treatment (6, 7). This dysfunction is usually associated with non-maturation of the newly created AVF or the formation of neointimal hyperplasia (NIH) which potentially results in decreased flow and eventual thrombosis (8). On the other hand, the low resistance track via the AVF may lead to impeded perfusion of the limb distally of the anastomosis while the large extra AVF flow may lead to the development of left ventricular hypertrophy (9, 10), both with severe consequences.

Numerous studies have investigated alternative preoperative mapping criteria for further reduction of AVF related complications (9, 11-15), however, current clinical use of these individual parameters does not take into account their potential interplay at a systemic level. Consideration of multiple prognostic parameters within a single patient is probably more valuable to improve outcome after VA surgery by tailoring the AVF to the individual patient.

One possible solution to deal with multiple independent prognostic factors is the implementation of a predictive computational tool that accounts for individual differences in physiologic, demographic, and hemodynamic parameters as well as the anatomic data collected with DUS nowadays. More importantly, by taking their complex interplay into consideration, simulation of outcome after AVF surgery is at hand. Given the high inter-subject variability these modeling tools need to be patient-specific for reliable prediction of VA outcome. Patient data on vascular and cardiac adaptation are of major importance, but until now full datasets containing the required data for modeling are unavailable, pointing out the need for a clinical study on ESRD patients undergoing AVF creation for HD treatment and their systematic prospective longitudinal follow-up.

The aim of this paper is to describe the rationale behind VA computational modeling and, subsequently, to introduce the ARCH clinical study which has been designed within the ARCH FP7 ICT project (ARCH; patient specific image-based computational modeling for improvement of short-term and long-term outcome of vascular access in patients on hemodialysis therapy). Within the current clinical study, longitudinal collection of cardiovascular data takes place with the intention to develop, calibrate and validate patient-specific modeling tools for surgical planning and assistance in the management of complications arising from AVF creation. Given the difficult and heterogeneous target population, the study protocol has been designed in such a way that pre and post-operative imaging could be performed strictly, aiming at complete datasets of structural, functional, and demographical data. Following the validation of the computational model, a proposal for a large-scale randomized observational study, aimed at evaluating the potential beneficial effect of the use of computational tools in reducing VA-related clinical problems, will be designed.

RATIONALE FOR VASCULAR ACCESS COMPUTATIONAL MODELING

Modeling has become a well-accepted approach to analyze cardiovascular hemodynamics. Ever since Grodins et al (16) created the first global dynamic model of the circulation using a mathematical approach, major improvements in medical imaging as well as advances in numeric methods and increased computational capabilities, have facilitated the development and use of image-based modeling technologies which already have been used to investigate hemodynamics in aortic aneurysmal disease (17-20) as well as in cerebral (21, 22) and coronary artery (23, 24) disease. In addition to investigating global and local hemodynamic parameters in cardiovascular diseases associated with atherosclerosis and aneurysm growth, recent modeling efforts focus on prediction of outcome following surgical and interventional procedures (25).

In order to be suitable for application in clinical practice, a model has to be accurate, predictive, economic, and useful (26). Only if predicted values reliably correspond with measured values, they provide additional insight into the physiologic processes associated with pathology at an individual patient level. For this, different mathematical models have been employed, capable of describing cardiovascular mechanical properties at various levels of detail: lumped parameter models, one-dimensional (1D) wave propagation models, and three-dimensional (3D) numeric models. For a detailed description of these modeling techniques the reader is referred to a recent review by Taylor et al (27).

Before patient specific cardiovascular modeling can take place, several criteria have to be met. First, it is essential to obtain patient-specific anatomic information by either non-invasive imaging techniques i.e. computed tomography (CT), magnetic resonance angiography (MRA), and DUS, or by invasive methods in the form of digital subtraction angiography. The standard of reference for non-invasive vascular imaging, contrast-enhanced MRA, is particularly suited for the acquisition of vascular geometry and depiction of vascular pathology because of its capability to obtain high-resolution 3D images. Subsequently, the anatomic information can be used to extract geometric models by making use of vascular segmentation techniques (28). To simulate hemodynamic conditions related to the geometric model, physiologic data needs to be collected. In order to calibrate the model to the individual patient, vessel diameter and flow profile need to be measured at specified locations. Total cardiac output (CO) and blood pressure (BP) distribution over the vascular tree are important quantities required as they define the boundary conditions in the model. To acquire these physiologic data, blood pressure measurements, DUS evaluation as well as phase-contrast MRI examination of the arteries, veins and heart are available in a clinical setting. As a result, hemodynamic models can be adapted to simulate pre-operative conditions, as well as to simulate a surgical procedure and its consequences on overall and local hemodynamics.

This approach is potentially valuable to gain insight into the mechanisms responsible for short-term and long- term AVF failure. Currently, post-operative changes in local hemodynamic profile are believed to be accountable for AVF failure (25) by inducing

vascular wall changes which potentially result in insufficient venous dilatation, or via the development of NIH with significant alteration in pressure and flow distributions. In particular, the geometric configuration of the anastomosis is considered to have profound influences on post-operative hemodynamics (flow, pressure, and wall shear stress [WSS] distribution) and thereby plays an important role in AVF-associated complications (25). Furthermore, connecting an artery with a vein induces remodeling of the vessels in order to keep the WSS within a physiologic range (29, 30).

Within the ARCH project, patient-specific computational modeling tools for short-term and long-term prediction of cardiovascular hemodynamic changes in patients with ESRD awaiting VA creation, are under development. These tools are currently being calibrated and validated, based on patient-specific anatomic, physiologic, and clinical data being collected in the prospective clinical study described in this paper.

STUDY DESIGN

The prospective clinical study reported is being performed as part of the ARCH project and was designed to collect anatomic data (based on state-of-the-art non-invasive medical imaging techniques), clinical data, and physiologic data, in order to ascertain information about the relations between anatomic and functional characteristics of individual patient vasculature and to provide information on vascular adaptation. These datasets will be used to calibrate and validate the modeling tool by identification of sets of parameters with significant influence on post-operative functioning. Computational modeling will be able to simulate hemodynamics for multiple AVF configurations in a single patient (e.g. upper arm, lower arm, end-to-side, side-to-side) and enable identifying the AVF configuration with the most favorable hemodynamic profile which might result in a lower probability of post-operative complications.

For calibration and validation purposes, a total of 80 consecutive patients with ESRD awaiting VA creation will be enroled in the four clinical partners of the project (Maastricht University Medical Center, The Netherlands; Univerzitetni Klinikni Center Ljubljana, Slovenia; Ospedali Riuniti di Bergamo, Italy; Ghent University Hospital, Belgium). ESRD has been defined as either the time at which creatinine clearance falls below 25ml/min and referral to the department of vascular surgery for creation of an AVF is indicated, or if HD is expected to be required within 1 year. A subgroup of patients enroled in Maastricht, undergoing wider investigations in addition to the standard protocol (as detailed in the following sections), is referred to as Subgroup 1, while all patients enroled in Ghent, undergo-

ing additional cardiac examinations, are referred to as Subgroup 2. Criteria for enrolment are listed in Table I. The medical ethics committees of all partners involved approved the contents of the study. Written informed consent was obtained from all individuals.

Study protocol

The flowchart of this study is based on systematic acquisition of medical history and clinical data from examinations performed in agreement with the current clinical work-up as advocated by the NKF K-DOQI Guidelines, 2006. Following patient enrolment, demographic and clinical factors are systematically collected together with blood pressure measurements. Subsequently, a peripheral DUS examination is performed to acquire a full upper limb vascular map, including arterial and venous vessel diameters and blood flow values in different vascular locations. As shown in Table II, patients in Subgroup 1 (enroled in Maastricht) are subjected to additional evaluations (advanced DUS and MRA) aimed at obtaining mechanical properties of the arterial wall as well as imaging the peripheral vasculature in detail. Subgroup 2 (enroled in Ghent) is subjected to additional cardiac evaluations to investigate cardiac mechanics behind AVF creation.

After completion of pre-operative data acquisition, the surgical VA procedure is performed, followed by routine post-operative ultrasound examinations. After commencing HD, additional follow-up data are gathered from the vascular laboratory and the dialysis ward, as detailed in Table III. Figure 1 shows the individual patient flowchart and illustrates actions to be taken following possible events or complications occurring during the study.

TABLE I - INCLUSION AND EXCLUSION CRITERIA FOR PARTICIPATION WITHIN THE STUDY PROTOCOL

Inclusion criteria

Written informed consent

Age > 18 years

Patient in need of vascular access in order to facilitate HD therapy

Patient has entered the pre-dialysis programme because of ESRD

Treatment of first choice is creation of an autogenous AVF

Exclusion criteria

Contraindication for creating an autogenous fistula

Life expectancy less than 1 year

Prior vascular access creation in the same arm

Patient is not suitable for MRI examination (Subgroup 1 and Subgroup 2 only)
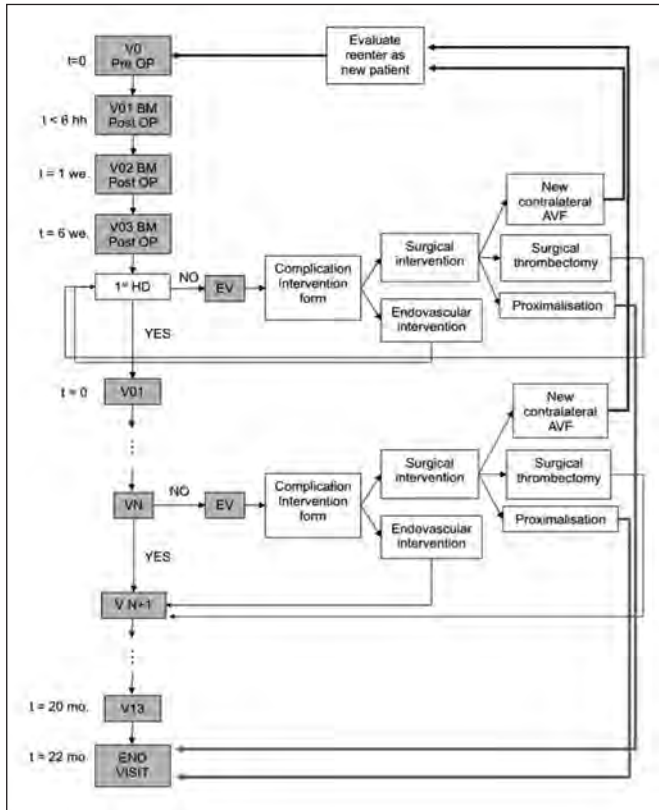
MRI, magnetic resonance imaging

Fig. 1 - *Block diagram of actions to be taken according to possible events during the clinical study.*

TABLE II - SUMMARY TABLE SHOWING INVESTIGATIONS PERFORMED IN THE WHOLE STUDY POPULATION AND ADDITIONAL INVESTIGATIONS PERFORMED IN DIFFERENT SUBGROUPS OF PATIENTS*

Whole study population

Pre-operative

    Patient demographics and clinical factors

    Standard peripheral ultrasound evaluation

    Blood pressure measurements

Post operative follow-up

Subgroup 1	Subgroup 2
Advanced peripheral ultrasound evaluation	MRI flow
Finger pressure measurements	MRI heart
MRA of peripheral vasculature	Cardiac ultrasound evaluation
MRI flow measurements	

MRA, magnetic resonance angiography; MRI, magnetic resonance imaging.
*Patients in Subgroup 1 were recruited in Maastricht, while those in Subgroup 2 were recruited in Ghent

Study investigations

In this section we provide a detailed description of investigations performed within the study, focusing in particular on standard and advanced DUS examinations, pressure measurements, MRA of the peripheral vasculature, and cardiac examinations.

Standard duplex examination: For all patients, a pre-operative ultrasound examination is performed in order to assess vascular diameters and flows as well as to identify potential vascular pathology. The full standard duplex examination is performed by either an experienced employee of the vascular laboratory or the physician himself with the patient in a supine position. A DUS machine with at least a 7.5 MHz convex transducer and a 10.0 MHz linear transducer is used for the measurements. Venous assessment comprises visualization of the cephalic vein from the wrist to the cephalic arch and the basilic vein from the wrist until it joins the brachial vein in the upper arm while making use of a proximal pressure cuff for congestion as reported by Planken et al (31). Short and long-axis diameter measurements are carried out and side branches are noted with their exact location and diameter. Venous compliance is evaluated by monitoring the difference in venous diameter with and without venous congestion pressure at selected locations. Assessment of the peripheral arterial vascular tree consists of diameter measurements and identification of vascular disease by measuring peak systolic velocity (PSV), end diastolic velocity (EDV), diameter, and volume flow. Finally, the central arterial and venous vessels are imaged to rule out any stenosis or occlusion that might hinder post-operative fistula function. Standardization of this examination was performed according to modeling requirements and can be seen schematically in Figure 2.

Advanced duplex examination: Additional DUS measurements are performed in a subset of patients (Subgroup 1) in order to investigate mechanical properties of the brachial arterial wall. To this end, the change in diameter of the brachial artery as a function of time is evaluated with a commercially available ECG-triggered DUS system, equipped with 'Artlab' software (ESAOTE, Maastricht, The Netherlands). Continuous integrated pressure registration (Nexfin, BMEYE, Amsterdam, The Netherlands) enables determination of arterial distensibility, arterial compliance, and pulse wave velocity.

Pressure measurements: Bilateral blood pressure measurements are carried out on the upper arm. Systolic and diastolic pressures are recorded together with cardiac frequency. Patients in Subgroup 1 are also subjected to pressure measurements using the NexFin device (BMEYE, Amsterdam, The Netherlands). By means of a cuff around the third digit, arterial finger pressure is continuously measured and interpolated into a brachial pressure. Pressure waveforms are stored within the raw ultrasound data and enable calculation of pulse wave velocity and the compliance coefficient in combination with distensibility data.
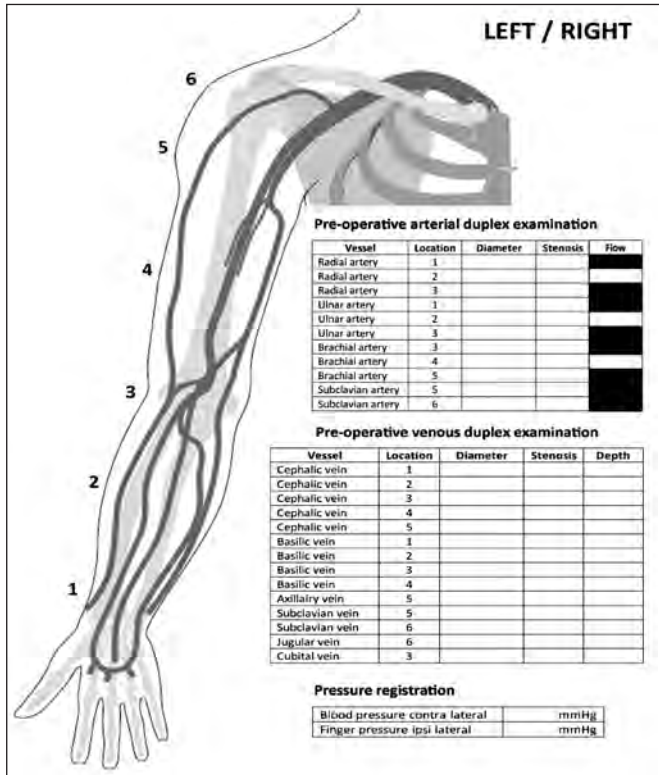
Fig. 3 - *Maximum intensity projection of a typical NCE-MRA acquisition of the distal upper arm with corresponding cross-sectional reformations; In spite of the fact that both arteries and veins are depicted in the NCE-MRA dataset, arteries and veins can easily be differentiated in the axial source images because of the high spatial resolution.*

Fig. 2 - *Schematic visualization of the pre-operative duplex examination. Multiple routine measurements are performed over the arterial and venous vascular tree of the arm, focusing on diameter, vascular pathology, flow and depth. The location of venous side branches also has to be registered.*

Post-operatively, finger pressures are measured, with and without compression of the fistula, to reveal the decrease in perfusion pressure which potentially results in the clinical manifestation of steal syndrome.

MRA examination of peripheral vasculature: 3D acquisition of the vascular anatomy in ESRD patients poses difficulties. Contrast-enhanced (CE) MRA has been associated with the development of nephrogenic systemic fibrosis (NSF) (32, 33), which can result in serious complications (34). Therefore, non-contrast enhanced (NCE) MRA techniques for depiction of vascular pathology and identification of arterial and venous geometry have attracted renewed interest (35). However, there are few publications beyond proof of concept studies and little is known about the feasibility and diagnostic accuracy of these NCE-MRA techniques for imaging the upper limb vascular tree. Therefore, part of this study is to assess the feasibility of a novel state-of-the-art NCE-MRA technique and to compare this technique with the current benchmark for diagnostic vessel imaging, CE-MRA.

MR acquisitions in Subgroup 1 are performed with a clinically available 1.5T MR scanner (Gyroscan Intera, software release 11.3.1, Philips Medical Systems, Best, The Net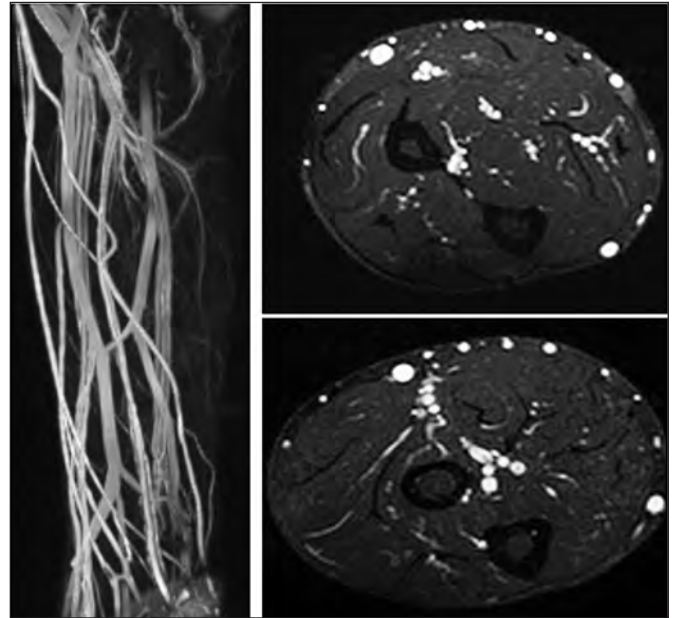herlands) using the Synergy Flex-L surface coil for the distal upper limb and the Synergy Body coil for the proximal upper limb and chest acquisitions.

For NCE-MRA acquisitions a modified version of the balanced turbo-field echo (bTFE) as reported by Gjesdal et al is used (36). The bTFE pulse sequence produces images with increased signal from fluid, analogous to T2-weighted sequences, along with retaining T1-weighted tissue contrast (Fig. 3). These acquisitions are compared to the standard of reference for non-invasive diagnostic vessel imaging, CE-MRA, which consists of a multiphase T1-weighted gradient denominated echo sequence. According to recent guidelines (37), patients already dependent on intermittent HD therapy by means of a CVC are scheduled to undergo a complete 4 hour dialysis session directly after the MR acquisition, followed by regular HD sessions two and four days later. Despite the fact that we use a stable, macrocyclic GBCA, every patient is monitored for symptoms related to NSF at regular intervals.

Cardiac examinations: In order to obtain longitudinal data regarding cardiac function and cardiac adaptation after AVF creation, subgroup 2 patients are scheduled to undergo echocardiography and MR cardiography examinations in the pre and post-operative setting (Tab. III). The echocardiography examinations (Vivid 7, GE Healthcare, Milwaukee, USA) provide standardized and reproducible measurements obtained from parasternal long and short-axis, apical and sub costal views. Anatomic as well as functional parameters can be generated and include velocities, flows, time intervals,

TABLE III - CLINICAL STUDY FLOWCHART, SHOWING FOLLOW-UP VISITS SCHEDULED IN THE STUDY PROTOCOL. TIME AND DETAILS ABOUT INVESTIGATIONS PERFORMED AT EACH VISIT ARE SHOWN

Visit	V0	V01 BM	V02 BM	V03 BM	V01	V02	V03	V04	V05	V06	V07	V08	V09	V10	V11	V12	V13	ENDV
Time	Pre OP	< 6 h post OP	1w post OP	6w post OP	1st HD T=0	2w	6w	10w	4 mo	6 mo	8 mo	10 mo	12 mo	14 mo	16 mo	18 mo	20 mo	22 mo
Patient demographics and clinical factors	X																	
Blood Analysis	X			X								X						X
Blood pressure measurements	X	X	X	X			X		X			X			X			X
Standard peripheral US	X	X	X	X			X		X			X			X			X
Advanced peripheral US *	X			X														
Peripheral vascular MRA *	X			X														X
Cardiac MRA **	X			X								X						
Cardiac US **	X	X		X					X			X						X
VA function clinical follow-up					X	X	X	X	X	X	X	X	X	X	X	X	X	X

BM, before maturation; HD, hemodialysis treatment; hh, hours; MRA, magnetic resonance angiography; mo, months;
Pre OP, pre-operative, Post OP, post-operative; US, ultrasound; VA, vascular access; w, weeks,
* investigations performed only for patients in Subgroup 1
** investigations performed only for patients in Subgroup 2

pressures, volumes, diameters, masses, and derived indices.

MR cardiography (Avanto 1.5T, Siemens AG, Muenchen, Germany) consists of traditional flow and volume assessment of the left and right ventricular volumes as well as determination of the ventricular mass, the regional wall motion, the myocardial thickness, and functioning of the cardiac valves by making use of non contrast-enhanced true FISP (balanced SSFP) and phase-contrast MRA sequences.

DATA MANAGEMENT

Since this clinical investigation involves four centers distributed in different European countries, the study is performed using secured web-based electronic case report forms (e-CRFs) to facilitate on-site computer-based collection of socio-demographic data, clinical data, and DUS measurements. All data is obtained in accordance with current good clinical practice (GCP) guidelines.
e-CRFs were generated using an open source, web-based software platform, Openclinica (Akaza Research, Boston, USA), which supports clinical data entry and management in compliance with GCP. Personal data entry access was provided to investigators from all

clinical centers involved. A computer-generated patient number and a local identifier uniquely identify patients enroled in the study, ensuring full anonymity. The raw, anonymous, image data (MRI examinations, standard duplex images, and advanced duplex datasets) are stored on a secured FTP server of the ARCH project (ARCHClient), accessible to all ARCH Project Consortium partners.

DISCUSSION

The study protocol reported here enables implementation of a clinical investigation on a difficult target: the assessment of structural and functional cardiovascular changes that take place during and following AVF creation. Patients requiring a VA for HD treatment that undergo autogenous AVF creation are exposed to potential dangerous complications which may hinder the continuation of dialysis therapy. The heterogeneous characteristics of individual patients make systematic observations at population level very difficult. Despite this, it is generally accepted that the massive increase in blood flow and blood pressure at the site of the arteriovenous anastomosis are responsible for venous wall re-

modeling (adaptation), it is not easy to obtain detailed information on patient specific hemodynamic changes induced by AVF creation. Computational tools have the potential to help the physician to study the local hemodynamic conditions of individual patients in more detail and may be of crucial importance for VA planning and post-operative management. As previously described in detail, development, calibration and validation of these computational tools must be performed based on extensive clinical observations. Within the ARCH project we designed a prospective clinical study to collect structural and functional data on patient vasculature, as well as clinical observations, before and after VA surgery. This study protocol has been successfully implemented in four clinical centers and the study is currently being performed.

Implementation of this protocol provides a detailed and controlled dataset (i.e. demographic data, dimensions of the arterial and vascular tree, geometry of the vascular network, mechanical properties of the vessel wall, boundary conditions for numeric simulations) which will be available for sensitivity analysis to identify the most relevant model parameters. After this, calibration and validation of the computational tool enables best fitting of measured preoperative hemodynamics. Moreover, the acquired datasets will be analyzed to derive short-term and long-term patency rates after VA creation and relate VA function and post-operative complications to pre-operative vascular geometry and flow distribution. Eventually, model-based evaluation of VA surgery has to generate detailed information regarding the relationship between hemodynamic changes and vascular changes with the aim of predicting VA dysfunction (i.e. non maturation, steal syndrome, cardiac failure, or the development of NIH with subsequent flow reduction and risk of thrombosis) in advance.

The electronic data input in web-based CRFs enables timely monitoring of patient enrolment and data collection. Image storage on a FTP server enables efficient centralization of study documentation and data exchange among scientific and technical partners involved in modeling tool development.

In conclusion, AVF surgery remains prone to complications in spite of the current pre-operative clinical work-up and practice according to clinical guidelines. Outcome may improve with a more in-depth assessment of structural and functional changes in the upper extremity circulation as well as by taking into account multiple prognostic parameters and their interaction. Our study protocol intends to gain insight into short and long-term cardiovascular changes upon AVF surgery and to facilitate the development, calibration, and validation of computational modeling tools in the field of vascular access surgery.

APPENDIX

ARCH Study organization: members of the ARCH project consortium were as follows: principal investigator: A. Remuzzi (Bergamo, Italy); principal investigator clinical studies: J.H.M. Tordoir (Maastricht, The Netherlands); project leader clinical studies: A.S. Bode (Maastricht, The Netherlands); co-ordinating center: Mario Negri Institute for Pharmacological Research, Clinical Research Center for Rare Diseases Aldo e Cele Dacco, Villa Camozzi, Ranica, (Bergamo, Italy).

Mario Negri Institute for Pharmacological Research, Clinical Research Center for Rare Diseases Aldo e Cele Dacco, Villa Camozzi, Ranica, (Bergamo, Italy): A. Remuzzi, L. Antiga, A. Caroli, S. Manini, K. Passera, B. Ene-Iordache, L. Botti. Maastricht University Medical Center (Maastricht, The Netherlands): J.H.M. Tordoir, A.S. Bode, M. Hameeteman, J.J.P.M. Leermakers, R.N. Planken, T. Leiner, W. Huberts, M. Merkx, J.W. Kroon, E.M.H. Bosboom, F.N. van de Vosse. Gent University (Gent, Belgium): K. van Canneyt, L. Araujo, P. Verdonck, P. Segers. University Medical Centre Ljubljana (Ljubljana, Slovenia): M. Malovrh. University of Sheffield (Sheffield, United Kingdom): A. Narracott, M. Bayley. Philips Medical Systems (Best, The Netherlands): M. Breeuwer, J. Olivan-Bescos. Philips Research (Eindhoven, The Netherlands): H. Obbink, W. van der Linden, M. Alves de Inda. ESAOTE Europe (Maastricht, The Netherlands): P. Brands.

Address for correspondence
A.S. Bode, MD
Department of Surgery
Maastricht University Medical Center
P. Debyelaan 25
6202 AZ Maastricht, The Netherlands
a.bode@mumc.nl

REFERENCES

1. Lysaght MJ. Maintenance dialysis population dynamics: current trends and long-term implications. J Am Soc Nephrol 2002; 13 Suppl 1: S37-40.
2. Himmelfarb J, Berns A, Szczech L, Wesson D. Cost, quality, and value: the changing political economy of dialysis care. J Am Soc Nephrol 2007; 18(7): 2021-7.
3. Grassmann A, Gioberge S, Moeller S, Brown G. ESRD patients in 2004: global overview of patient numbers, treatment

modalities and associated trends. Nephrol Dial Transplant 2005; 20(12): 2587-93.

4. Grassmann A, Gioberge S, Moeller S, Brown G. End-stage renal disease: global demographics in 2005 and observed trends. Artificial organs 2006; 30(12): 895-7.

5. Tordoir J, Canaud B, Haage P, et al. EBPG on Vascular Access. Nephrol Dial Transplant 2007; 22 Suppl 2: ii88-117.

6. Ikizler TA, Himmelfarb J. Trials and trade-offs in haemodialysis vascular access monitoring. Nephrol Dial Transplant 2006; 21(12): 3362-3.

7. Allon M, Robbin ML. Increasing arteriovenous fistulas in hemodialysis patients: problems and solutions. Kidney international 2002; 62(4): 1109-24.

8. Roy-Chaudhury P, Spergel LM, Besarab A, Asif A, Ravani P. Biology of arteriovenous fistula failure. Journal of nephrology 2007; 20(2): 150-63.

9. Tordoir JH, Dammers R, van der Sande FM. Upper extremity ischemia and hemodialysis vascular access. Eur J Vasc Endovasc Surg 2004; 27(1): 1-5.

10. MacRae JM. Vascular access and cardiac disease: is there a relationship? Curr Opin Nephrol Hypertens 2006; 15(6): 577-82.

11. III. NKF-K/DOQI Clinical Practice Guidelines for Vascular Access: update 2000. Am J Kidney Dis 2001; 37 (1 Suppl 1): S137-81.

12. Lin SL, Huang CH, Chen HS, Hsu WA, Yen CJ, Yen TS. Effects of age and diabetes on blood flow rate and primary outcome of newly created hemodialysis arteriovenous fistulas. American journal of nephrology 1998; 18(2): 96-100.

13. Konner K. Primary vascular access in diabetic patients: an audit. Nephrol Dial Transplant 2000; 15(9): 1317-25.

14. Sidawy AN, Gray R, Besarab A, et al. Recommended standards for reports dealing with arteriovenous hemodialysis accesses. J Vasc Surg 2002; 35(3): 603-10.

15. Silva MB, Jr., Hobson RW, 2nd, Pappas PJ, et al. A strategy for increasing use of autogenous hemodialysis access procedures: impact of preoperative noninvasive evaluation. J Vasc Surg 1998; 27(2): 302-7; discussion 7-8.

16. Grodins FS. Integrative cardiovascular physiology: a mathematical synthesis of cardiac and blood vessel hemodynamics. Q Rev Biol 1959; 34(2): 93-116.

17. Vorp DA. Biomechanics of abdominal aortic aneurysm. Journal of biomechanics 2007; 40(9): 1887-902.

18. Breeuwer M, de Putter S, Kose U, et al. Towards patient-specific risk assessment of abdominal aortic aneurysm. Med Biol Eng Comput 2008; 46(11): 1085-95.

19. Les AS, Shadden SC, Figueroa CA, et al. Quantification of hemodynamics in abdominal aortic aneurysms during rest and exercise using magnetic resonance imaging and computational fluid dynamics. Annals of biomedical engineering; 38(4): 1288-313.

20. Tang BT, Cheng CP, Draney MT, et al. Abdominal aortic hemodynamics in young healthy adults at rest and during lower limb exercise: quantification using image-based computer modeling. American journal of physiology 2006; 291(2): H668-76.

21. David T, Moore S. Modeling perfusion in the cerebral vasculature. Med Eng Phys 2008; 30(10): 1227-45.

22. Cebral JR, Castro MA, Burgess JE, Pergolizzi RS, Sheridan MJ, Putman CM. Characterization of cerebral aneurysms for assessing risk of rupture by using patient-specific computational hemodynamics models. Ajnr 2005; 26(10): 2550-9.

23. Hunter PJ, Pullan AJ, Smaill BH. Modeling total heart function. Annu Rev Biomed Eng 2003; 5: 147-77.

24. Gijsen FJ, Wentzel JJ, Thury A, et al. A new imaging technique to study 3-D plaque and shear stress distribution in human coronary artery bifurcations in vivo. Journal of biomechanics 2007; 40(11): 2349-57.

25. Migliavacca F, Dubini G. Computational modeling of vascular anastomoses. Biomech Model Mechanobiol 2005; 3(4): 235-50.

26. Smye SW, Clayton RH. Mathematical modelling for the new millenium: medicine by numbers. Med Eng Phys 2002; 24(9): 565-74.

27. Taylor CA, Figueroa CA. Patient-specific modeling of cardiovascular mechanics. Annu Rev Biomed Eng 2009; 11: 109-34.

28. Lesage D, Angelini ED, Bloch I, Funka-Lea G. A review of 3D vessel lumen segmentation techniques: models, features and extraction schemes. Med Image Anal 2009; 13(6): 819-45.

29. Ene-Iordache B, Mosconi L, Remuzzi G, Remuzzi A. Computational fluid dynamics of a vascular access case for hemodialysis. J Biomech Eng 2001; 123(3): 284-92.

30. Ene-Iordache B, Mosconi L, Antiga L, et al. Radial artery remodeling in response to shear stress increase within arteriovenous fistula for hemodialysis access. Endothelium 2003; 10(2): 95-102.

31. Planken RN, Keuter XH, Kessels AG, Hoeks AP, Leiner T, Tordoir JH. Forearm cephalic vein cross-sectional area changes at incremental congestion pressures: towards a standardized and reproducible vein mapping protocol. J Vasc Surg 2006; 44(2): 353-8.

32. Sadowski EA, Bennett LK, Chan MR, et al. Nephrogenic systemic fibrosis: risk factors and incidence estimation. Radiology 2007; 243(1): 148-57.

33. Grobner T. Gadolinium--a specific trigger for the development of nephrogenic fibrosing dermopathy and nephrogenic systemic fibrosis? Nephrol Dial Transplant 2006; 21(4): 1104-8.

34. Penfield JG, Reilly RF, Jr. What nephrologists need to know about gadolinium. Nature clinical practice 2007; 3(12): 654-68.

35. Miyazaki M, Lee VS. Nonenhanced MR angiography. Radiology 2008; 248(1): 20-43.

36. Gjesdal KI, Storaas T, Geitung JT. A noncontrast-enhanced pulse sequence optimized to visualize human peripheral vessels. Eur Radiol 2009; 19(1): 110-20.

37. Leiner T, Kucharczyk W. NSF prevention in clinical practice: summary of recommendations and guidelines in the United States, Canada, and Europe. J Magn Reson Imaging 2009; 30(6): 1357-63.