High Power Short Duration Radiofrequency Ablation of Atrial Fibrillation using the QDOT MICRO* Catheter

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Cardiac arrhythmias
Study type	Interventional

Summary

ID

NL-OMON52104

Source
ToetsingOnline

Brief title
Q-POWER

Condition

- Cardiac arrhythmias

Synonym
A-fib, Atrial fibrillation

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W,Biosense Webster (a Johnson & Johnson company),Zie G2a

Intervention

Keyword: Atrial fibrillation, Catheter ablation, High power short duration, Radiofrequency

Outcome measures

Primary outcome

• procedure duration

• presence, location, extent and composition of acute (24-48 hours) and chronic

(3 months) ablation lesions on CMR

Secondary outcome

• micro-electrode and macro-electrode derived unipolar and bipolar atrial

electrograms

• procedural fluoroscopy time and radiation dose

• percentage *single round* isolation for each PV pair

• acute PV reconnection for each PV pair

• percentage freedom from atrial tachyarrhythmias at 1 year12 months follow-up

• incidence of procedure related adverse events including: atrio-esophageal

fistula, cardiac tamponade/perforation, death, embolic event, esophageal

injury, major vascular access complication, myocardial infarction,

pericarditis, phrenic nerve injury/diaphragmatic paralysis, pulmonary vein

stenosis, stroke/transient ischemic attack

Study description

Background summary

Recurrence of atrial fibrillation (AF) after pulmonary vein isolation (PVI) is common and electrical reconnection between the pulmonary veins and the left atrium is a frequent finding in patients undergoing redo ablation procedures. Efforts to improve outcome of catheter ablation for AF are directed towards creation of complete and durable lesion circles. Conventional radiofrequency (RF) ablation is typically performed with power set at 30-40 Watt for a duration of 20-30 seconds. Previous preclinical studies suggest that ablation with higher power and shorter duration (HPSD) may result in more continuous and more durable ablation lesions with a similar safety profile as compared to conventional ablation lesions. This new technique may consequently improve outcomes of RF ablation for AF. Moreover, HPSD ablation of AF may significantly reduce RF duration, which could potentially lead to shorter anaesthesia, fluoroscopy and procedure duration.
Recent developments in catheter design resulted in the QDOT MICRO* catheter (Biosense Webster), a novel CE-marked contact force-sensing catheter optimized for temperature-controlled RF ablation with microelectrodes and 6 thermocouples for real-time temperature monitoring. This catheter enables very high power short duration (VHPSD, 90W-4s) ablation when used in combination with a RF ablation algorithm that modulates power to maintain target temperature during VHPSD lesion formation.
Recent improvements in cardiac magnetic resonance (CMR) imaging and image analysis enable studying atrial wall tissue characteristics. By applying this imaging strategy after ablation, transient (edema) and persistent (fibrosis) effects of RF ablation in the left atrial wall and surrounding tissues may be visualized and quantified.
However, the short-term and long-term effects of VHPSD ablation on ablation lesion formation as assessed by CMR are currently unknown. We hypothesize that VHPSD ablation results in limited edema formation due to improved catheter stability, while concurrently providing predictable lesion formation without collateral tissue damage.

Study objective

The main goals of this study are to study the effects of VHPSD ablation on the duration of a pulmonary vein isolation procedure, and on transient (edema) and persistent (fibrosis) effects of VHPSD ablation in the left atrial wall.

Study design

Prospective single-center intervention study.

Intervention

Patients will undergo PVI ablation with the QDOT MICRO* catheter using VHPSD-settings (90 watt, 4 seconds). CMR imaging will be performed at 24-48

hours and 3 months follow-up

Study burden and risks

Compared to conventional ablation, VHPSD ablation using the QDOT MICRO* catheter has been shown to result in similar ablation lesion volumes, but with a larger diameter and a smaller depth. This favourable profile yielded predictable ablation lesion dimensions both in animal experiments and in recent clinical studies, which may increase safety and improve procedural efficacy. Experience with this new technique, however, remains limited.
All patients will receive standard preprocedural and follow-up medical care for PVI including CMR imaging at baseline and Holter monitoring at follow-up. In addition, CMR imaging will be performed immediately after PVI (24-48 hours after PVI procedure) and at 3 months follow-up to assess post-ablation effects. The additional risks associated with repeated CMR imaging are minimal. Gadolinium is a safe contrast agent, which is frequently used in clinical practice. Intravenous gadolinium administration may cause minimal injection site reactions (e.g. pain, cold or burning sensation). As with other contrast-agents, anaphylactic-like reactions may occur, although this is very unusual. Patients with a known (suspected) allergic reaction to gadolinium or severe kidney failure (GFR <30 ml/min/kg) will be excluded.
This study is designed to study the effects of VHPSD-ablation in AF patients. Future AF patients and patients with other arrhythmias who are eligible for ablation may benefit from insights gained by this study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

All patients > 18 years of age with atrial fibrillation, eligible for index pulmonary vein isolation according to current ESC guidelines

Exclusion criteria

• Unwilling or unable to give written informed consent
• Prior left atrial ablation
• Other left atrial arrhythmias including atrial flutters
• Prior left atrial surgery
• Severe mitral valve regurgitation
• Contraindication for gadolinium-based contrast agents
• Contraindications for CMR (including metallic implants, cochlear implants, cardiac devices, neurostimulation systems, claustrophobia)
• Renal insufficiency (eGFR < 30 ml/min)

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting

Start date (anticipated):	21-06-2023
Enrollment:	40
Type:	Actual

Medical products/devices used

Generic name:	QDOT MICRO
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	26-04-2023
Application type:	First submission
Review commission:	METC Amsterdam UMC

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
CCMO	NL76376.029.21