Temperature controlled high power short duration ablation with 90 watts for 4 seconds: Outcome, safety, biophysical characteristics and cranial MRI findings in patients undergoing pulmonary vein isolation

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Abstract

Background High power short duration (HPSD) radiofrequency-ablation (RFA) is highly efficient and safe while reducing procedure and RF time in pulmonary vein isolation (PVI). The QDot-catheter is a novel contact-force ablation catheter that allows automated flow and power adjustments depending on the local tissue temperature to maintain a target temperature during 90watts/4seconds lesions. We analysed intraprocedural data and periprocedural safety using the QDot-catheter in patients undergoing PVI for paroxysmal atrial fibrillation (PAF). Methods We included n=48 patients undergoing PVI with the QDot-catheter with a temperature controlled HPSD ablation mode with 90watts/4seconds (TC-HPSD). If focal reconnection occurred besides repeat ablation the ablation mode was changed to 50watts/15seconds (QMode). N=23 patients underwent cerebral MRI to detect silent cerebral lesions. Results Mean RF-time was 8.1+/-2.8min, procedure-duration was 84.5+/-30min. The overall maximal measured catheter-tip temperature was 52.0°C +/- 4.6°C, mean overall applied current was 871mA +/-44mA and over all applied energy was 316J +/-47J. The mean local impedance-drop was 12.1 +/- 2.4 Ohms. During Adenosine challenge n=14 (29%) patients showed dormant conduction. A total of n=24 steam pops were detected in n=18 patients (39.1%), while no pericardial tamponade occurred. No periprocedural thromboembolic complications occurred, while n=4 patients (17.4%) showed silent cerebral lesion. Conclusion TC-HPSD ablation with 90watts/4seconds using the QDot-catheter led to a reduction of procedure and RF time, while no major complications occurred. Despite optimized temperature control and power adjustment steam pops occurred in a rather high number of patients, while none of them lead to tamponade or to clinical or neurological deficits.

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Abstract:

Background

High power short duration (HPSD) radiofrequency-ablation (RFA) is highly efficient and safe while reducing procedure and RF time in pulmonary vein isolation (PVI). The QDot?-catheter is a novel contact-force ablation catheter that allows automated flow and power adjustments depending on the local tissue temperature to maintain a target temperature during 90watts/4seconds lesions. We analysed intraprocedural data and periprocedural safety using the QDot-catheter in patients undergoing PVI for paroxysmal atrial fibrillation (PAF).

Methods

We included n=48 patients undergoing PVI with the QDot-catheter with a temperature controlled HPSD ablation mode with 90watts/4seconds (TC-HPSD). If focal reconnection occurred besides repeat ablation the ablation mode was changed to 50watts/15seconds (QMode). N=23 patients underwent cerebral MRI to detect silent cerebral lesions.

Results

Mean RF-time was 8.1+/-2.8min, procedure-duration was 84.5+/-30min. The overall maximal measured catheter-tip temperature was 52.0degC +/- 4.6degC, mean overall applied current was 871mA +/-44mA and over all applied energy was 316J +/-47J. The mean local impedance-drop was 12.1 +/- 2.4 Ohms. During Adenosine challenge n=14 (29%) patients showed dormant conduction. A total of n=24 steam pops were detected in n=18 patients (39.1%), while no pericardial tamponade occurred. No periprocedural thromboembolic complications occurred, while n=4 patients (17.4%) showed silent cerebral lesion.

Conclusion

TC-HPSD ablation with 90watts/4seconds using the QDot-catheter led to a reduction of procedure and RF time, while no major complications occurred. Despite optimized temperature control and power adjustment

steam pops occurred in a rather high number of patients, while none of them lead to tamponade or to clinical or neurological deficits.

Main Text

Background

Ablation of atrial fibrillation (AF) using radiofrequency (RF) energy is considered an effective and safe treatment option (1). Due to technical and procedural optimization in RF ablation long-term success rates for pulmonary vein isolation (PVI) in patients with paroxysmal atrial fibrillation (PAF) are satisfying. Nevertheless, the main cause for AF recurrence is related to pulmonary vein (PV) reconnection due to initially non-transmural lesions and tissue edema (2;3).

Recently published data demonstrate that high power delivery over a short period of time (HPSD) in radiofrequency-ablation (RFA) is highly efficient and safe while reducing procedure and RF time in PVI (4). Potential reasons for a superiority of HPSD ablation are diverse. A shift of increased resistive heating and decreased conductive heating which is outweighed using standard ablation with 30 to 40 watts leads to a better lesion to lesion contiguity and transmurality. A larger HPSD lesion diameter with less lesion depth compared to standard ablation lesions results in a reduced risk for collateral damage of extra-cardiac structures like esophagus or phrenic nerve (5). Furthermore, as shown by Anter et al, catheter stability is improved due to shorter ablation duration using HPSD. Nevertheless, HPSD has its limitations with reduced effectiveness in areas with thicker atrial tissue like the mitral isthmus (6).

Two HPSD ablation modes are currently available. In a temperature controlled ablation mode novel ablation catheters with very distal temperature probes allow automated flow and power adjustments depending on local tissue temperature. In a power controlled ablation mode using conventional ablation catheters with rather proximal temperature probes, power is ramped up to a fixed power without automated temperature dependent adjustments of flow or power. While in most HPSD publications power controlled standard ablation catheters are used only a few studies are published with specifically designed catheters for the use of temperature controlled HPSD (6;7).

The QDot catheter (Biosense Webster Inc., Irvine, California) is a novel contact force ablation catheter. It allows automated flow and power adjustments depending on the local tissue temperature to maintain a targeted temperature. During ablation using the QMode+ with 90 watts for a maximum of 4 seconds, the QDot catheter only adjusts power depending on local temperature. Additional irrigation adjustment is only possible using the QMode with a maximum of 50watts (figure 1). Aim of this study was to analyse intraprocedural and biophysical data as well as periprocedural safety of very HPSD ablation (QDot catheter with 90watts for 4 seconds) in patients undergoing PVI for paroxysmal atrial fibrillation (PAF). Of special interest was the occurrence of steam pops during ablation and potential silent cerebral embolisms detected by cranial MRI. Furthermore, we sought to determine sites where lesions with 90 watts/4 seconds where not durable and the ablation mode had to be changed from HPSD to medium power and longer duration with 50watts for 15 seconds.

Methods

We included n=48 patients with PAF that were scheduled for PVI. We used the QDot catheter (Biosense Webster) in all patients with a temperature controlled HPSD ablation mode with 90 watts for 4 seconds. All patients underwent point-by-point cirumferential PVI. If focal reconnection occurred after repeat ablation with 90watts/4 seconds (QModePlus), the ablation mode was changed to 50watts for 15 seconds (QMode). After PVI, all veins were checked with Adenosine for dormant conduction. In n=23 patients cerebral MRI was performed to detect silent cerebral lesions.

In addition, periprocedural complications and biophysical characteristics were analysed.

All patients underwent contrast enhanced cardiac computertomography for intracardiac thrombus exclusion and cardiac segmentation <24h prior to ablation. If intracardiac thrombus could not be excluded or

contraindications for contrast agent admission existed, a transoesophageal echocardiogram (TEE) was performed. All ablations where performed on uninterrupted anticoagulation using direct oral anticoagulants or vitamin K antagonists with an International Normalized Ratio (INR) between 2-3. Heparin was administered to gain an ACT >300 seconds during the procedure. The electrophysiological study was performed under conscious sedation with Propofol, Midazolam and Fentanyl. All patients underwent single transseptal puncture with double access to the left atrium with a steerable 11.7F sheath. Thereafter, 3D mapping of the LA was obtained using the CARTO 3 System with the LASSO Catheter (Biosense Webster, Inc.). In all patients an antral circumferential PVI was performed using a point by point ablation technique. The primary ablation mode was the temperature controlled QMode Plus with 90watts for 4 seconds for both the anterior and posterior portion of PVs. Catheter irrigation was set to 8ml/min, contact force was aimed to be higher than 5g. The cut off temperature for down titration of power was set to 60 degrees on the hottest surface thermocouple. A mandatory pre and post ablation irrigation with 8ml for 3 seconds was applied for each lesion. PVI completion was confirmed using the LASSO mapping catheter placed in the PV ostia after elimination of all PV potentials followed by a 20 minute waiting period. If PVs were not isolated after encircling both ipsilateral veins, additional segmental PVI was performed. If focal reconnection occurred besides repeat ablation with 90watts/4 seconds, the ablation mode was changed to (temperature controlled) 50watts for 15 seconds (QMode). After confirmed PVI, intravenous Adenosine was rapidly administered, with at least 9mg separately for each vein. Adenosine dose was increased if neither third-degree atrioventricular (AV) block nor sinus arrest occurred. In case of PV reconnection, additional segmental ablation was applied at the earliest PV activation time on the level of the circumferential lesion in order to achieve complete PVI under recurrent Adenosine testing.

All patients received a duplex sonography of the access site the day after the procedure. In the duplex scan vascular complications were assessed as described in the consensus report from the Bleeding Academic Research Consortium All patients underwent a local examination to exclude groin infection prior to hospital discharge. Echocardiography to rule out pericardial effusion was performed at the end of the procedure and on the following day. Oral anticoagulation was continued with patients' standard dose for at least 3 months depending on the calculated CHADS2VASC2 score. Definitions for bleeding and thromboembolic complications were used as described previously by our group (8;9).

N=23 patients underwent post-procedural cerebral MRI within 48h to detect silent cerebral lesions. Cerebral MRI was performed using a 1,5 tesla device (Siemens Healthineers, Erlangen, Germany). In our protocol a T2-weighted axial fluid-attenuated inversion recovery sequence (FLAIR) (TI=2,340ms, TR=9000ms, TE=118ms, slice thickness 5.0 mm, FoV 230 x 187 mm, in-plane resolution: 0.7 x 0.7 mm) and a diffusion-weighted echo-planar imaging sequence (TR=4,700ms, TE 100ms, slice thickness 5.0 mm, FoV 230 x 230 mm, in-plane resolution: 0.9 x 0.9 mm) were used. An additional apparent diffusion coefficient (ADC) maps was obtained.

In addition, Biophysical procedural characteristics were analysed.

Statistics

Continuous variables are presented as mean +/- standard deviation or median. Categorical data are expressed as frequencies and percentages. Univariate comparisons were performed using t-test (continuous variables) and the X2-Test. A p-value of <0.05 was considered statistically significant. Cumulative event rates were calculated using the Kaplan-Meier method. A log-rank test was performed to compare event distribution between both groups. All analysis were performed using SPSS for Mac version 27.0 (SPSS Inc., Chicago, IL, USA).

Results

Patients characteristics:

Mean age was 61 +/-12 years with 43.8% of patients being female (n=21). The overall rate for comorbidities was moderate with 63% of patients suffering from hypertension and 15% from congestive heart failure.

Procedural data:

Procedural data are shown in Table 1. Mean RF time was 8.1+/-2.8min, procedure duration was 84.5+/-30min. Fluoroscopy dose was 146.7 +/- 221.4 cGym^2. Complete PVI was achieved in all patients. During Adenosine challenge n=14 (29%) patients showed dormant conduction. Following additional ablation, all PVs showed entrance block confirmed by the LASSO catheter.

Average contact force, local temperature and impedance drop, applied current and energy as well as mean applied power are displayed for each segment of the pulmonary veins in Figure 2. The overall maximal measured catheter tip temperature was 52.0degC +/- 4.6degC, mean overall applied current was 871mA +/-44mA and over all applied energy was 316J +/-47J. The mean local impedance drop was 12.1 +/- 2.4 Ohms.

The ablation mode had to be changed to QMode with 50watts/15seconds in 59% of patients (n=27) due to ineffectiveness of local electrogram abolition using 90watts/4 seconds. Especially in areas with thicker myocardial tissue like the ridge or the carinas between the veins an ablation mode change from 90 watts/4sec to 50watts/15sec was necessary.

Complications:

All complications are displayed in Table 2. A total of n=24 steam pops was detected in n=18 patients (39.1%). No pericardial tamponade occurred. No atrioesophageal fistula was reported. No periprocedural thromboembolic complications occurred. On cMRI scans, n=4 patients (17.4%) showed silent cerebral lesion (SCL). Comparing patients with steam pop and without revealed no significant difference in terms of SCL with n=2 in each group (p=0.58)(Figure 3).

A total of 3365 ablation lesions where created using 90watts/ 4 seconds. During 24 ablation lesions a steam pop occurred. Steam pops occurred after 3.6 seconds compared to 3.9 seconds of lesions without a steam pop. In an univariate analysis steam pop lesions had significantly higher impedance drops of 10.4% +/- 2.1% compared to 9.4% +/- 2.4% in lesions without a steam pop (measured from baseline impedance). Steam pops occurred in different locations without a local accumulation.

Discussion

Efficacy of HPSD ablation

Temperature controlled high power short duration ablation with 90watts for 4 seconds using the QDot catheter lead to short procedure and RF times, while no major complications occurred. PVI was achieved in all patients. Short-term effectiveness during Adenosine challenge without dormant conduction (DC) was high and DC occurred only in 29% of patients. In the QDot Fast Trial published by Reddy et al. dormant conduction during Adenosine testing was 26.9% (4). Compared to historical data by Mackle et al and Kottmaier et al showing dormant conduction in 58% and 54% respectively using standard power settings a reduction of approximately 25% can be stated (4;10). These data are in line with recently published data stating that HPSD ablation leads to shorter procedure times and better outcomes while remaining safe using standard irrigated tip catheters. Published data stated that using a power controlled ablation mode in HPSD ablation leads to a better lesion to lesion contiguity and a beneficial lesion geometry with larger lesion diameters and less lesion depth (5;11).

Safety

Leshem et al demonstrated that HPSD ablation has a narrow efficacy to safety window. Small changes in ablation duration can potentially lead to non-transmural lesions in case of duration reduction or steam pops due to longer ablation duration or rapid temperature changes. Therefore, real time temperature feedback might be crucial to prevent overheating. Standard irrigated tip catheters used in the above mentioned HPSD ablation studies lack the ability to precisely measure tissue temperature in any catheter orientation due to a rather proximal temperature sensor placement in the catheter tip. It has been shown that HPSD ablation with 90 watts for 4 seconds using the QDot catheter with an enhanced thermocouple system was

sensitive enough to detect small temperature changes (5;7). Adding an algorithm to scale the recorded temperature to actual tissue temperature leads to power adjustments due to temperature limit cutoffs and prevent overheating. The use of HPSD ablation with standard irrigated tip catheters in a power controlled mode is criticized by some authors irrespectively of published safety data arguing that temperature feedback is crucial (12).

Despite optimized temperature control and power adjustment, steam pops occurred in a rather high number of patients in our study (39%). None of them lead to severe complications like pericardial tamponade or clinical or neurological deficits. Not all patients with steam pops showed silent cerebral lesions detected on cMRI and the same number of patients without steam pops showed SCL (both n=2). Overall the number of SCL found in cMRI was comparable to other trials investigating cMRI findings using open-tip irrigated catheters (13).

Leshem et al reported one of the first clinical uses of the QDot? catheter. In their work no steam pops were detected and the temperature controlled ablation mode with automated power reduction lead to a mean applied power of 60 watts (5). Using the same ablation mode and the same catheter we detected a mean power of 82 watts. A 20% of power increase in our group using the alleged same equipment and protocol might be an explanation of the high number of steam pops. A potential explanation for this finding is that in the first QDOT? trials with 90watts/4sec the nMARQ? ablation generator was used (5). During the early evaluation of the QDot? catheter the use of the nGEN? ablation generator was recommended by Biosense Webster?. In late December 2020 Biosense Webster? published a safety alert due to a higher then expected number of "char" complaints during the external evaluation of nGEN? Generator when using the 90w/4sec. At the date of publication the use of the QMODE+ using the nGEN? ablation generator is stopped.

Limitations of very HPSD ablation

Masateru et al could demonstrated that the beneficial lesion geometry using the QDOT catheter in an ex vivo porcine model with a temperature controlled ablation mode is found as well (14). Our data show that especially in areas with thicker tissue (like the ridge between the left superior vein and the left atrial appendage) the ablation mode had to be changed to lower power for longer duration (50watts/15seconds) significantly more often to achieve durable lesions. These findings are in line with Yavin et al who demonstrated that HPSD ablation with 50 watts for the ablation of the mitral isthmus only led to successful mitral isthmus block in 43% of patients versus 70% of the control group using standard power settings (6). These findings support the assumption; the application of lower power for longer duration leads to deeper and more sufficient lesions in thicker myocardial structures.

Conclusion

Temperature controlled high power short duration ablation with 90watts for 4 seconds for PVI using the QDot catheter lead to a short procedure and RF time with no major complications in this trial. Despite optimized temperature control and power adjustment, steam pops not leading to clinical implications like tamponade or neurological deficits occurred in 39% of patients. The different amount of steam pops compared to initial trials maybe due to the used ablation generator.

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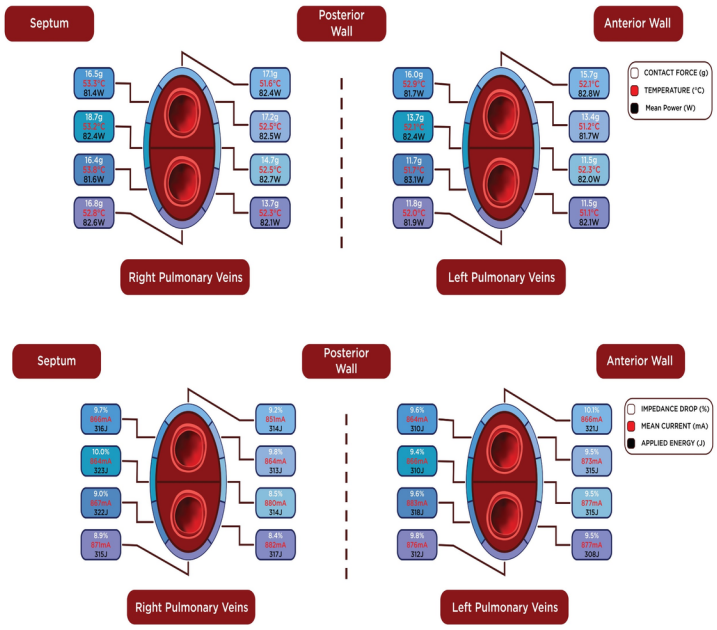

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