Vascular remodeling after the creation of an arteriovenous fistula as angioaccess for hemodialysis: the predictive value of a patient-specific computer simulation model.

Published: 11-01-2008
Last updated: 10-05-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON31512

Source
ToetsingOnline

Brief title
AVF model

Condition

- Other condition

Synonym
Maturation; AVF failure

Health condition

Het al dan niet falen van een geschikte vaattoegang voor patienten die lijden aan terminaal nierfalen en die behandeld gaan worden met hemodialyse.

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: arteriovenous fistula, computer model, patient-specific, postoperative blood flow predictions

Outcome measures

Primary outcome

- A model that is able to predict the patient-specific postoperative flow with

a maximum deviation of 10% compared to the

measured postoperative flow.

- A model for postoperative flow prediction that is clinically evaluated for 60

patients.

- A model that can predict long term patency of arteriovenous fistula by imput

of patient specific parameters

- A model that is able to predict hypoperfusion.

- A model for hypoperfusion that is clinically evaluated for 60 patients.

Secondary outcome

- A measurement protocol to determine the vessel compliances by using

ultrasound and blood measurements

- A measurement protocol to determine the patient's geometry by using both

non-contrast enhanced and contrast

enhanced MRA.

Study description

Background summary

Hemodialysis dependent patients, suffering from end-stage renal disease, need a well-functioning vascular access to connect them with the dialyzer. Usually, the vascular access is surgically created by making a connection between an artery and a vein (arteriovenous fistula=AVF). Due to the low resistance leak created and the high arterial-venous pressure difference, vessel adaptation (remodeling) would occur with an enormous increase in blood flow and proximal vessel dilatation. As a results, proper cannulation and the connection with the dialyzer becomes possible. The use of an autogenous wrist AVF (between the radial artery and cephalic vein) is preferred due to its better long-term patency and its smaller complication rate compared to more proximal AVF's and grafts. However, a significant amount of wrist AVF's fail directly after the surgical intervention due to thrombosis and/or insufficient vessel remodeling. Unless the fact that all those patients are selected based on preoperative diagnostics (duplex, physical examination and CE-MRA), 30% of all newly created wrist AVF's fail within six weeks after surgery and are useless for hemodialysis. For the planning of the type of vascular access for each individual patient, it is very important to preoperatively predict the postoperative flow increase and vessel remodeling. When insufficient vessel remodeling is likely, based on preoperative diagnostics, another type of vascular access can be chosen.
The hypothesis is that the amount of failing AVF's can be reduced, if the blood flow increase through the AVF can be better predicted with the available preoperative diagnostics, since vessel adaptation is related to blood flow increase. A patient-specific computer simulation model, based on preoperative MRA, duplex data and bloodexaminations for biomarkers can possibly give insight in the postoperative blood flow increase and failure incidence for different fistula configurations. The big advantage of the computer model is that the combination of the different factors, influencing AVF failure, like vessel diameters, vessel compliances and accessory veins, can be varied and examined.

Study objective

The objective of this study is to examine if a patient-specific computer simulation model is able to predict the blood flow increase after AVF creation. The interaction between the different factors that influence the blood flow increase will be investigated. In addition, the ability of the model to predict the peripheral perfusion is examined, which ultimately should be able to predict hypoperfusion (ischemia). Second, a non-contrast enhanced MRA sequence will be developed to overcome the problem of contrast administeration in patients with end-stage renal disease. Finally, a biomarker ucMGP will be correlated to vascular compliance, which is an important factor in calibrating

the model.

Study design

A computer model that is able to preoperatively predict the postoperative blood flow increase through the AVF, is developed and tested. The choice for the type of vascular access in the individual patient in this study, is based on the results of preoperative diagnostics. The preoperative computer simulations are in this study not used to determine the clinical policy, but only to compare the postoperative measured pressure and flow with the simulated pressure and flow.
The preoperative models are adapted to patient-specific conditions by using data that are obtained from available preoperative modalitities: duplex, CE-MRA, bloodexamination, blood pressure measurements and cardiac output/flow examinations. The measurements protocols are developed in earlier research, but should be adapted for our application. Therefore, a pilot study with 5 volunteers is performed before the main project starts. This pilot study should result in a measurement protocol that is specific for our application. This protocol is used in the main project to obtain the patient-specific data for the model.
The results of the preoperative model are compared with preoperative pressure and flow measurements to validate the model. Thereafter the postoperative blood flow and pressure are simulated. The simulated blood flow is correlated with the measured blood flow (duplex and MRA) to determine the accuracy of the postoperative model predictions. In addition, the simulated and measured postoperative blood pressure are compared. Follow-up after surgery will take place on a regular basis. MRA examination will take place preoperative, 1 week post-operative, 6 weeks post-operative, 6 months post-operative and 18 months post-operative. Bloodwithdrawel will take place previous to the OR, out of the venous canula which is placed in order to perform surgery. No additional venapunctions will be performed.
For both the patients with a failed AVF and the patients with a well-functioning AVF, is examined if the model was able to accurately predict the postoperative blood flow increase.

Study burden and risks

All participants in this study will receive all pre- and postoperative MRA examinations according to the follow-up protocol, a duplex examination and pressure measurements (radial artery and finger). The duration of all examinations in total is approximately 500 minutes (90 minutes per MRI and 10 minutes per duplex). All measurements are performed when the patient is already in the hospital for hemodialysis, for another examination not related to this study or when they are in the hospital one day before surgery.
For the CE-MRA examination a Gadolinium containing contrast agent is injected by intravenous infusion. The total incidence of adverse events related to

gadolinium use for CE-MRA is less than 5%. The incidence of any single event is even lower than 1%. The most common events are nausea, headache and emesis. When used intravenously, no nephrotoxicity has been detected and the rates of adverse events are extremely low. However, recently, concerns have arisen regarding the use of gadolinium because some gadolinium containing contrast agents are associated with Nephrogenic Systemic Fibrosis (NSF) in patients with severe renal impairment. NSF is a rare, debilitating and sometimes fatal disease. Therefore, the contrast agent gadobutrol (Gadovist(c), Bayer Schering Pharma AG, Germany) with a very low dose of gadolinium is used in this study. Although, this contrast agent contains a low dose of gadolinium, this contrast agent is uptil now not associated with the development of NSF and is at the moment specifically used in the clinic to make CE-MRA scans in patients with a renal disorder. If this contrast agent will be associated with the development of NSF in future, the use of gadobutrol is stopped immediately. Before the CE-MRA scan, the patient will be informed thoroughly by the surgeon.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

-Pre-dialysis patients with a detoriation of kidney function and an expected start with hemodialysis within three months and patients that are approved to receive a vascular access based on preoperative diagnostics.
-Dialysis patients for which it becomes necessary to create a new vascular access because the old vascular access has become useless for proper hemodialysis. In addition, the patients should be approved to receive a vascular access in the contralateral arm based on preoperative diagnostics.
- Only patients with an age of 18 years and older are included.
See also page 5 and 6 of the protocol.

Exclusion criteria

-Standard contra-indications for CE-MRA (ferromagnetic implants that can possibly move, pacemakers or claustrofobia). For patients with such implants, we use Shellock's most updated manual to determine if we can make the scan or not.
-Possible or proved over-sensitivity for the Gadolinium containing contrast agent.
-If it is possible to do a revision of the already available vascular access.
- Patients younger than 18 years old.
See also page 6 of the protocol.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-07-2008
Enrollment:	75

Type:	Actual

Ethics review

Approved WMO Date:	11-01-2008
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	22-07-2008
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	15-12-2008
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
Other	ISRTCN: In afwachting
CCMO	NL20009.068.07