Minimal Floroskopisi Gerektiren Ablasyon Sistemleri - EnSite

Volkan Tuzcu MD
İstanbul Medipol Üniversitesi
Çocuk ve Genetik Aritmi Merkezi
Elektroanatomik Anatomik Mapping Sistemleri

- Floroskopiyi azaltır.
- Mapping ve ablasyonu kolaylaştıtırır.
EAM Avantajları

- Floroskopinin ciddi oranda azaltılması
- Anatomik rekonstrüksiyon
- EP kateterlerinin navigasyonu
- Önemli yerlerin işaretlenmesi (lezyon yeri, His, frenik sinir, vs)
- Aktivasyon ve voltage*scar mapping.
Radyasyonun Zararları

- Deterministic effect (cell death)
  - Skin injury and hair loss
  - Eyes (cataract)
  - Other organs (thyroid, paratroid)
- Stochastic effect (viable cell with mutation)
  - Neoplasm (leukemias, breast cancer, skin cancer)
  - Heritable genetic effect

13.04.2015

Radiation therapy has been associated with increased risk for late mortality, development of second neoplasms, obesity, and pulmonary, cardiac and thyroid dysfunction as well as an increased overall risk for chronic health conditions. Development of subsequent malignant neoplasms of the central nervous system, thyroid and breast.


multiple diagnostic radiation exposures have been informative about increased mortality from breast cancer with increasing radiation dose, and case-control studies of childhood leukemia and postnatal diagnostic radiation exposure have suggested increased risks with an increasing number of examinations. Risks of radiation-related cancer are greatest for those exposed early in life, and these risks appear to persist throughout life.

H2AX Foci as a Biomarker for Patient X-Ray Exposure in Pediatric Cardiac Catheterization: Are We Underestimating Radiation Risks? Laurence Beels, MSc; Klaus Bacher, PhD; Daniël De Wolf, MD, PhD; Joke Werbrouck, MSc; Hubert Thierens, PhD. Circulation. 2009;120:1903-1909.

Very low doses of radiation may be more harmful than previously suspected and that the relationship may not, in fact, be linear in the pediatric population at all
Çoğu EP Prosedüründe Floroskopi Önlenebilir mi ?
Yes We Can!

Single catheter in 21 children with right sided WPW wucing CARTO.

CONCLUSIONS: The use of a nonfluoroscopic system for catheter navigation significantly reduced fluoroscopy exposure and total procedure duration of RCA of common SVT substrates in children.

METHODS AND RESULTS: Electrophysiologic studies were performed in 26 consecutive cases (12.7 +/- 7.5 years) using NavX without fluoroscopy. The procedure time was 98.7 +/- 49.7 minutes. CONCLUSION: This study demonstrates that nonfluoroscopic electrophysiologic studies and right-sided catheter ablations for supraventricular tachycardia can be safely and effectively performed in the majority of patients with normal cardiac anatomy using NavX.

Pediatrik EPS Ablasyonda Floroskopi

<table>
<thead>
<tr>
<th></th>
<th>Early Era</th>
<th>Late Era</th>
</tr>
</thead>
<tbody>
<tr>
<td>N (total)</td>
<td>4,193</td>
<td>3,407</td>
</tr>
<tr>
<td>Fluoroskopi Süreleri</td>
<td>50.9 + 39.9</td>
<td>40.1 + 35.1</td>
</tr>
<tr>
<td>Yaş (yıl)</td>
<td>12.4 + 4.7</td>
<td>12.2 + 4.6</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>USA national data (2004)*</th>
<th>Boston (2008)**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Floroskopi süresi</td>
<td>38 dak</td>
<td>30 dak</td>
</tr>
<tr>
<td>Vakalar &gt;50 dak. Floroskopi</td>
<td>22%</td>
<td>14%</td>
</tr>
</tbody>
</table>

Prospective RF registry. JCE 2004 / ** Miyake CY. HRS 2011
Pediatric RF registry. Kugler, j CardiovasElectrophsyology 2002
Floroskopisiz Ablasyon Metodları

a) Biosense CARTO (Carto 3) mapping system
b) EnSite NavX (Velocity, St Jude Med) mapping system
c) EnSite Array (Noncontact mapping)
d) RHYTHMIA (Boston Scientific)
e) Magnetic Navigation System (Niobe, Stereotaxis System)
f) Intracardiac echocardiography (ICE) image integration
g) Digital Image (MRI-CT) Fusion
h) Dynamic 4-D mapping system (MediGuide, St Jude Med.)

With courtesy of Enes E. Gul
The CARTO mapping system
(Biosense, Diamond Bar, CA, USA)

- Utilizes a low-level magnetic field (5 x 10^{-6} to 5 x 10^{-5} Tesla) delivered from three separate coils in a locator pad beneath the patient.

- Location sensor embedded tip of a specialized mapping catheter.

- The strength of each coil's magnetic field measured by the location sensor is inversely proportional to the distance between the sensor and coil.
Intracardiac Echocardiography (ICE) image integration with CARTO

- 64-electrode basket design, bi-directional steerable catheter
- Rapid collection of clear signals
- Multicatheter support (visualize and use the diagnostic and ablation catheters)
- Accurate tracking and high-resolution 3-D mapping

With courtesy of Enes E. Gul
Continuous Mapping

- Continuous acquisition of points based on user-defined criteria creates maps in 1/3 of the time
- Repeatable maps generated in minutes offer more predictability and less variability
- Seamless map creation for all rhythm types, including ectopic beat maps
- 99.8% accuracy in automated annotation algorithm eliminates the need for manual beat acceptance

High-Resolution, 3D Electroanatomical Map Captured in 3 Minutes

1-minute
# of EGMs = 2,572

2-minute
# of EGMs = 4,481

3-minute
# of EGMs = 5,005


With courtesy of Enes E. Gul
Magnetic Navigation System

- The NIOBE magnetic navigation system (MNS, Stereotaxis, St. Louis, MO, USA) consists of two neodymium-iron-boron magnets positioned on each side of a single-plane fluoroscopy table
- Provides remote, robotic control of diagnostic devices
- Maintains stability of devices
- Provides precise movement of devices
- Very safe (due to the specific catheter design no catheter-related cardiac perforations have been reported)
- Was associated with longer procedure times and higher procedural expense (recent data showed comparable procedure times)
- Decreased fluoroscopic exposure

Bradfield et al. PACE 2012
### Meta-Analysis Summary for Success

#### Acute success-MNS

<table>
<thead>
<tr>
<th>Type of study</th>
<th>n studies</th>
<th>n</th>
<th>Pct</th>
<th>Lower</th>
<th>Upper</th>
<th>Diff</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>AVNRT</td>
<td>7</td>
<td>221</td>
<td>95.0%</td>
<td>90.5%</td>
<td>97.4%</td>
<td>-0.3%</td>
<td>0.9222</td>
</tr>
<tr>
<td>AVRT</td>
<td>7</td>
<td>189</td>
<td>79.3%</td>
<td>69.6%</td>
<td>86.4%</td>
<td>-5.1%</td>
<td>0.4847</td>
</tr>
<tr>
<td>AFIB</td>
<td>6</td>
<td>342</td>
<td>91.8%</td>
<td>86.6%</td>
<td>95.1%</td>
<td>-7.1%</td>
<td>0.0094</td>
</tr>
<tr>
<td>Flutter</td>
<td>4</td>
<td>117</td>
<td>85.7%</td>
<td>64.5%</td>
<td>95.2%</td>
<td>-5.5%</td>
<td>0.3173</td>
</tr>
<tr>
<td>VT-structural normal</td>
<td>7</td>
<td>149</td>
<td>93.2%</td>
<td>84.1%</td>
<td>97.2%</td>
<td>-0.2%</td>
<td>0.9826</td>
</tr>
<tr>
<td>VT-structural disease</td>
<td>4</td>
<td>98</td>
<td>81.3%</td>
<td>57.4%</td>
<td>93.3%</td>
<td>-10.4%</td>
<td>0.6732</td>
</tr>
<tr>
<td>Complex congenital</td>
<td>3</td>
<td>20</td>
<td>60.7%</td>
<td>20.3%</td>
<td>90.4%</td>
<td>-8.3%</td>
<td></td>
</tr>
</tbody>
</table>

#### Acute success-manual

<table>
<thead>
<tr>
<th>Type of study</th>
<th>n studies</th>
<th>n</th>
<th>Pct</th>
<th>Lower</th>
<th>Upper</th>
<th>Diff</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>AVNRT</td>
<td>4</td>
<td>125</td>
<td>95.3%</td>
<td>89.9%</td>
<td>98.1%</td>
<td>-0.3%</td>
<td>0.9222</td>
</tr>
<tr>
<td>AVRT</td>
<td>2</td>
<td>50</td>
<td>84.4%</td>
<td>71.7%</td>
<td>92.0%</td>
<td>-5.1%</td>
<td>0.4847</td>
</tr>
<tr>
<td>AFIB</td>
<td>3</td>
<td>406</td>
<td>99.0%</td>
<td>97.1%</td>
<td>99.6%</td>
<td>-7.1%</td>
<td>0.0094</td>
</tr>
<tr>
<td>Flutter</td>
<td>2</td>
<td>129</td>
<td>94.2%</td>
<td>82.5%</td>
<td>96.3%</td>
<td>-6.5%</td>
<td>0.3173</td>
</tr>
<tr>
<td>VT-structural normal</td>
<td>2</td>
<td>57</td>
<td>92.9%</td>
<td>35.4%</td>
<td>99.7%</td>
<td>-6.2%</td>
<td>0.8926</td>
</tr>
<tr>
<td>VT-structural disease</td>
<td>2</td>
<td>64</td>
<td>91.7%</td>
<td>19.0%</td>
<td>99.8%</td>
<td>-10.4%</td>
<td>0.6732</td>
</tr>
<tr>
<td>Complex congenital</td>
<td>0</td>
<td>0</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td></td>
</tr>
</tbody>
</table>

### Meta-Analysis Summary for Procedural Data

#### NNS

<table>
<thead>
<tr>
<th>Outcome</th>
<th>dx category</th>
<th>n Studies</th>
<th>Mean</th>
<th>SE</th>
<th>Mean diff</th>
<th>SE d</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procedure time</td>
<td>AVNRT</td>
<td>7</td>
<td>138.6</td>
<td>19.4</td>
<td>-18.9</td>
<td>38.51</td>
<td>0.6362</td>
</tr>
<tr>
<td>Procedure time</td>
<td>AVRT</td>
<td>10</td>
<td>173.1</td>
<td>15.3</td>
<td>23.0</td>
<td>54.03</td>
<td>0.6706</td>
</tr>
<tr>
<td>Procedure time</td>
<td>A fib</td>
<td>4</td>
<td>241.8</td>
<td>27.9</td>
<td>77.1</td>
<td>43.35</td>
<td>0.1955</td>
</tr>
<tr>
<td>Procedure time</td>
<td>A flutter</td>
<td>4</td>
<td>106.7</td>
<td>27.8</td>
<td>20.1</td>
<td>35.04</td>
<td>0.5692</td>
</tr>
<tr>
<td>Procedure time</td>
<td>VT-normal</td>
<td>6</td>
<td>154.3</td>
<td>22.3</td>
<td>-51.3</td>
<td>58.97</td>
<td>0.4179</td>
</tr>
<tr>
<td>Procedure time</td>
<td>VT-structural</td>
<td>3</td>
<td>163.6</td>
<td>32.3</td>
<td>-42.0</td>
<td>63.40</td>
<td>0.5550</td>
</tr>
<tr>
<td>Procedure time</td>
<td>Congenital</td>
<td>2</td>
<td>278.9</td>
<td>79.8</td>
<td>-16.4</td>
<td>46.33</td>
<td>0.3323</td>
</tr>
<tr>
<td>Fluoroscopy time</td>
<td>AVNRT</td>
<td>7</td>
<td>13.3</td>
<td>1.4</td>
<td>-6.3</td>
<td>7.69</td>
<td>0.4306</td>
</tr>
<tr>
<td>Fluoroscopy time</td>
<td>AVRT</td>
<td>10</td>
<td>15.6</td>
<td>3.1</td>
<td>-14.5</td>
<td>17.10</td>
<td>0.4153</td>
</tr>
<tr>
<td>Fluoroscopy time</td>
<td>A fib</td>
<td>4</td>
<td>23.4</td>
<td>7.0</td>
<td>-14.5</td>
<td>11.67</td>
<td>0.2697</td>
</tr>
<tr>
<td>Fluoroscopy time</td>
<td>A flutter</td>
<td>4</td>
<td>13.2</td>
<td>1.9</td>
<td>-3.8</td>
<td>8.31</td>
<td>0.6733</td>
</tr>
<tr>
<td>Fluoroscopy time</td>
<td>VT-normal</td>
<td>6</td>
<td>13.6</td>
<td>1.3</td>
<td>-17.5</td>
<td>12.83</td>
<td>0.2208</td>
</tr>
<tr>
<td>Fluoroscopy time</td>
<td>VT-structural</td>
<td>3</td>
<td>14.2</td>
<td>7.2</td>
<td>-16.9</td>
<td>46.33</td>
<td>0.3323</td>
</tr>
<tr>
<td>Fluoroscopy time</td>
<td>Congenital</td>
<td>2</td>
<td>30.2</td>
<td>12.9</td>
<td>-2.6</td>
<td>4.85</td>
<td>0.6061</td>
</tr>
</tbody>
</table>

#### Control

#### Difference = MNS - control

Bradfield et al. PACE 2012
Digital Image Fusion (DIF)
MediGuide

- MediGuide Technology (St. Jude Medical) GPS e benzer ve vücudun içindeki kateterin yerini gösterir.
- Siemens Healthcare MediGuide teknolojisini Artis Zee anjiyografi sistemlerine entegre etti
- Önceden alınmış floroskopi imajı üzerinde 4-D mapping imkanı
MediGuide components

1. Transmitters that generate a low-intensity (< 200 μT) alternating electromagnetic field and are integrated in the Artis zee fluoroscopy detector.

2. Miniaturized passive single-coil sensor in the tip of the EP catheter

3. Electromagnetic field reference sensor attached to the patient’s sternum.

The movements of the catheter are detected based on the voltage changes generated in the magnetic field.
Non-fluoroscopic catheter visualization using MediGuide™ technology: experience from the first 600 procedures

P. Sommer · S. Richter · G. Hindricks · S. Rolf
Background—A technological platform (MediGuide) has been recently introduced for nonfluoroscopic catheter tracking. No data on the safety of this technology are yet available in a large cohort of patients.

Methods and Results—Data from a prospective ablation registry were analyzed. All patients undergoing atrial fibrillation ablation procedures supported by nonfluoroscopic catheter visualization technology were included. Patient characteristics and procedural data and complications within the first 3 months were recorded. Between May 2012 and February 2014, a total of 375 patients underwent atrial fibrillation ablation using nonfluoroscopic catheter visualization technology. The patients were predominantly men (68%); the majority were ablated for the first time (71%); left atrium was 43±6 mm; and left ventricular function was normal (59±9%). The median ablation procedure time was 135 (113–170) minutes, median fluoroscopy time 2.8 (1.5–4.4) minutes, and median radiation dose 789 (470–1466) cGy*cm². Regression analysis demonstrated a significant decrease of fluoroscopy time, dose, and procedure time. To confirm the result and show overall changes, the initial 50 cases (group 1) to the last 50 cases (group 2) of the series were compared: fluoroscopy time decreased from 6.0 (4.1–10.3) minutes in group 1 to 1.1 (0.7–1.5) minutes in group 2 and radiation dose from 2363 (1413–3475) to 490 (230–654) cGy*cm², respectively. Ten patients (2.7%) experienced complications: 5 cardiac tamponades (1.4%), 4 pseudoaneurysms (1.1%), and 1 stroke (0.3%).

Conclusions—Atrial fibrillation ablation using the nonfluoroscopic catheter visualization technology is safe with a rate of complications of 2.7%. Procedure time (135 minutes) is not prolonged. A dramatic reduction in fluoroscopy time and dose was achieved. *(Circ Arrhythm Electrophysiol. 2014;7:869-874.)*
The Real-Time Position Management (RPM) System
(Cardiac Pathways, Sunnyvale, CA, USA)

- Employs ultrasound ranging to localize reference and mapping/ablation catheter positions.
- Two reference catheters, one typically situated in the RA, CS, or RV, and the mapping/ablation catheter each contain an ultrasound transducer along their shaft.
- Continuous real-time location of ablation and reference catheters.
- Disadvantages: distortion of cardiac geometry, and the need to use specific reference and ablation catheters equipped with ultrasound transducers.
This is achieved by applying a low-level 5.6 kHz current through orthogonally-located skin patches. The recorded voltage and impedance at each catheter's electrodes generated from this current allows their distance from each skin patch, and ultimately, their location in space, to be triangulated with the help of a reference electrode.
Noncontact mapping
(Ensite, Endocardial Solutions Inc., St. Paul, MN, USA)

- Uses multi-electrode array (MEA) catheter (inflatable balloon with 64 electrodes on its surface) to simultaneously record multiple areas of endocardial activation.

- Can be performed from even a single beat of tachycardia.

- Three-dimensional (3D) localization of the MEA surface electrodes is achieved by applying a low-level 5.6 kHz current between an electrode on the distal end of the MEA catheter and two ring electrodes along its shaft, proximal and distal to the MEA itself.

- Different mapping catheter's position can be determined

- EnSite system to have excellent locator precision and accuracy at distances <50 mm from the MEA.

- Timing correlation significantly worsened at a threshold distance of >34 mm from the MEA center;
Both CT and MR images can be integrated with EAM systems in order to improve the 3D geometry.
<table>
<thead>
<tr>
<th>System</th>
<th>Strength</th>
<th>Weakness</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carto</td>
<td>• Record local endocardial activation times for arrhythmia mapping,</td>
<td>• Difficulties mapping for nonsustained or unstable tachycardia</td>
</tr>
<tr>
<td></td>
<td>• Generate 3D chamber geometry.</td>
<td>• Need a special (NaviSTAR) catheter,</td>
</tr>
<tr>
<td></td>
<td>• Record locations of important anatomic landmarks</td>
<td>• Inability to easily relocate a displaced reference catheter,</td>
</tr>
<tr>
<td></td>
<td>• Recording ablation lesion location</td>
<td>• Inability display the location of diagnostic/reference catheters.</td>
</tr>
<tr>
<td>Ensite</td>
<td>• Same as Carto</td>
<td>• Difficulty in mapping of nonsustained or unstable tachycardia</td>
</tr>
<tr>
<td></td>
<td>• Can use any diagnostic or ablation (even cryo) catheter</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Respiratory motion artifact can also be eliminated</td>
<td></td>
</tr>
<tr>
<td>Noncontact mapping</td>
<td>• Can map single beat (non-sustained arrhythmias)</td>
<td>• Inaccuracy of electrogram timing and morphology at greater distances</td>
</tr>
<tr>
<td></td>
<td>• Can be used in poorly tolerated arrhythmias</td>
<td>from the MEA,</td>
</tr>
<tr>
<td></td>
<td>• Compatible with any mapping/ablation catheter</td>
<td>• Difficulty in positioning the MEA balloon,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Inaccuracy in reconstructing certain features of chamber geometry.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Difficult to use in small heart (child)</td>
</tr>
</tbody>
</table>
Fluoroscopy Times for SVT procedures (n:225)

Mean fluoro times: 3.8±8.4 min
VT prosedürlerinde Floroskopi (n:18)

- >20 min: 44%
- 0-5 min: 17%
- 5-20 min: 11%
- No fluoro: 28%

Mean fluoro zamanı: 15.2±15.01
left lateral AP...no-transseptal puncture, acces from pfo..no fluroscopy use
Left post fas VT..procedure time 135min..fluoro:4 min.
JET li bir infant
CS içinde slow pathway kriyoablasyonu
RVOT VT...total procedure time: 130 min...fluoro: 0 min
IART ablation (opere TOF), procedure: 330 min, Fluoro:0.
AVNRT de florosuz ablasyon neredeyse 100%
Önemli lokasyonlar farklı şekilde işaretlenebilir.
Fontan li hastada aktivasyon mapping ve ablasyon
13.04.2015
Voltage Map during SR
Dynamic substrate map (DSM)

Low voltage zone border (30% of maximal PNV)

DSM: Ratio to Global Negative

EnGuide: R = 13.0 (Z = -4.5)

Proximity to EnSite surface: ~1.8 mm

Taipei VGH
Multiple VT morphology in ARVC/D

Sinus rhythm voltage map
Transseptal Girişimler

- EAM sistemleri ile florosuz veya sınırlı floroskopili transseptal yapılabilir.
- ICE ek olarak kullanılabilir.
- MediGuide sistemi.

Clark et al. Pacing Clin Electrophysiol 2008
Reddy et al. Heart Rhythm 2010
Mansour et al. Pacing Clin Electrophysiol 2015
The fluoroless approach should be considered not only for certain populations, such as pregnant, obese, or pediatric patients, but for all patients, as we know that the method is safe, effective and feasible.
Sonuçlar

- Hem hasta hem de hekim için güvenli
- İşlemi kolaylaştırır
- Kısa ve uzun vadeli prosedür başarısı özellikle bazı arıtmilerde artar
- Hem çocuk hem de erişkinde faydalı
- Zor vakalarda (AF, iskemik VT) ICE da birlikte kullanılabilir