What Does The Future Hold in Ablation

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Disclosures

• Research Grants: Biosense Webster, Farapusle, Affera, Vytronus, Medlumics, Luxcath, Cardiofocus, Cardionext

• Consultant: Abbott, Farapulse

This talk discusses various investigational non-FDA approved devices and technologies
The Future of Thermal ablation

Radiofrequency, Laser, Utrasound
Advantages of Interface Temperature

– Another measure of contact - not just force

– Direct measure of mechanism of tissue injury

• Allows for controlled lesion delivery
• Avoid char/ steam pops
• Temperature monitoring – is also stability monitoring
Embedded surface temperature sensors in 56 hole porous tip
Different ways to deliver RF using an irrigated catheter tips

Temperature-Controlled Radiofrequency Ablation for Pulmonary Vein Isolation in Patients With Atrial Fibrillation

Jin Iwasawa, MD, Jacob S. Konuth, MD, Jan Petru, MD, Libor Dujka, MD, Stepan Kralovec, Katerina Mzourkova, Srinivas R. Dukkipati, MD, Petr Neuzil, MD, PhD, Vivek Y. Reddy, MD
Temperature Controlled-Irrigated RF: Diamond tip ablation

- Diamond-tip radiofrequency (RF) irrigated catheter
- Six thermocouples

Iwasawa J, Koruth JS, Reddy VY. J Am Coll Cardiol 2017 Aug
Irrigated RF and Atrial Ablation…..

High-Power and Short-Duration Ablation for Pulmonary Vein Isolation: Biophysical Characterization
Leshem E, Anter E. JACC Clin Electrophysiol. 2018
Fast Ablation: Right Superior PV Isolation
90W/4 Seconds
Pulmonary Vein Isolation With Very High Power, Short Duration, Temperature-Controlled Lesions

The QDOT-FAST Trial

Vivek Y. Reddy, MD, MS,1 Massimo Grimaldi, MD,2 Tom De Potter, MD,3 Johan M. Vigen, MD,4 Alan Bulava, MD, PhD,5 Mattias Francis Duytschaever, MD,6 Martin Martinek, MD,1 Andrea Natale, MD,1 Sebastien Knecht, MD, PhD,6 Petr Neuzil, MD, PhD,6 Helmut Pürerfellner, MD6

- 52 PAF pts
- Procedure time = 105 mins
- Fluoroscopy = 6.6 mins
- 79% PVI with vHPSD alone
Combined ablation and mapping catheter

- 8F bidirectional deflectable - expandable conductive nitinol mesh
- Diameter- 9mm with 9 Temp sensors/mini electrodes
- Central irrigation
Lattice Ablation (Sphere 9) Catheter

Temperature controlled irrigated RF

- Mini electrodes + Central electrode
- Tissue stability - Compressible
- Faster, Wider, Deeper lesions

- Electroanatomical mapping - magnetic sensor
- Anatomy acquisition - respiratory gating
- Contact: Impedance between microelectrodes and center electrode
**Wide Tip RF delivery**

Average Current Density = \[
\frac{\text{Current}}{\text{Surface Area}} = \frac{I}{S}
\]

Max Current
\(I \approx 2.75A\)

Average Current Density
\(\frac{I}{S} \approx 10mA/mm^2\)

Max Current @50W & 110Ω
\(I \approx 0.67A\)

Effective Surface Area
\(S \approx 275mm^2\)

Effective Surface Area
\(S \approx 28mm^2\)

A Novel Radiofrequency Platform Allowing High Current at Low Density for Rapid, Titratable, and Durable Lesions

Michael Barkagan, Elad Anter
Preclinical Swine Survival

Koruth, Kuroki, Reddy 2019 (Under Review)
Preclinical

Koruth, Kuroki, Reddy 2019 (Under Review)

Slide: Courtesy Reddy / Neuzil 2019
9 swine, ventricular ablation at Tmax60°C versus 40 W was performed for 60 seconds
What is Pulsed Field Ablation (IRE)?

- Novel ablation- Ultra-short, high-voltage electrical impulses
- Large increase in the electric field across cell membrane - Nanoscale pores
- Specific thresholds for target tissue
- Permanent nanopores - Cell death

Pulsed Field Ablation

- **Non-thermal ablation** - despite electric field of 1000 V/cm - short duration, limited pulses

- **Effect/Lesion volume** determined by
  - Electric field distribution
  - Tissue specific thresholds

- **Affects only cell membrane**: Extracellular matrix is intact
Pulsed Field Ablation

- IRE - Unipolar pulse(s) applied for a duration of microseconds: ++muscle contractions requiring NM blockade

- IRE - Bipolar pulse: Effective but with less muscular contractions


High-frequency irreversible electroporation (H-FIRE) Arena CB, Davalos RV Biomed Eng Online. 2011 Nov 21; 10():102.
**Epicardial ablation**
- 50-360 J
- 5/56 arteries: intimal hyperplasia (<50% stenoses)
- 5 direct LAD – no change
- Depth - 6.5 ± 2.7 mm

**Epicardial ablation:**
- 50-200-J
- Depth - 5-12 mm
- Width - 16-20 mm
- 200-J: Transmural lesions & significant tissue shrinkage were observed


Epicardial Pulsed Electric Field Therapy

Ends are cinched together to draw catheter around pulmonary veins.
Pulsed Field Ablation: Catheter Design

- 12F OTW pentaspline catheter
- PFA-specific generator
- Bipolar/biphasic waveform
- Farawave/Farapulse
Pre-Clinical Evaluation of Pulsed Field Ablation: Electrophysiological and Histological Assessment of Thoracic Vein Isolation

Jacob Koruth MD, Kenji Kuroki, MD, Vivek Reddy MD
(Accepted, CircEP)
Ablation of Atrial Fibrillation With Pulsed Electric Fields
An Ultra-Rapid, Tissue-Selective Modality for Cardiac Ablation

Vivek Y. Reddy, MD,1,2,3 Jacob Koruth, MD,1 Pierre Jais, MD,1 Jan Petru, MD,3 Ferdinand Timko, MD,4 Ivo Skalsky, MD,4 Robert Hebele, MD,4 Louis Labrousse, MD,4 Laurent Barandon, MD,4 Stepan Kralovec,4 Moritoshi Funosako, MD,4 Boochi Babu Mannuva, MD,4 Lucie Sediva, MD,5 Petr Neuzil, MD, PhD5

- Acute isolation: 57 PVs in 15 patients
- Mean of 3.26 ± 0.5 lesions/PV
- Procedure: 67 ± 10.5 min
- PEF catheter entry into LA to time of removal: 26 ± 4.3 min
- Total ablation time (was 19 ± 2.5 min (range 16 to 23 min)
- All lesions was <60 s/patient
Pulsed Field Ablation for Pulmonary Vein Isolation in Atrial Fibrillation

Vivek Y. Reddy, MD, a,b Petr Neuzil, MD, PhD, a Jacob S. Koruth, MD, b Jan Petru, MD, a Moritoshi Funosako, MD, a Hubert Cochet, MD, c Lucie Sediva, MD, a Milan Chovanec, MD, a Srinivas R. Dukkipati, MD, b Pierre Jais, MD c
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Immediate Post-PFA

3-Month Remap

![Graph showing durability on remapping](image)
Pulsed Field Ablation: Delayed Enhancement
Endocardial Focal PFA
Bipolar and Biphasic

12F Deflectable “FLEX” Catheter
• Four splines / four electrodes each
Endocardial Focal PF Ablation

- CS and RV pacing catheters
- Synchronized delivery during joined RV and CS pacing
- Pre- and post-ablation pacing threshold recorded in 2/4 swine:
  Pulse width of 2ms pacing through distal bipoles

Koruth, Kuroki, Reddy et al- Europace 2019
Endocardial Focal PFA Ablation

Koruth, Kuroki, Reddy et al - Europace 2019
Endocardial Focal PFA Ablation

Width
22.7+3.3mm

Depth
4.8+1.9mm

Koruth, Kuroki, Reddy et al- Europace 2019
Histological Findings - Focal PFA

Koruth, Kuroki, Reddy et al - Manuscript under review
8F Deflectable “POINT” Catheter

Post fixation
Endocardial Surface

Post fixation
Epicardial Surface

L3
7.3mm MAX
5.4mm MIN

L2
6.8mm MIN
9.7mm MAX
Pulse Field Ablation - ICE Imaging

- Echodense lesion immediate post ablation
- Echodensity/edema progresses over time
What’s out there in PFA?
RF Balloon Ablation Catheter
Visually-Guided, Titrate-able RFA

One Shot Multipoint Irrigated RF
May improve procedural efficiency

Built-in Cameras
Validation of electrode contact via real-time direct visualization

Integrated Mapping and Pacing

Courtesy V Reddy
Multi-Electrode Balloon Ablation Catheter
Helios: Directionally-Titratable RF Energy
Visually-Guided Laser Balloon

Next-Gen Improvements ➔ Shorten Procedure Time

- **Gen 2: Excalibur**
  - More Compliant Balloon
  - **Goal:** Easier, faster, maximal balloon-tissue conformance

- **Gen 3: X3 RAPID**
  - Continuous ablation at higher power ➔ ‘drag and burn’ lesion
  - Dose-equivalent to current titration
  - Controlled by single-axis motor
  - **Goal:** Isolate PV < 3 minutes of ablation … but preserve ability to titrate energy along balloon circumference