ΙVUS-OCT βοηθάει μόνο στην κατανόηση της παθοφυσιολογίας – κατά

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Β΄ Καρδιολογική κλινική,
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REAL-TIME, TWO-DIMENSIONAL CATHETER ULTRASOUND: A NEW TECHNIQUE FOR HIGH-RESOLUTION INTRAVASCULAR IMAGING

ABSTRACT
The new technique is designed to provide real-time imaging of the coronary arteries. The catheter is equipped with a rotating spherical transducer that emits ultrasound waves. The transducer sends out two-dimensional images of the coronary arteries, allowing for real-time visualization of blood flow and vessel walls.

IMAGE INTERPRETATION
The images obtained with the new technique show high-resolution views of the coronary arteries. The high-contrast images allow for the detection of small changes in vessel structure and function.

SYSTEM DESIGN
The catheter design allows for easy insertion and retrieval. The transducer is mounted on a flexible shaft, allowing for precise control of the imaging direction.

METHODS
Three-dimensional reconstruction techniques were used to create detailed images of the coronary arteries. The imaging was performed in vivo, allowing for real-time visualization of blood flow and vessel walls.

RESULTS
The new technique was able to visualize the coronary arteries with high resolution and contrast. The images showed detailed views of the vessel walls, with high clarity and sharpness.

CONCLUSIONS AND IMPLICATIONS
The new technique offers a powerful tool for the study of coronary artery disease. It allows for real-time visualization of blood flow and vessel walls, providing important insights into the progression of disease.

Yock et al. Circulation 1988;78:II-21
ADAPT-DES - Current Cohort -
Assessment of Dual AntiPlatelet Therapy with Drug-Eluting Stents

8582 pts prospectively enrolled
No clinical or anatomic exclusion criteria
11 sites in US and Germany

PCI with ≥1 non-investigational DES
Successful and uncomplicated

IVUS Use: 3361 pts
No IVUS: 5221 pts

Clinical FU at 30 days, 1 year, 2 years

IVUS Impact on Procedures: ADAPT-DES

No change (26%)

Change in Procedure strategy (74%)
How did IVUS change the procedure?

IVUS changed the procedure 74% of the time

- Larger Size of Stent/Balloon
- No Change
- Higher Pressure
- Post Dilation
  - Under-Expansion
  - Malapposition
- Additional Stent
- Others
Relationship Between IVUS Use and Definite/Probable Stent Thrombosis Within 2 Years

HR: 0.47 [95% CI: 0.28, 0.80]
P = 0.004

No IVUS Used
1.16%

IVUS Used
0.55%

Number at risk:
- IVUS Used: 3361, 3260, 3182, 3065, 1791
- IVUS Not Used: 5221, 5019, 4886, 4713, 2279

Time in Months
Two year follow-up data from ADAPT-DES (3361 pts treated with IVUS-guidance vs 5221 pts treated with angiographic guidance)

Maehara et a. Circulation Cardiovasc Interven. 2018
“That’s a registry. Where is the RCT data?”
IVUS-XPL Randomized Clinical Trial

Patients with long coronary lesions (Implanted stent ≥28 mm in length)
N = 1400

DES implantation with IVUS guidance
n = 700

DES implantation with angiography guidance
n = 700

Clinical follow-up at 12 months
Primary end point: MACE
Cardiac death, target-lesion related MI, and ischemia-driven TLR

Hong et al. JAMA 2015;314:2155-63
MACE at 1 Year

HR, 0.48 (95% CI, 0.28-0.83)
Log-rank $P = .007$

Patients with Primary End Point Event, %

Time Since Randomization, mo

Angiography-guidance

IVUS-guidance

No. at risk
Angiography arm 700 673 660 643 624
IVUS arm 700 671 665 654 641
MACE at 1 Year in the IVUS Group

HR, 0.31 (95% CI, 0.11-0.86)
Log-rank P = .017

*IVUS criteria
MLA > distal reference lumen area

Patients with Primary End Point Event, %

- Patients not meeting the IVUS-criteria for stent optimization
- Patients meeting the IVUS-criteria for stent optimization

Time Since Randomization, mo

No. at risk
Not meeting the criteria
Meeting the criteria

<table>
<thead>
<tr>
<th></th>
<th>0</th>
<th>3</th>
<th>6</th>
<th>9</th>
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<td>315</td>
<td>299</td>
<td>297</td>
<td>394</td>
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<td>362</td>
<td>345</td>
<td>338</td>
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</table>
“That’s just one study.”
# Meta-analysis of 8 Randomized Trials of IVUS vs Angio-Guided DES Implantation

<table>
<thead>
<tr>
<th>Study</th>
<th>Year</th>
<th>#</th>
<th>OR</th>
<th>IVUS MACE</th>
<th>Angio MACE</th>
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<tbody>
<tr>
<td>IVUS-XPL</td>
<td>2015</td>
<td>1400</td>
<td>0.49</td>
<td>19/700</td>
<td>39/700</td>
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<tr>
<td>CTO-IVUS</td>
<td>2015</td>
<td>402</td>
<td>0.37</td>
<td>5/201</td>
<td>14/201</td>
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<tr>
<td>AIR-CTO</td>
<td>2015</td>
<td>230</td>
<td>0.82</td>
<td>25/115</td>
<td>29/115</td>
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<tr>
<td>Tan-LM</td>
<td>2015</td>
<td>123</td>
<td>0.42</td>
<td>8/61</td>
<td>17/62</td>
</tr>
<tr>
<td>MOZART</td>
<td>2014</td>
<td>83</td>
<td>0.41</td>
<td>2/41</td>
<td>5/42</td>
</tr>
<tr>
<td>RESET</td>
<td>2013</td>
<td>543</td>
<td>0.60</td>
<td>12/269</td>
<td>20/274</td>
</tr>
<tr>
<td>AVIO</td>
<td>2013</td>
<td>284</td>
<td>0.67</td>
<td>24/142</td>
<td>33/142</td>
</tr>
<tr>
<td>Home-DES</td>
<td>2010</td>
<td>210</td>
<td>0.91</td>
<td>11/105</td>
<td>12/105</td>
</tr>
<tr>
<td><strong>OVERALL</strong></td>
<td></td>
<td>3275</td>
<td><strong>0.59</strong></td>
<td><strong>106/1634</strong></td>
<td><strong>169/1641</strong></td>
</tr>
</tbody>
</table>

**IVUS better** | **Angio better** | **6.5%** | **10.3%**

<table>
<thead>
<tr>
<th>Event</th>
<th>IVUS events</th>
<th>Angio events</th>
<th>OR</th>
<th>95% CI</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>MACE</td>
<td>6.5%</td>
<td>10.3%</td>
<td><strong>0.59</strong></td>
<td>0.46-0.76</td>
<td><strong>&lt;0.0001</strong></td>
</tr>
<tr>
<td>CV mortality</td>
<td>0.5%</td>
<td>1.2%</td>
<td><strong>0.46</strong></td>
<td>0.21-1.00</td>
<td>0.05</td>
</tr>
<tr>
<td>MI</td>
<td>0.9%</td>
<td>1.6%</td>
<td><strong>0.58</strong></td>
<td>0.30-1.11</td>
<td>0.10</td>
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<tr>
<td>TLR</td>
<td>4.1%</td>
<td>6.6%</td>
<td><strong>0.60</strong></td>
<td>0.43-0.84</td>
<td>0.003</td>
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<tr>
<td>TVR</td>
<td>5.5%</td>
<td>8.7%</td>
<td><strong>0.61</strong></td>
<td>0.41-0.91</td>
<td>0.02</td>
</tr>
<tr>
<td>ST</td>
<td>0.6%</td>
<td>1.3%</td>
<td><strong>0.49</strong></td>
<td>0.24-0.99</td>
<td>0.04</td>
</tr>
</tbody>
</table>


Am J Cardiol 2014; 113: 1338-47.
Intravascular Ultrasound Versus Angiography-Guided Drug-Eluting Stent Implantation

The ULTIMATE Trial

Hazard ratio: 0.530 (95% CI: 0.312, 0.901)
Log-Rank: p = 0.019

<table>
<thead>
<tr>
<th>Time Since Randomization (Months)</th>
<th>0</th>
<th>3</th>
<th>6</th>
<th>9</th>
<th>12</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number at risk</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Angiography</td>
<td>724</td>
<td>706</td>
<td>698</td>
<td>685</td>
<td>676</td>
</tr>
<tr>
<td>IVUS</td>
<td>724</td>
<td>715</td>
<td>710</td>
<td>704</td>
<td>696</td>
</tr>
</tbody>
</table>
First In-vivo (swine) Images Using OCT

Studies on percutaneous coronary interventions with OCT guidance

**CLI-OPCI.** Euroint 2012

**Ilumien I.** Eur Heart J 2015

**Ilumien II.** JACC Int 2015

**Opinion.** Eur Heart J 2017

**Doctors.** Circulation 2016

**Ilumien III.** Lancet 2017
Optical frequency domain imaging vs. intravascular ultrasound in percutaneous coronary intervention (OPINION trial): one-year angiographic and clinical results

Takashi Kubo¹, Toshiro Shinke², Takayuki Okamura³, Kiyoshi Hibi⁴,
Primary Endpoint

Final post-PCI MSA by OCT

OCT 5.79 mm² [4.54, 7.34]
IVUS 5.89 mm² [4.67, 7.80]

97.5% one-sided CI: [-0.70, -]

\[ P_{\text{noninferiority}} = 0.001 \]

Angiography
5.49 mm² [4.39, 6.59]
\[ P_{\text{superiority}} = 0.12 \]
Clinical outcomes following intravascular imaging-guided vs. angiography-guided PCI
Meta-Analysis of 31 Studies and 17,882 patients
Buccheri et al. JACC:Cardiovasc. Interv. 2017

MACE

<table>
<thead>
<tr>
<th>Study</th>
<th>P-value</th>
<th>Odds Ratio (95% CrI)</th>
</tr>
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<tbody>
<tr>
<td>IVUS vs Angiography</td>
<td></td>
<td></td>
</tr>
<tr>
<td>direct</td>
<td></td>
<td>0.79 (0.67, 0.92)</td>
</tr>
<tr>
<td>indirect</td>
<td>0.8318</td>
<td>0.72 (0.30, 1.7)</td>
</tr>
<tr>
<td>network</td>
<td></td>
<td>0.79 (0.67, 0.91)</td>
</tr>
<tr>
<td>OCT/OFDI vs Angiography</td>
<td></td>
<td></td>
</tr>
<tr>
<td>direct</td>
<td></td>
<td>0.68 (0.47, 1.0)</td>
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<tr>
<td>indirect</td>
<td>0.9842</td>
<td>0.69 (0.30, 1.6)</td>
</tr>
<tr>
<td>network</td>
<td></td>
<td>0.69 (0.49, 0.98)</td>
</tr>
<tr>
<td>OCT/OFDI vs IVUS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>direct</td>
<td></td>
<td>1.0 (0.50, 2.0)</td>
</tr>
<tr>
<td>indirect</td>
<td>0.6106</td>
<td>0.81 (0.54, 1.3)</td>
</tr>
<tr>
<td>network</td>
<td></td>
<td>0.87 (0.61, 1.3)</td>
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</table>
### 2018 ESC/EACTS Guidelines on myocardial revascularization

#### Recommendations on intravascular imaging for procedural optimization

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>Class</th>
<th>Level</th>
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<tbody>
<tr>
<td>IVUS or OCT should be considered in selected patients to optimize stent implantation.</td>
<td>IIa</td>
<td>B</td>
</tr>
<tr>
<td>IVUS should be considered to optimize treatment of unprotected left main lesions.</td>
<td>IIa</td>
<td>B</td>
</tr>
</tbody>
</table>

603,612,651–653
35

© ESC 2018
Case example. Female, 70yrs old, with non-STEMI. PCI in LAD with a stent Resolute 2,75/22mm 6 months ago because of STEMI.

PCI RESULT 10/2017

New angiography 4/2018
Malapposition

Underexpansion
MSA=4.2 mm²

Neointima hypeplasia+thrombus

OCT pullback LAD
PCI result after implantation of a stent Promus 3,0/20mm in 20Atm
OCT in LAD Post-PCI

Stent underexpansion

Ca

MSA=3.8 mm²
Final result after post dilatation with non compliant balloon 3,5/15mm
OCT after final dilatation

Tissue protrusion

MSA = 6.2 mm$^2$
Conclusions

1. Compared with coronary angiography, the use of intravascular imaging techniques during PCI reduces the risk of major adverse cardiovascular events.

2. The clinical benefit of imaging guidance may be greatest in high risk patients and complex lesions (e.g. left main, long lesions, CTOs).

3. Consequently, intravascular imaging (either IVUS or OCT) should be available in every busy catheterization laboratory.