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Ulnar artery intervention non inferior to radial approach: Reality or myth? AJmer
ULnar ARtery working group study.
A randomized parallel group Non-Inferiority trial

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Disclosures

Nothing to disclose by any author.
Background

• Worldwide radial artery cannulation has been accepted as a default technique for coronary access because of obvious safety advantages over femoral access.
Limitations of Radial Access

– Frequent vasospasm,
– More anatomical variation,
– Small caliber and
– Unsuitability of radial artery to be used as graft for CABG after cannulation.
Can *Ulnar artery* be a viable alternative to radial artery for coronary access?
Scenario Till Date..

Trans ulnar access is inferior to Trans radial

**Events(%)**

- MACE: 2.8 vs 3.4  \( P \text{ value}<0.0001 \)
- Large hematoma: 3.2 vs 0.5  \( P \text{ value}=0.03 \) *(crossed non-inferiority)*
- Spasm: 12.7 vs 16.9  \( P \text{ value}=0.4 \)
- Vagal Reaction: 2.6 vs 2.3  \( P \text{ value}=0.0002 \)
- Arterial Occlusion: 10.4 vs 8.9  \( P \text{ value}=0.47 \)
- Crossover: 32.3 vs 5.9  \( P \text{ Value}=0.004 \) *(crossed non-inferiority)*

Scenario Till Date..

Limitations

– *Inexperienced Ulnar operators.*
– *Attempted to cannulate even nearly absent ulnar artery.*

“...High crossover rate in Transulnar cannulation group made it inferior to Trans Radial cannulation....”

Does Experience Matter?
Our observation:

- OR: 3.16 (CI: 1.7-8.51); p value = 0.02
- OR: 1.49 (CI: 0.61-3.59); p value = 0.37
- OR: 1.23 (CI: 0.95-1.59); p value = 0.12
So.....
Experience Does Matter..
Does Ulnar artery cannulation *still* remain inferior, even if performed by an *Experienced* operator?
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Prerequisites

• “..Default radialist with a minimum experience of 50 transulnar cannulations ..”

• “...Cannulation attempted only if ulnar artery easily palpable and anatomy is favorable....”
Trial Design
Randomized Single center Non-Inferiority Trial

Patients undergoing elective CAG and ad-hoc PTCA

1:1 Randomization

Trans Ulnar Cannulation
N=1270

Trans Radial Cannulation
N=1262

Primary end Point
Composite of MACEs, major vascular events (large hematoma and occlusion) during hospital stay and crossover rate.

Secondary end Points
- Individual Components of Primary end Points
- Spasm
- Failed attempts (> 3 attempts)
- Total procedural and fluoroscopy time
- Amount of contrast used
Exclusion Criteria

• Inability to palpate either radial or ulnar artery,
• Primary angioplasty,
• Cardiogenic shock,
• Patients on chronic hemodialysis,
• Vasospastic disease (Raynaud’s disease),
• Severe forearm skeletal deformities,
• Post CABG.
Patient Flow During Study

Informed Consent from all patients
Approved by Institute Ethical Committee

2700 Patients Screened

Excluded
- Total: 117
- Inability to palpate both arteries: 41
- Cardiogenic shock: 26
- Hemodialysis: 20
- CABG with IMA: 18
- Arm deformities: 12

Consent Not Given: 27

2556 enrolled for randomization

Incomplete Data: 24

ITT Analysis
- Transulnar 1270
- 1176 Patients

PP Analysis
- Transradial 1262
- 1140 Patients

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Primary End Points

Composite of:
- MACEs
- Major vascular events (large hematoma and occlusion) during hospital stay and
- Crossover rate.

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MACE's

- Transulnar Access: 2.9%
- Transradial Access: 3.2%

p value: 0.79
Large Hematoma

\[ p \text{ value: 0.69} \]

- Transulnar Access: 1\%
- Transradial Access: 0.9\%
Crossover

P Value: 0.44

Transulnar Access: 4.4%
Transradial Access: 3.8%
Spasm

- Transulnar Access: 6.9%
- Transradial Access: 8.7%

p value: 0.095
**Intention to treat Analysis**

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Ulnar N=1270(%)</th>
<th>Radial N=1262(%)</th>
<th>RR</th>
<th>95% Upper CI</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>MACE</td>
<td>38(2.9)</td>
<td>40(3.2)</td>
<td>0.94</td>
<td>1.46</td>
<td>0.79</td>
</tr>
<tr>
<td>Crossover</td>
<td>56(4.40)</td>
<td>48(3.8)</td>
<td>1.16</td>
<td>1.69</td>
<td>0.44</td>
</tr>
<tr>
<td>Occlusion</td>
<td>78(6.14)</td>
<td>83(6.6)</td>
<td>0.93</td>
<td>1.26</td>
<td>0.65</td>
</tr>
<tr>
<td>Large Hematoma</td>
<td>13(1.0)</td>
<td>11(0.9)</td>
<td>1.17</td>
<td>0.52-2.6</td>
<td>0.69</td>
</tr>
<tr>
<td>&gt;3 Attempts</td>
<td>136(10.7)</td>
<td>119(9.4)</td>
<td>1.14</td>
<td>1.43</td>
<td>0.29</td>
</tr>
<tr>
<td>Spasm</td>
<td>88(6.9)</td>
<td>110(8.7)</td>
<td>0.79</td>
<td>1.04</td>
<td>0.095</td>
</tr>
<tr>
<td>Primary End Points</td>
<td>185(14.6)</td>
<td>182(14.4)</td>
<td>1.01</td>
<td>1.2</td>
<td>0.92</td>
</tr>
</tbody>
</table>

‘M’ indicates Non-Inferiority Margin, 1.93 in this case

Zone of Non-Inferiority
Per Protocol Analysis

<table>
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<tr>
<th>Outcomes</th>
<th>Ulnar</th>
<th>Radial</th>
<th>RR</th>
<th>95% Upper CI</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>MACE</td>
<td>33(2.8)</td>
<td>36(3.2)</td>
<td>0.89</td>
<td>1.42</td>
<td>0.62</td>
</tr>
<tr>
<td>Occlusion</td>
<td>61(5.2)</td>
<td>76(6.7)</td>
<td>0.78</td>
<td>1.07</td>
<td>0.13</td>
</tr>
<tr>
<td>Large Hematoma</td>
<td>12(1.0)</td>
<td>9(0.8)</td>
<td>1.29</td>
<td>0.55-3.06 (2-sided 95% CI)</td>
<td>0.56</td>
</tr>
<tr>
<td>&gt;3 Attempts</td>
<td>128(10.8)</td>
<td>106(9.2)</td>
<td>1.17</td>
<td>1.49</td>
<td>0.20</td>
</tr>
<tr>
<td>Spasm</td>
<td>77(6.5)</td>
<td>98(8.6)</td>
<td>0.76</td>
<td>1.02</td>
<td>0.06</td>
</tr>
</tbody>
</table>

‘M’ indicates Non-Inferiority Margin, 1.93 in this case

Zone of Non-Inferiority
Analysis of Trans Radial Cross-Over Events (n=48)

Ulnar cannulation considered

Initial allocated site
Radial Artery
Cross Over (N=48)
Contra-lateral RA: 10 (20.8%)
Contra-lateral RA: 10 (20.8%)
UA of either side: 36 (75%)
Femoral Artery: 02 (4.2%)
Femoral Artery: 38 (79.2%)

Ulnar cannulation not considered

Radial Artery
Cross Over (N=48)

Forearm access ↓ by 75%
Femoral access ↑ by 75%
So Obvious advantage...

• ... if you have expertise in ulnar cannulation, 75% of femoral artery cannulations can be avoided ....
Take Home Message

1. Trans Ulnar cannulation is also an easy, safe and comfortable procedure.

2. If used as a default strategy it is non-inferior to transradial approach, when performed by an experienced operator – “It’s Reality, not a myth”.

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Thank you for your attention.