Linear catheter ablation by DC-shock

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Ethical review	Not approved
Status	Will not start
Health condition type	Cardiac arrhythmias
Study type	Interventional

Summary

ID

NL-OMON36286

Source
ToetsingOnline

Brief title
ACDC-linear

Condition

- Cardiac arrhythmias

Synonym
Atrial fibrillation

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Atrial fibrillation, Catheter ablation

Outcome measures

Primary outcome

Adequate position of the linear DC-ablatie caheter.

This is defined be visually good wallcontact by intracardiac ultrasound (ICE)

and electrical signals from the electrodes on the linear ablation catheter

Acute effect.

This is defined as a successful ablation line with a complete and bidirectional

electrical block.

Adverse events.

1. Pericardial effusion
2. Cardiac tamponade
3. Thrombo-embolic complications
4. Illness or trauma due to catheter ablation
5. Temporary or permanent loss of bodily function
6. Any event that leads to early abortion of the procedure
7. Any event that leads to prolonged hospitalization
8. Any event that leads to a surgical intervention
9. Death

Clinical one-year follow-up.

1. Documented atrial fibrillation or atrial tachycardia of >30 seconds

duration, confirmed by a 12-channel ECG or Holter-ECG

2. Occurance of abovementioned adverse events during the outpatient time period.

Secondary outcome

We will register the duration of the total ablation procedure and the duration of the individual phases of the procedure:

1. The time necessary to position the linear catheter on any of the 2 target areas and the time of the ablations in both areas.

2. The necessity of using the steerable sheath for the correct positioning of the linear catheter will also be investigated in this pilot study.

Study description

Background summary

Catheter ablation is a standard treatment for atrial fibrillation. For this method of ablation, 2 catheters are necessary in the left atrium: 1 diagnostic spiral *Lasso* catheter with which electrograms in the pulmonary veins can be measured and 1 ablation catheter with which radiofrequent energy (RF) can create sequential circular heating lesions in the left atrium. With these lesions the pulmonary veins are electrically isolated from the rest of the left atrium. Cardiac arrhythmia*s, which often originate from the pulmonary veins, can no longer reach the left atrium.
This method works reasonably to well in patients with paroxysmal atrial fibrillation. But, in patients with persistent atrial fibrillation this method works poorly. Almost all patients need at least a second ablation procedure. Scientific research has shown that creating extra linear lesions in the left atrium gives a better treatment result. With the current RF-technique these linear lesions are difficult to create. The borders of application of the current techniques are within sight. Oftentimes the linear lesions are not complete and there remain electrical conduction *gaps* in the linear lesion, through which other atrial arrhythmia*s can easily be created. This is why physicians oftentimes do not create the linear lesions, because an incomplete linear lesion is pro-arrhythmogenic (e.g. atrial tachycardia).
Before the RF-ablation era direct current (DC) ablation was administered. With

this technique a high-energy shock (350-500 Joule) was applied through the distal electrode of an endocardial catheter. Subsequently a relatively large (>2 cm diameter) lesion was created, Nowadays it is known that this mechanism of ablation is based on a high current density which destroys the ion channels in the cell membranes. Myocardial cells die due to electroporation and are being replaced by fibrous tissue. During this high-energy shock a spark was formed, which causes a small explosion. The explosion caused a pressure wave and in the past incidentally serious complications have been reported. When RF-ablation was being developed around 1990, the development and the use of DC-ablation was stopped. The use of current shocks through catheters however remained in use as a method for electrocardioversion of atrial fibrillation.
Recently we have restarted the research for this method of ablation and at this moment we can create relatively large lesions without the adverse side effects. Due to increasement of the large electrode surface with a factor 10 and decreasement of the energy to 200 Joule, we can stay below the threshold where sparks can be created. The lesions are about 1 cm deep and there has never happened any complication of adverse event during one of the approximately 260 ablations which we have conducted in 30 pigs until now. The reaction of the body on an ablation like this is similar to the reaction of an endocardial electrocardioversion.
The new method is being used in animal experiment for circular as well as straight linear lesions, both in the left atrium. For the linear DC-ablations we want to use an existing catheter which is designed for endocardial electrocardioversions. We have come to the conclusion that this catheter is also eligible for performing DC-ablations (off-label use). With the department of Medical Techniques & Clinical Physics we have agreed on a method to use these catheters for this human pilot study. The required DC-generator is currently being developed by the department of Medical Techniques & Clinical Physics.

Study objective

The purpose of this study is to investigate the applicability of this method of ablation in human patients.
The investigation will be conducted in patients with persistent atrial fibrillation who, with use of the current method (RF-ablation), can only be treated very difficultly. With the current technique this group of patients almost always requires several lengthy treatments and even then the success rate is lower than in other groups of patients with atrial fibrillation.
Scientific research has shown that the treatment result can be improved by creating 2 linear lesions in the left atrium. These linear lesions are very difficult to create with the current RF-ablation technique.

The investigation consists of 2 parts:
Firstly, the linear catheter must be positioned well of the area where we want to perform the linear lesion. We anticipate that we will be able to do this in the majority of patients.

Secondly, the linear catheter must be able to creat a linear leasion. In test animals (pigs) this worked really well and 1 shock was sufficient to create an approximately 3 cm long and transmural lesion in the left atrium.

Study design

The patient will be catheterized in the standard manner. A 4-polar catheter will be introduced in the right atrium, a thin screw-catheter will be placed in the atrial septum, and an 8-polar catheter will be placed in the coronary sinus. Specially for the new treatment an intracardiac ultrasound catheter (ICE) with be placed in the right atrium. With this ICE-catheter the interior of both atria and the contact between the catheter and the myocardium can be visualized. In many hospitals, both nationally and internationally, this ICE-catheter is used in a standard fashion when performing ablation procedures in the left atrium.
Then 1 or 2 transseptal punctures will be performed in order to place catheters in the left atrium. Subsequently, a spiral Lasso catheter will be introduced through a transseptal sheath and an RF-catheter will be introduced either adjacent to a single transseptal sheath or through a second transseptal sheath. For the new treatment we will use a steerable transseptal sheath. The spiral catheter is a circular catheter with which electrograms in the pulmonary veins can be recorded. The RF-ablation catheter has a slightly larger distal electrode with irrigation holes through which a saline irrigation solution is being sprayed during the ablations. With this RF-ablation catheter the regular pulmonary vein isolation will be conducted. This happens by means of sequential RF-applications around the ipsilateral ostia of the pulmonary veins. After complete pulmonary vein isolation the linear lesions will be applied with DC-ablation:
The RF-ablation catheter will be replaced by a linear DC-ablation catheter, which will be placed in the left atrium through the steerable transseptal sheath. With help of the ICE-catheter the DC-ablation catheter will be directed to the region between the left inferior pulmonary vein and the mitral valve annulus. Only when on the images by the ICE-catheter and according to the electrical signals from the electrodes of the DC-ablation catheter there is good contact between the DC-ablation catheter and the myocardium 1 or several 200 Joule DC-shock(s) will be applied. These shocks will be delivered after sedation with propofol or etomidate, as is customary with any electrocardioversion. If no good contact between the DC-ablation catheter and the myocardium can be achieved no DC-shock will be applied. After each DC-shock the (bidirectional) completeness of the linear lesion will be checked with differential pacing between the spiral catheter placed in the left appendix and the catheter in the coronary sinus.
After that the linear ablation catheter will be placed against the roof of the left atrium. Also here 1 or several DC-shocks will be applied. Also, if no good contact between the DC-ablation catheter and the myocardium can be achieved no DC-shock will be applied. After each DC-shock the (bidirectional) completeness of the linear lesion will be checked with differential pacing between the

spiral catheter and the catheter in the coronary sinus.

Intervention

The following extra actions are required for linear DC-ablations:
1. Instead of a non-steerable sheath through the interatrial septum we will use a steerable sheath. The steerable sheath is registered for transseptal procedures and is nationally and internationally routinely used in ablation procedures in the left atrium.
2. For extra visualization an ICE-catheter will be placed in the right atrium. This is a routine procedure in many national and international centres in ablation procedures in the left atrium.
3. The conventional RF-catheter will be replaced by the linear DC-ablation catheter.
4. The patient will be sedated with propofol or etomidate for a short time. This will take place under continuous observation of heart rhythm, blood pressure and oxygen saturation. Propofol or etomidate are routinely being used for electocardioversions.
5. One of several 200 Joule shock(s) with be applied by the linear DC-ablation catheter.

Study burden and risks

The strain on the patient is in our opinion similar or less compared to the current ablation method.
The total time of the extra actions is estimated to be 1 to 1,5 hours. This is shorter than the time which it currently takes to create linear lesions with sequential RF-ablations. Also, RF-ablation lesions oftentimes seem to be incomplete. This significantly increases the risk of occurence of other cardiac arrhythmia*s.

Possible risks for the patients.
In the mean while we have performed more than 250 DC-ablations in 30 test animals (pigs), no complication has occured. Possible complications could be:
1. Cardiac perforation, this can happen with any diagnostic or therapeutic catheter. Perforation could lead to cardiac tamponade.
2. The ablation shock causes contraction of the myocardium, similar to an electrocardioversion. When there are blood clots present in the left appendix (due to atrial fibrillation), these blood clots could embolize due to the contraction and cause a stroke. This is a risk that every patient has during any treatment with RF-ablation also, because during ablation of persistent atrial fibrillation almost always 1 or more electrocardioversion(s) is/are needed. To minimize this risk all patients who are being treated with ablation for atrial fibrillation currently have to undergo a transesophageal ultrasound, also patients who participate in the study.
3. In none of the approximately 250 animal experimental DC-shocks a

complication has occurred. However, we can not exclude the occurrence of any yet unknown complication due to 200 Joule DC-ablation shocks. The current intensity of these DC-shocks is 2 times higher than the customary 50 Joule endocardial electrocardioversion.
4. In animal experiments the coronary arteries seem to remain undamaged after a waiting time of 3 weeks after application of DC-ablations in very close proximity of the coronary arteries. However, we can not exclude the possibility that, on the long run, the coronary arteries will sustain any damage. With RF-ablation, the current standard technique to perform linear ablations, acute and chronic complications have repeatedly been reported. We expect therefore that the DC-ablation method is safer for the coronary arteries than the present RF-ablation method.
5. It is possible that we will not succeed in positioning the linear ablation catheter well against the myocardium. When we will not perform any DC-ablation and all extra actions taken have been in vain.

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

Persistent atrial fibrillation

Exclusion criteria

Patients who have undergone a previous catheter ablation procedure for atrial fibrillation.

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	30
Type:	Anticipated

Medical products/devices used

Generic name:	Catheter ablation
Registration:	Yes - CE outside intended use

Ethics review

Not approved

Date:	06-04-2011

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL34069.041.11