The Future of AF Ablation

PV isolation

Jacob S. Koruth, MD
Director, Experimental Laboratory
Helmsley Electrophysiology Center,
Mount Sinai Medical Center,
New York, NY

Jacob.koruth@mountsinai.org
Disclosures

• Research Grants: Biosense Webster, Iowa approach, Vytronus, Medlumics, Luxcath, Abbott, Cardionext:
• Biosense Webster, Abbott, ACT - Consultant
• Iowa approach, Medtronic- Advisory board

This talk discusses various investigational non-FDA approved devices and technologies
Clinical case slides- Courtesy Dr Vivek Reddy
A Decade of Atrial Fibrillation Ablation

AF ablation

i) More heterogeneous patient population
ii) Earlier after patients were diagnosed with AF
iii) Increasingly being performed in persistent AF and in patients with reduced EF
iv) Lower complication rates, eg PV stenosis/stroke
v) Has gained the trust of the referring physician

“Remarkably, 1-year single procedure success and rate of PV reconnections observed during redo procedures have remained similar”

RF Ablation in AF: Why are we struggling?

- AF ablation efficacy suboptimal
  - Insufficient lesion width and depth
  - Lack of circumferentiality and contiguity

- AF ablation safety
  - Risk of thromboembolism, steam pop & perforation
  - Risk of phrenic nerve injury, AE fistula and PV stenosis
Improving Point by point RF Ablation

“Bigger, Faster & Safer lesions”

• How can we improve catheter based RF ablation?
  • Lesion assessment- lesion –yes/no, transmural yes/no, gap yes/no- thickness detection
  • Different modes of RF delivery: ‘Tissue’ temp controlled, Lesion sensing technology controlled : Power control is not enough
  • Fast ablation- make up for what contact assessment cant fix: Prolonged contact is the weakness
  • Delivery tools- change from 3.5mm tip 9 mm print
Microwave radiometry-based assessment of tissue temperature despite irrigation

Microwave radiometry is a technique whereby microwave energy that is emitted from a heat source can be measured.

Measure the average temperature within a volume surrounding the tip.

Allows increase and decrease of power depending on how “hot” tissue gets.

Controlling the Lesion based on Visualization

- Integrated high-frequency ultrasound (US) and ablation catheter

- **Safety & efficacy**: Real time assessment of contact: visualize transmurality and assess steam formation

- ? Superior to using contact force + empiric power and time settings

Controlling the Lesion based on Visualization

Optical coherence reflectometry

- Untreated myocardial tissue exhibits significant “Phase Retardation”

- Birefringent property disappears by applying RF- fiber denaturalization
  - Depth detection 0.75mm
Controlling the lesion based on visualization

**NADH fluorescence approach**

- Loss of endogenous fluorescence of NADH-
  - immediate marker of RF myocardial damage

Commercially available irrigation-tip ablation catheter that has been modified

- Spectrometer analysis of returned light
- Optical signature of ablated tissue
- Lesion creation detection

Direct Assessment of Catheter-Tissue Contact and RF Lesion Formation:
Koruth /Reddy et al HRS 2015,
NADH fluorescence approach

Direct Assessment of Catheter-Tissue Contact and RF Lesion Formation: Koruth /Reddy et al HRS 2015
Controlling the lesion based on “tissue temperature”
Will catheter –tissue interface temperature suffice?

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 pop
  • Temperature monitoring – is also stability monitoring
Chamber specific
Lesion Dimension Prediction

Embedded surface temperature sensors in 56 hole porous tip

Different ways to deliver RF using an irrigated catheter tips.
Temperature Controlled-Irrigated RF
Diamond tip ablation

- Diamond-tip radiofrequency (RF) irrigated catheter
- Six thermocouples - separated by two diamonds
- Allow heat shunting - high thermal diffusivity
- Split-tip configuration - high resolution egms - rapid lesion assessment

Temperature-Controlled Radiofrequency Ablation for Pulmonary Vein Isolation in Patients With AF
Iwasawa J, Koruth JS, Reddy VY. J Am Coll Cardiol 2017 Aug
The Problem with 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 PV isolation

Traditional ablation RF time 40-50 min

Fast ablation RF time 4-5 min
Expandable irrigated tip catheter with surface thermocouples: 9mm irrigated-tip that also contains thermocouples:
Temperature-controlled mode

Uniform RF delivery over the entire electrode-tip, providing a much larger effective surface area (250-275mm²)

Wider lesions compared to traditional RF tips (that are typically 3.5-4mm in length)

By abbreviating the duration of lesion and using higher powers, it creates shallow lesions
“One Shot” tools to deliver RF for Pulmonary Vein Isolation

- Multi-electrode catheters
- Balloons
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
Alternate Energy Sources

Laser balloon ablation

Advantages:

• Non contact – Not dependent on contact force and catheter stability
• Visually guided
• Need to remove blood by displacing it with a balloon for lesion to form in the tissue
Visually-Guided Laser Balloon vs RF Energy

Heartlight IDE → FDA Approval in April 2016

- RCT of 353 pts from 19 U.S. centers
  - Drug-Resistant Paroxysmal AF
  - Aggressive follow-up
- Operators: Experienced w/ RFA, but Naive to Laser

Aiming Beam

“Static” Blood in LSPV

LSPV
LIPV
LAA


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**
  - High power, shorter duration, ‘drag and burn’ lesion
  - Dose ‘equivalent’ to current system
  - Controlled by single-axis motor
  - **Goal:** Isolate PV < 3 minutes of ablation … *but preserve ability to titrate energy along balloon circumference*
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**
  - High power, shorter duration, ‘drag and burn’ lesion
  - Dose ‘equivalent’ to current system
  - Controlled by single-axis motor
  - **Goal:** Isolate PV < 3 minutes of ablation … but preserve ability to titrate energy along balloon circumference
**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
Alternate Energy Sources

Ultrasound ablation

Advantages:

• Non contact – Not dependent on contact force and catheter stability
• Can map the target anatomy: built in mapping system
• Can detect tissue thickness and offer tailored ablation that stops when the lesion reaches the epicardium
Low Intensity Collimated Ultrasound (LICU) Automated Geo Creation & Linear Lesion Formation

The VytronUS Ablation System is not available for sale. Investigational Use Only.
Gen-2 LICU System
3D Cardiac Motion Captured During Imaging

Continuous Energy Delivery Along Lesion Path

Images Courtesy of P. Neuzil & V. Reddy
Epicardial Pulsed Electric Field Therapy

Ends are cinched together to draw catheter around pulmonary veins.
Endocardial pulsed electric field therapy - preclinical
Endocardial pulsed electric field therapy - First in Man

Ablation of Atrial Fibrillation With Pulsed Electric Fields
An Ultra-Rapid, Tissue-Selective Modality for Cardiac Ablation

Vivek Y. Reddy, MD, a, 1,2 Jacob Koruth, MD, a Pierre Jais, MD, 1,3 Ian Petru, MD, 1 Ferdinand Timko, MD, d
Ivo Salak, MD, d Robert Heberer, MD, d Louis Labrousse, MD, d Laurent Barandon, MD, d Stepan Kralovec, d
Moritoshi Funosako, MD, d Boochi Babu Mannuva, MD, d Lucie Sediva, MD, d Petr Neuzil, MD, PhD

- PEF ablation electrically isolated all 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
The Extent of Mechanical Esophageal Deviation to Avoid Esophageal Heating During Catheter Ablation of Atrial Fibrillation - Palinswamy/ Koruth/Reddy JACCEP - 2017