Best clinical practice for prevention of radial artery occlusion after transradial intervention

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Scranton, PA
Disclosures

• Speaker: Terumo, Medtronic
• Equity: VasolInnovations, Inc.
RAO Happens !!!!!!

2015 PubMed RAO Rates

![Graph showing RAO incidence rates from various studies.

- Rotterdam: 0.039
- AIULAR: 0.089
- Ehris et al.: 0.149
- HANGAR: 0.092
- Degirmenci et al.: 0.055
- Halebi et al.: 14%

Mean Reported RAO Incidence: 0.092

RAO Incidence

Proprietary and Confidential
Mechanism of RAO

- Thrombosis (acute)
- Rapid organization with fibrotic lumen obliteration
Mechanism of RAO
RAO: Flow cessation

Sanmartin et al CCI 2007; 70: 185-9
Patent Hemostasis

Incidence of Radial Artery Occlusion

- Traditional Hold (Group I)
  - Early occlusion (24h): n=27, P<0.05
  - Persistent occlusion (30d): n=11

- Patent hemostasis (Group II)
  - Early occlusion (24h): n=16, P<0.05
  - Persistent occlusion (30d): n=4


VII ЕЖЕГОДНЫЙ ТРАНСРАДИАЛЬНЫЙ ЭНДОВАСКУЛЯРНЫЙ КУРС / VII TRANSRADIAL COURSE TREC-2020
### TABLE III. Results of the Study Population

<table>
<thead>
<tr>
<th></th>
<th>Group A (MAP)</th>
<th>Group B (15 cm³)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compression time (min)</td>
<td>208.8 ± 133.6</td>
<td>203.2 ± 54.8</td>
<td>0.60</td>
</tr>
<tr>
<td>Control postprocedural (days)</td>
<td>1.9 ± 3.2</td>
<td>1.78 ± 2.0</td>
<td>0.48</td>
</tr>
<tr>
<td>Vascular access complications</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Major (%)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>1</td>
</tr>
<tr>
<td>Minor: Total hematoma (%)</td>
<td>25 (14.2)</td>
<td>22 (12.6)</td>
<td>0.65</td>
</tr>
<tr>
<td>Large hematoma (%) (&gt;6 cm)</td>
<td>3 (17.7)</td>
<td>1 (0.6)</td>
<td>0.05</td>
</tr>
<tr>
<td>Mild hematoma (%) (&lt;6 cm)</td>
<td>22 (12.5)</td>
<td>21 (12.0)</td>
<td>0.85</td>
</tr>
<tr>
<td>Re-bleeding (%)</td>
<td>3 (1.7)</td>
<td>5 (2.8)</td>
<td>0.42</td>
</tr>
<tr>
<td>Radial occlusion (%)</td>
<td>2 (1.1)</td>
<td>21 (12.0)</td>
<td>0.0001</td>
</tr>
</tbody>
</table>

MAP, mean artery pressure.
Patent Hemostasis Efficacy Corroborated

ACS Cohort from UK

Wilson SJ et al Int J Cardiol 2017

Cohort from Iran


Figure 1: Patent hemostasis leads to a significant decrease in the incidence of radial artery occlusion at 24-h and 7-day follow-up.
Patency = Pressure * Duration

Compression

BP + Wall stress
Duration of compression

Radial artery occlusion

<table>
<thead>
<tr>
<th>Group</th>
<th>ERAO</th>
<th>CRAO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group I</td>
<td>12</td>
<td>8.5</td>
</tr>
<tr>
<td>Group II</td>
<td>5.5</td>
<td>3.5</td>
</tr>
</tbody>
</table>

* P < 0.02
** P < 0.03

Pancholy S, Patel T, CCI 2010
CRASOC

![Graph 1: RAO nurses (observed and binomial confidence interval).](image1.png)

![Graph 2: RAO Doppler (observed and binomial confidence interval).](image2.png)

Figure 2. RAO nurses (observed and binomial confidence interval).

Figure 3. RAO Doppler (observed and binomial confidence interval).

Dangoisse V et al Am J Cardiol 2017
Decreasing Pressure and Duration of Compression
Decrease RAO

Figure 2. RAO nurses (observed and binomial confidence interval).

Figure 3. RAO Doppler (observed and binomial confidence interval).

Dangoisse V et al Am J Cardiol 2017
CRASOC

BUT INCREASES REBOUND BLEEDING

Figure 5. Rebleeding/recompression (observed and binomial confidence interval).
RAP AND BEAT

VII ЕЖЕГОДНЫЙ ТРАНСРАДИАЛЬНЫЙ ЭНДОВАСКУЛЯРНЫЙ КУРС / VII TRANSRADIAL COURSE TREC-2020
Beware of Rebound Bleeding

Table 3: Procedural Outcomes

<table>
<thead>
<tr>
<th></th>
<th>TR Band</th>
<th>TRB + PTFEP</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time to TRB deflation (mean ± SD)</td>
<td>160 ± 43</td>
<td>43 ± 14</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>N=67</td>
<td>N=63</td>
<td></td>
</tr>
<tr>
<td>Time to discharge* (mean ± SD)</td>
<td>201 ± 55</td>
<td>150 ± 83</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>N=61</td>
<td>N=57</td>
<td></td>
</tr>
</tbody>
</table>

* Patients presenting for outpatient catheterization and discharged the same day.

Table 4: Clinical outcomes

Hematoma classification from Bertrand (8)

| Outcome                          | TR Band | TRB + PTFEP | P-value |
|                                 | N=67    | N=69       |         |
| Major hematoma                  | 0 (10.3%)| 6 (17.1%)  | 0.20    |
| Grade I (0-1cm)                 | 8       | 12         | 0.68    |
| Grade II (2-5cm)                | 1       | 4          | 0.37    |
| Radial artery occlusion         | 0       | 0          | 0.50    |
Table 3:
Procedural Outcomes

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<tr>
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<th>TRB-PRUF</th>
<th>P-value</th>
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<tr>
<td>Time to TRB deflation (mean ± SD)</td>
<td>160 ± 43</td>
<td>48 ± 14</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td></td>
<td>N=87</td>
<td>N=82</td>
<td></td>
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Table 4: Clinical outcomes
Hemostasis classification from Leodrad [6]

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<tbody>
<tr>
<td>Any hematoma</td>
<td>9 (10.2%)</td>
<td>16 (17.2%)</td>
<td>0.33</td>
</tr>
<tr>
<td>Grade I (5cm)</td>
<td>8</td>
<td>12</td>
<td>0.64</td>
</tr>
<tr>
<td>Grade II (5-10cm)</td>
<td>1</td>
<td>4</td>
<td>0.27</td>
</tr>
<tr>
<td>Radial artery occlusion</td>
<td>0</td>
<td>0</td>
<td>0.92</td>
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Table 3:
Procedural Outcomes

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Hemostasis classification from LeBrait et al [6]

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<tr>
<td>Grade I (0-5cm)</td>
<td>8</td>
<td>12</td>
<td>0.46</td>
</tr>
<tr>
<td>Grade II (5-10cm)</td>
<td>1</td>
<td>4</td>
<td>0.37</td>
</tr>
<tr>
<td>Radial artery occlusion</td>
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<td>0.46</td>
</tr>
<tr>
<td>Grade II (15-25cm)</td>
<td>1</td>
<td>4</td>
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<td>0</td>
<td>0</td>
<td>0.92</td>
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PRACTICAL Trial
568 patients 20 minutes vs 60 minutes compression

- 22% of 20 minute compression group patients had rebound bleeding

- 36% of rebound bleeding patients developed RAO

- Rebound bleeding was the ONLY independent predictor of RAO

Lavi S..... Bagur R JAHA 2018
Heparin Dose matters!

Bernat I et al Am J Cardiol
Higher Dose of Heparin

Best Practices not followed

3.5 h hemostatic compression

Hahalis G et al, JACC Interv 2018
Is more anticoagulation more effective?

Pacchione A, Reimers B et al. Circ Interv 2019
Rebound Bleeding = Revengeful Pressure

RAO
MEMORY Trial

**Figure 3** Incidence of Efficacy (Radial Artery Occlusion) and Safety (Hematoma and Bleeding) Study Endpoints

Incidence of radial artery occlusion, hematoma, and bleeding at 24 h post-procedure in patients with mechanical (red bars) and manual (blue bars) hemostasis.

Petrogiou, Ziakas et al. JACC Interv 2018

13 + 8 minutes
Radio-Ulnar circuit
Radio-Ulnar circuit
Radio-Ulnar circuit
Ulnar compression

UA compressed

UA released

Pancholy S et al, J Inv Cardiol 2015
Radial VTI with Ulnar compression

VTI (m.s²)

1900n1900ral

1900n1900ral 8.4

1900n1900ral

1900n1900ral

Baseline  Ulnar...

P < 0.0001

N = 150

Pancholy S et al, J Inv Cardiol 2015
PROPHET-II
(Preservation of Radial Artery Occlusion – Prophylactic Hyperperfusion Evaluation Trial)

Figure 2: CONSORT Diagram

Enrollment
- Assessed for eligibility (n=4238)
  - Excluded (n=1238)
    - Ad hoc PCI (n=818)
    - Previous ipsilateral TRA (n=80)
    - Barbeau pattern D (n=211)
    - Warfarin therapy (n=110)
    - No ulnar pulse (n=19)

Randomized (n=3000)

Allocation
- Group 1 (n=1497)
  - Patent hemostasis
- Group 2 (n=1503)
  - Patent hemostasis with ulnar compression

Follow-up
- Lost to follow-up (n=35)
  - 4 mortalities, 31 unreachable
- Lost to follow-up (n=34)
  - 2 mortalities, 32 unreachable

Analysis
- Analyzed (n=1462)
- Analyzed (n=1469)

Pancholy S et al, JACC Interv 2016
Figure 3: Incidence of Radial Artery Occlusion

Pancholy S et al, JACC Interv 2016
PROPHET-II
(Prevention of Radial Artery Occlusion – Prophylactic Hyperperfusion Evaluation Trial)

Figure 1: Ipsilateral Ulnar Compression During Radial Artery Hemostasis
Observational Data

ULnar Artery Transient Compression Facilitating Radial Artery Patent Hemostasis (ULTRA): A Novel Technique to Reduce Radial Artery Occlusion After Transradial Coronary Catheterization

Michael J. Koutouzis, MD, PhD; Christos D. Maniotis, MD, PhD; Grigorios Avdikos, MD; Andreas Tsoumeleas, MD; Constantinos Andreou, MD, PhD; Zenon S. Kyriakides, MD, PhD
**Table 3. Radial artery patency after intervention.**

<table>
<thead>
<tr>
<th></th>
<th>Conventional Method (n = 121)</th>
<th>ULTRA Method (n = 119)</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>No pulsation</td>
<td>15 (12.4%)</td>
<td>3 (2.5%)</td>
<td>.01</td>
</tr>
<tr>
<td>No duplex flow</td>
<td>6 (5.0%)</td>
<td>0 (0.0%)</td>
<td>.01</td>
</tr>
</tbody>
</table>

Data presented as number (%).
VS
287 patients referred for TRA

253 patients randomized

TR Band (Group 1, N = 126)

Vasoband (Group 2, N = 127)

Radial Compression x 120 minutes

Ipsilateral ulnar Compression x 1 hour

Patent Hemostasis (Radial Patency at 15 minutes)

Primary Endpoint

Radial Artery Occlusion At Discharge

• 4 on warfarin
• 29 with previous Ipsilateral TRA
• 3 needed heparin infusion
• 2 had persistent plethysmographic Waveform after radial and ulnar occlusion

Excluded Patients
**Patent Hemostasis**

<table>
<thead>
<tr>
<th>TR Band</th>
<th>VasoBand</th>
</tr>
</thead>
<tbody>
<tr>
<td>74.8</td>
<td>96.8</td>
</tr>
</tbody>
</table>

**Radial Artery Occlusion**

<table>
<thead>
<tr>
<th>TR Band</th>
<th>VasoBand</th>
</tr>
</thead>
<tbody>
<tr>
<td>10.2</td>
<td>1.6</td>
</tr>
</tbody>
</table>
• Dual bladder band with ipsilateral ulnar compression for the first 60 minutes, increases the ability to achieve “Patent Hemostasis”

AND

• Lowers the incidence of RAO at the time of discharge

WITHOUT the need for frequent radial patency monitoring
Have we made a difference?
Early Late

Prophylactic Ulnar Compression

NR NR 0

Cubero Bernat PROPHET-II ULTRA

Early Late

Patent Hemostasis

Sammar... Plante
Thank you