Prevention of complications during atrial fibrillation ablation with the second-generation cryoballoon

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To evaluate different cryoenergy application times using absence of DC as a surrogate for permanent PV isolation to establish optimal duration for formation of contiguous lesions and prevention of right PNP and esophageal thermal lesions during...

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

Summary

ID

NL-OMON41330

Source
ToetsingOnline

Brief title
Optimal ablation protocol second-generation cryoballoon

Condition

- Cardiac arrhythmias

Synonym
atrial fibrillation, cardiac arrhythmia

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Atrial fibrillation, Catheter ablation, Complications, Cryoballoon

Outcome measures

Primary outcome

The incidence of dormant conduction during the ablation procedure will be established en compared for three different ablation timeframes including 90, 120 or 150 seconds of additional cryoballoon ablation after acute PV isolation

Secondary outcome

1. The efficacy of AF ablation with the second-generation cryoballoon at 1 year follow-up will be investigated and also compared for the three different ablation timeframes

2. The incidence of (transient) phrenic nerve injury for the three groups will be registered and compared. The influence of the distance measured on CT scan between the RSPV ostium and the right phrenic nerve on the incidence will be assessed.

3. The incidence of esophageal lesions for the three groups will be established with gastroendoscopy and compared. The influence of minimal luminal esophageal temperature (LET) and cryoballoon temperature, duration of cryoenergy application and mean LET decrease on the formation of thermal lesions will be evaluated.

Study description

Background summary

Pulmonary vein isolation (PVI) is a cornerstone procedure for the treatment of atrial fibrillation (AF), since 90-95% of the triggers originate from the pulmonary veins (PVs). PVI can be performed with a cryoballon, which has an efficacy of approximately 70% at one-year follow-up. The most frequent complication of cryoballoon ablation is the occurrence of phrenic nerve palsy, which can cause dyspnea. The distance between the phrenic nerve and the superior right PV, as measured on a CT-scan, seems to predict the risk of this complication. The most feared complication is atria-esophageal fistula, which often has a fatal course.

Recently, the original cryoballoon catheter was modified leading to more homogeneous and deeper cooling of the balloon. Improved cooling may lead to higher rates of permanent PV isolation with reduced energy application times, increasing the efficacy of the ablation. The first study results indeed show a shorter time to PVI (an average of 52 instead of 79 seconds).
The number of complications has also increased however. Phrenic nerve palsy was found in 8% of the procedures performed with the old balloon compared to 24% with the new balloon.
Gastroscopy can be used to evaluate if any esophageal lesions have occurred as a result of cryoballoon ablation. After ablation with the old balloon, no lesions were objectified. Ablation with the new balloon resulted in esophageal lesions in 12% of patients. A temperature below 12 degrees, measured with a temperature probe located in the esophageal lumen, was found to predict the occurrence of these lesions.

At this moment, the optimal cryoenergy application duration with the new balloon is unknown. To maximize the efficacy, the maufacturer advises 2 4-minute applications. A recent study showed that PVI already occurs in 81% of the PVs after 1 freeze. To increase efficacy, it is possible to identify incomplete PVI by infusion of adenosine. If PV potentials re-occur during adenosine infusion, so-called dormant conduction, the chance of PV reconnection increases. Identification and treatment of dormant conduction after ablation with the old balloon was found to increase ablation efficacy at 1-year follow-up.

Altogether, these data suggest that reducing cryoenergy application time with the new cryoballoon catheter may reduce complication rate while maintaining the efficacy, especially when the presence of DC is evaluated with adenosine and, if present, is treated with additional ablation.

Study objective

To evaluate different cryoenergy application times using absence of DC as a surrogate for permanent PV isolation to establish optimal duration for formation of contiguous lesions and prevention of right PNP and esophageal thermal lesions during ablation with the second-generation cryoballoon

Study design

The study will be performed with 3 groups. Seventy-five patients will be 1:1:1 randomized to a single cryoenergy application continuing for 90, 120 or 150 seconds after PVI. Both acute PV isolation and isolation after a 30-minute waiting period will be established. If reconnection occurs, one or more additional cryoballoon applications will be performed. Thirty minutes after PVI, adenosine will be infused in increasing doses up to 30 mg until at least one beat of AV-block is observed to assess the presence of dormant conduction. If DC is present, additional cryoenergy applications using the same protocol as above. This procedure will be repeated until no more DC is observed for each vein.

a temperature probe (Sensitherm, St. Jude Medical) will be placed in the esophagus to monitor luminal esophageal temperature (LET) throughout the entire procedure. If a LET of < 12 degrees is reached, ablation will be discontinued. If a LET of <12 degrees is observed during ablation, a gastroesophageal endoscopy is performed within 2 days after ablation.
Phrenic nerve pacing from the superior vena cava will be performed during ablation of the right PVs to prevent right phrenic nerve injury. In case of reduced capture, cryoballoon ablation will immediately be discontinued. In case PNP occurred during ablation, potential related complaints will be registered and a chest X-ray will be performed if necessary.

Follow-up will be performed at 3, 6 and 12 months after ablation as part of standard clinical care. Efficacy of the procedure is assessed by symptoms, 12-lead ECG and 24-hour holter recordings. Registration of any atrial arrhythmia on ECG or an episode of >30 seconds on holter after a 3-month blanking period is defined as AF-recurrence and ablation failure.

Intervention

The 3 groups undergo cryoballoon ablation with the new balloon, with a duration of cryoenergy application of 90, 120 or 150 seconds after PVI.

Study burden and risks

By decreasing cryoenergy application duration, the efficacy of the procdure may decrease. This may lead to a higher number of patients that need to undergo a second procedure and/or more patients that need anti-arrhythmic medication. We will try to prevent this by evaluating PVI in multiple ways and at multiple

timepoints. The risk of complications is expected to decrease when cryoenergy application times a shortened, which is a benefit for the patients.

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

Any patient with atrial fibrillation scheduled for a first ablation procedure

Exclusion criteria

Previous catheter or surgical ablation for atrial fibrillation, (longstanding) persistent atrial fibrillation, a diameter of one or more pulmonary veins > 28 mm and > 3 veins on the right

side

Study design

Design

Study phase:	4
Study type:	Interventional
Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	16-06-2014
Enrollment:	75
Type:	Actual

Ethics review

Approved WMO

Date:	21-05-2014
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	12-08-2015
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL47833.058.14