Robots Moving Into The Cath Lab

Alvaro A. Gomez, MD, FACC
Interventional Cardiologist
Miami Cardiac and Vascular Institute
Percutaneous Coronary Intervention

- Performed with more predictability in recent years but optimization at a “hard stop”
- Innovation is constrained to limitations of implantable devices (stents)
- Unlike many other invasive procedures, today’s PCI procedure remains largely unchanged
  - Radiation and orthopedic risk - we are standing bedside, in a non-ergonomic position within a radiation field
  - Limits on the precision that is required by today’s complex cases

Dr. Andreas Gruentzig
1977

Dr. Alvaro Gomez
2015
Occupational Risks in the Cath Lab
Radiation and orthopedic injury

• Cases of brain tumors are predominately left-side amongst interventionalists¹
  – 86% of tumors in study are on left-side
  – Population data indicates tumor side should be evenly split

• Orthopedic injuries²
  – 42% report spine problems
  – 28% report hip, knee, or ankle problems
  – 33% miss work due to orthopedic issues

• Interventional cardiologists experience the highest amounts of radiation exposure of any medical professional³

¹ Roguin A. Radiation hazards to interventional cardiologists: A report on increased brain tumors among physicians working in the cath lab. SOLACI 2014; April 23, 2014; Buenos Aires, Argentina.
Clinical Challenges with PCI

Procedural Challenges in PCI
- Difficulty visualizing lesion
- Lesion length measurement / stent sizing
- Placement accuracy
- Device movement during deployment

Longitudinal Geographic Miss (LGM)

Worse Clinical Outcomes

CorPath – Precision Vascular Robotics
CorPath Robotic Angioplasty

- Precise robotic-assisted control of:
  - Guidewire
  - Rapid-exchange balloon/stent
- Open platform – select device of your choice
  - Use any 0.014” guidewire and preferred rapid-exchange device
- Physician sitting at a radiation shielded cockpit
  - Option to remain scrubbed

Bedside Unit  View from Interventional Cockpit
Robotic Arm
Shielded, sterile-field cockpit
Shielded, sterile field, scrubbed
CorPath-Working Screen
CorPath - Instruction Screen

1. Open Cover.
2. Load device(s).
3. Close Cover.

Balloon/Stent
-0.6 0.0
Measurement (mm)

Guidewire
347.1 0.0
Measurement (mm)
Features Unique to Robotic-assisted PCI

• **Precision** – Device movements controlled to 1mm
• **Measurement** – Sub-mm measurement capability
• **Visualization** – Monitors are positioned in optimal view
• **Control** – Simultaneous control of both guidewire and stent
• **Fixation** – Holding the guidewire, balloon/stent to avoid unwanted movements
CorPath Measurement
PRECISE Study
Percutaneous Robotically-Enhanced Coronary Intervention Study

- **Design:** Prospective, non-randomized, clinical evaluation of the CorPath system.
- **Objectives:** To evaluate the safety and effectiveness of the clinical and technical performance of the robotic system in the delivery and manipulation of coronary guidewires balloons and stents used in PCI.
- **Multicenter:** 9 Sites, n=164

PRECISE Results

- Device success: 162/164 patients (98.8%)
  - Hybrid manual operation - 2 patients
- Clinical success: 160/164 patients (97.6%)
- 95.2% reduction in radiation exposure
- No device related complications
- Compared favorably to historical data

<table>
<thead>
<tr>
<th>30-day follow up results</th>
<th>n = 164</th>
</tr>
</thead>
<tbody>
<tr>
<td>MACE</td>
<td>4 (2.4%)</td>
</tr>
<tr>
<td>Death</td>
<td>0</td>
</tr>
<tr>
<td>Myocardial Infarction</td>
<td>4 (2.4%)</td>
</tr>
<tr>
<td>- Q-wave MI</td>
<td>0</td>
</tr>
<tr>
<td>- Non Q-wave MI</td>
<td>4 (2.4%)</td>
</tr>
<tr>
<td>Target vessel revascularization</td>
<td>0</td>
</tr>
<tr>
<td>Stent thrombosis</td>
<td>0</td>
</tr>
</tbody>
</table>
Operator Radiation Exposure

95.2% reduction (p<0.0001)
median radiation exposure to operator

CorPath Learning Curve
Short learning curve demonstrated in PRECISE trial

- Advanced-experience cases were associated with\(^1\):
  - Shorter procedure duration
  - Shorter fluoroscopy time
  as compared to early-experience cases

- The short learning curve highlights the easy adoption of robotic technology for PCI.

- Early experience = 60 cases represent the first 3 cases for each operator in the trial

<table>
<thead>
<tr>
<th>Procedural Parameter</th>
<th>Early Experience N=60</th>
<th>Advanced Experience N=104</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Procedure duration (min)</td>
<td>51.3 ± 25.5</td>
<td>42.2 ± 16.4</td>
<td>0.008</td>
</tr>
<tr>
<td>PCI duration (min)</td>
<td>42.0 ± 17.4</td>
<td>34.5 ± 14.0</td>
<td>0.003</td>
</tr>
<tr>
<td>X-ray duration (min)</td>
<td>12.9 ± 7.8</td>
<td>10.1 ± 4.8</td>
<td>0.009</td>
</tr>
<tr>
<td>Contrast media volume (ml)</td>
<td>138.4 ± 52.9</td>
<td>147.5 ± 78.9</td>
<td>NS</td>
</tr>
</tbody>
</table>

“After performing 3 cases, physician were able to complete robotic-enhanced PCI faster, with reduced radiation, and without compromising safety”\(^1\).

\(^1\) Weisz et al, “The association between experience and proficiency with robotic-enhanced coronary intervention-insights from the PRECISE multi-center study”, Acute Cardiac Care Journal, 2014,
Robotic vs. Manual¹
Single center trial, New York Presbyterian

Study design
- 40 patients enrolled for robotic PCI
- 80 consecutive patients who underwent conventional PCI met the same study entry criteria

Results:
- 17% less fluoro time with Robotic PCI compared to manual PCI
  - Translate to less radiation dose robotic vs. manual
- Trends toward lower contrast media volume is consistent

<table>
<thead>
<tr>
<th>Procedural Characteristics</th>
<th>Robotic PCI N=40</th>
<th>Manual PCI N=80</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contrast Media Volume, ml</td>
<td>121 ± 47</td>
<td>137 ± 62</td>
<td>0.07</td>
</tr>
<tr>
<td>Fluoroscopy Time, min</td>
<td>10.1 ± 4.7</td>
<td>12.3 ± 7.6</td>
<td>0.047</td>
</tr>
<tr>
<td>Radiation Dose, mGy</td>
<td>1389 ± 599</td>
<td>1665 ± 102 6</td>
<td>0.06</td>
</tr>
<tr>
<td>Peak CPK</td>
<td>92 ± 49</td>
<td>103 ± 71</td>
<td>0.40</td>
</tr>
<tr>
<td>CPK &gt;2x ULN</td>
<td>0</td>
<td>0</td>
<td>1.0</td>
</tr>
</tbody>
</table>

“These benefits were observed despite using a new system with no or minimal previous experience, and can be attributed to improved visualization, easy wire and catheter manipulation, and precise balloon and stent positioning that are enhanced by the robotic system”¹

Case Example – Optimizing Our Stent(s) Placement

• 68 y.o female

• History of hypertension, dyslipidemia, statin intolerant
• Recent stenting of prox-mid LAD
• Recurrent angina not well controlled on medical therapy.
LCX- RAO caudal
LCX- LAO caudal
Post PCI
Why Robotics in the Cath Lab?

• Operator Safety
  • Reduction of radiation exposure to the physician
    • Cumulative PCI radiation exposure is a significant issue
    • Reduce fluoroscopy time and contrast volume

• Clinical
  • Procedure is not compromised and may be improved
  • Robotic precision to optimize the procedure
  • Control of guidewire and balloon/stent catheter simultaneously facilitates procedure control
  • Improved stent sizing potentially improving outcomes

• Economic impact
  • Potential reduction in number of stents/lesion
Experience Feedback

• Robotic precision is a key benefit
• Measurement enables optimized stent selection
• Force feedback (tactile sensation) not an issue
• Fast learning curve
• CorPath requires change in workflow so staff proficiency is important for successful program
  • Full support from Clinical Specialist
  • Advanced “super user” meeting for my team
• Support from executive and hospital management
Thank You!