Transradial PCI, Antithrombotic Safety and Potency: What Do We Know? What Do We Need to Know?

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Director, Worldwide Clinical Affairs
Critically Important Issues Exist When Making These Decisions
Benefits vs. Risks: Transradial

What factors influence this?
## XIENCE V USA: Access Site
(5054 patients and 5321 procedures)

<table>
<thead>
<tr>
<th></th>
<th>XIENCE V Index Procedures</th>
<th>XIENCE V Staged Procedures</th>
<th>XIENCE V All Procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Femoral</strong></td>
<td>97.0% (4901/5054)</td>
<td>98.5% (263/267)</td>
<td>97.0% (5164/5321)</td>
</tr>
<tr>
<td><strong>Radial</strong></td>
<td>2.7% (134/5054)</td>
<td>0.7% (2/267)</td>
<td>2.6% (136/5321)</td>
</tr>
<tr>
<td><strong>Brachial</strong></td>
<td>0.3% (16/5054)</td>
<td>0.7% (2/267)</td>
<td>0.3% (18/5321)</td>
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</tbody>
</table>

**Discussion:**
What is the threshold to make this a viable business opportunity? (> 20%?)
# XIENCE V INDIA: Access Site

(990 patients and 997 procedures)

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<tbody>
<tr>
<td>Femoral</td>
<td>64.3% (637/990)</td>
<td>57.1% (4/7)</td>
<td>64.3% (641/997)</td>
</tr>
<tr>
<td>Radial</td>
<td>35.7% (351/990)</td>
<td>42.9% (3/7)</td>
<td>35.5% (354/997)</td>
</tr>
<tr>
<td>Brachial</td>
<td>0.0% (0/990)</td>
<td>0.0% (0/7)</td>
<td>0.0% (0/997)</td>
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**Discussion:**

What is the threshold to make this a viable business opportunity? (> 50%?)

They have figured it out.
Global Transradial Percentages: Case Study

How does global variability affect industries’ evolving leadership philosophy?
If US were 50% what would we be telling the rest of the world?
# XIENCE V USA: Achieve Hemostasis
(5052 patients and 5321 procedures)

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<tr>
<td><strong>Manual Compression</strong></td>
<td>48.1% (2428/5052)</td>
<td>41.6% (111/267)</td>
<td>47.7% (2539/5319)</td>
</tr>
<tr>
<td><strong>Product 1</strong></td>
<td>24.8% (1254/5052)</td>
<td>29.6% (79/267)</td>
<td>25.1% (1333/5319)</td>
</tr>
<tr>
<td><strong>Product 2</strong></td>
<td>9.0% (457/5052)</td>
<td>2.2% (6/267)</td>
<td>9.2% (489/5319)</td>
</tr>
<tr>
<td><strong>Product 3</strong></td>
<td>4.6% (232/5052)</td>
<td>2.2% (6/267)</td>
<td>4.5% (238/5319)</td>
</tr>
</tbody>
</table>

Discussion:
Timing of endpoints: In hospital vs. 30 day?
Trial Design: Manual compression vs. newer closure devices vs. transradial?

Transradial Workshop  2010 Abbott
### XIENCE V INDIA: Achieve Hemostasis
(990 patients and 997 procedures)

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<tr>
<td>Manual Compression</td>
<td>81.1% (803/990)</td>
<td>100.0% (7/7)</td>
<td>81.2% (810/997)</td>
</tr>
<tr>
<td>Other</td>
<td>18.9% (187/990)</td>
<td>0%</td>
<td>18.8% (187/997)</td>
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Benefits of Transradial Cardiac Catheterization

• Perceived easier access to the circulation (for those with experience)
• Less risk of trauma to adjacent nerves and blood vessels
• A shorter post-procedure “recovery” and evaluation period
  – Decrease length of stay
• A lower risk of complications
  – Decrease in major bleeding
  – Decrease in transfusion
• Perceived reduced cost
• Patient satisfaction is huge
  – First choice for many patients
• Throughput in the cath lab is high
• High nurse satisfaction
  – With training vessel closure high too

Happy patients
Happy staff
Happy administrators
What currently works well in this area?

- Radial approach is generally preferred by patients because:
  - Reduced peri-procedural discomfort
  - Decreased time to ambulation
  - Improved post-procedural quality-of-life
- Radial approach reduces
  - Access site complications
  - Decreases length of hospital stay
  - Yields better outcomes at lower costs
- Femoral approach works well too
  - Newer equipment and supplies
  - Established training programs
What are the biggest/highest priority problems? What is broken or unavailable currently in this area?

- Lack of Standardized Training Programs
  - Organization (SCAI) vs. Industry led programs
  - Fellows learn technique from the very beginning
  - Staff needs to be trained too
- Variability in Case Volumes to Feel Comfortable (~100)
  - **US**
    - More small, medium, and high volume cath labs (relatively fewer cases to gain experience)
  - **Outside the US**
    - Fewer cath labs and more cases (thus can gain experience faster)
- Lack of Identification of Appropriate Patient Types
  - All STEMIls (and Infarcts)
  - All CTOs (Germany, Japan, Canada)
  - Only obese
  - Only thin women
  - Only African Americans due to higher vascular complication rates
  - Diagnostic vs. emergent caths (What is the best protocol to prepare both sites?)
What are the biggest/highest priority problems? (cont.)

• There is a significant learning curve which could incur early on:
  – Higher procedure failure rates
  – Increased radiation exposure (patient and operator)
  – Longer procedure durations
  – Higher costs associated with learning

• Success rates for experience operators are >95%

• Radial artery occlusion is the most common complication of radial artery access, with a varied incidence of 3% to 9%

• Inability to access the radial artery is the most common cause of failure for the transradial catheterization procedure
What are the biggest/highest priority problems? (cont.)

• Criteria for Pre-Screening
  – Insufficient veins
  – Varicose veins of lower extremity
  – Renal dialysis
  – History of saphenous vein harvesting/injury

• Equipment Available
  – Sterile preps for both sites
  – Mid-air instead of over the patient’s legs
    (table)
  – Lack of site-specific (right vs. left) guide wires and guide catheters being developed

• Medication Guidelines for Transradial
  – Verapamil and/or Cardizem, Nitro, and heparin to prevent spasm/clot

• Regulatory Guidance
  – Labeling
What are the highest priorities over the near term?

• Support consistent and comprehensive educational programs

• Encourage quality outcomes by patient type (at a reasonable cost)

• Same operators interested in transradial are also interested in structural heart
  – Generally never above 6 French radial applications
  – Generally never below 10-16 French for structural heart applications

• Thus maintain awareness of both procedures
  • Support access that is best for patient types
Benefits vs. Risks: Transradial

Risks to Franchise

<table>
<thead>
<tr>
<th>Benefits to Franchise</th>
<th>Low</th>
<th>Moderate</th>
<th>High</th>
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<tbody>
<tr>
<td>High</td>
<td>++++</td>
<td>+++</td>
<td>+/-</td>
</tr>
<tr>
<td>Moderate</td>
<td>+++</td>
<td>++/--</td>
<td>---</td>
</tr>
<tr>
<td>Low</td>
<td>++/-</td>
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<th>Market Size</th>
<th>Leadership Philosophy</th>
<th>Product Development and Life-Cycle Long-term Safety &amp; Quality Outcomes</th>
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<td>Market Share</td>
<td>Regulatory Guidance</td>
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