A COMPREHENSIVE EVALUATION OF A DISRUPTIVE TECHNOLOGY: TRANSCATHETER AORTIC VALVE IMPLANTATION

Laurie Lambert, PhD for the Cardiovascular Evaluation Unit
The Cardiovascular Evaluation Unit: A multidisciplinary team

- Director
- Biostatistician
- Coordinator and Administrative support
- Medical record librarians
- Graphic artist
- Economist
- Scientific Researchers
- Clinical experts
- Web specialist
- Knowledge translation expert
Our goal is to help the health care system provide equal access to high quality and timely care to the population of Québec.
## Composition of expert committee

<table>
<thead>
<tr>
<th>Left Column</th>
<th>Right Column</th>
</tr>
</thead>
<tbody>
<tr>
<td>Michel Carrier (RQCT)</td>
<td>Anita Asgar (ICM)</td>
</tr>
<tr>
<td>Éric Dumont (IUCPQ)</td>
<td>Réda Ibrahim (ICM)</td>
</tr>
<tr>
<td>Yoan Lamarche (ICM et HSCM)</td>
<td>Josep Rodés-Cabau (IUCPQ)</td>
</tr>
<tr>
<td>Nicolas Noiseux (CHUM)</td>
<td>Donald Palisaitis (HSCM)</td>
</tr>
<tr>
<td>Benoît de Varennes (CUSM)</td>
<td>Brian Potter (CHUM)</td>
</tr>
<tr>
<td>Jean-Pierre Beauchemin (IUCPQ)</td>
<td>Giuseppe Martucci (CUSM)</td>
</tr>
<tr>
<td>Jonathan Afilalo (JGH)</td>
<td>Nicolo Piazza (CUSM)</td>
</tr>
<tr>
<td>Normand Racine (RQCT)</td>
<td>Benoît Daneault (CHUS)</td>
</tr>
<tr>
<td>Peter Bogaty (Conseil INESSS)</td>
<td></td>
</tr>
</tbody>
</table>
Systematic Review/Meta-analysis

Transcatheter Aortic Valve Implantation: Recommendations for Practice Based on a Multidisciplinary Review Including Cost-Effectiveness and Ethical and Organizational Issues

Lucy J. Boothroyd, PhD, Marco Spaziano, MD, Jason R. Guertin, MSc, Laurie J. Lambert, PhD, Josep Rodés-Cabau, MD, Nicolas Noisieux, MD, Michel Nguyen, MD, Éric Dumont, MD, Michel Carrier, MD, Benoit de Varennes, MD, Reda Ibrahim, MD, Giuseppe Martucci, MD, Yongling Xiao, PhD, Jean E. Morin, MD, and Peter Bogaty, MD.

"Institut national d’excellence en santé et en services sociaux (INESSS), Montréal, Québec, Canada"
Field evaluation : Methods

- Selection of variables and their definitions
- Documentation of variables by the TAVI teams
- Review of documentation according to specified definitions by medical record librarian from INESSS in collaboration with the TAVI clinical team
- Data entry into a centralized, secure website (RedCAP)
- TAVI teams have real time access (read only) to their own data
Canadian Cardiovascular Society
Quality Indicators

Accepted Manuscript

Quality of Care for Transcatheter Aortic Valve Implantation: Development of Canadian Cardiovascular Society Quality Indicators

Anita W. Asgar, MD, Sandra Lauck, PhD, Dennis Ko, MD, Faisal Alqoofi, MD, Eric Cohen, MD, Anne Forsey, Laurie J. Lambert, PhD, Garth H. Oakes, PhD, Marc Pelletier, MD, John G. Webb, MD

PII: S0828-282X(15)01584-6
DOI: 10.1016/j.cjca.2015.11.008
Reference: CJCA 1932
Evolution of use of TAVI

Number of patients by choice of treatment in Germany

Most frequent reasons for TAVI as choice of treatment:
- age
- operative risk
- frailty
- patient preference

Abdelghani et Serruys (2016)
Cost effectiveness of TAVI vs surgical replacement among high risk patients

New RCT evidence for patients at moderate risk
New randomized trials concerning TAVI

Patients at low risk

• The Safety and Effectiveness of the SAPIEN 3 Transcatheter Heart Valve in Low Risk Patients With Aortic Stenosis (PARTNER 3) (NCT02675114)
• Medtronic Transcatheter Aortic Valve Replacement in Low Risk Patients (NCT02701283)
• Comparison of Transcatheter Versus Surgical Aortic Valve Replacement in Younger Low Surgical Risk Patients With Severe Aortic Stenosis (NOTION-2) (NCT02825134)

Asymptomatic patients

• Evaluation of Transcatheter Aortic Valve Replacement Compared to SurveillLance for Patients With AsYmptomatic Severe Aortic Stenosis (EARLY TAVR) (NCT03042104)
Elaboration of quality standards for Quebec (2016-17)

- Update of the literature review
- Proposal of quality standards according to results of literature review and field evaluation
- Successive rounds of consultation by email with the expert committee
- In person meeting to finalize wording of quality standards and to discuss those without consensus
- External review
Second report from the field evaluation

• Portrait of care according to newly established quality standards for Quebec and CCS priority QI
  – structures
  – processes of care
  – clinical outcomes

• Trends over a four year observation period from 2013-14 to 2016-17
Geographic location of TAVI programmes in Quebec
Annual volume of TAVI in Quebec

- **2013-2014**: 294
  - Range: 12 - 115
- **2014-2015**: 340
  - Range: 30 - 99
- **2015-2016**: 360
  - Range: 30 - 125
- **2016-2017**: 370
  - Range: 36 - 120
Rate of TAVI across Canada (2013-14)

Canadian Cardiovascular Society (2016)
Documentation of STS predictive risk of operative mortality score in the patient medical chart, by year

Canada 2013-14: 56%
Documentation of treatment recommendation by a Heart Team (≥1 interventionist and surgeon)

Canada 2013-14: 87%

- 2013-2014: 80%
- 2014-2015: 83%
- 2015-2016: 83%
- 2016-2017: 92%

Documented consultation with a cardiac surgeon: range 48% - 100%

Documentation of a Heart Team decision: range 80% - 100%
## TAVI Wait Times

<table>
<thead>
<tr>
<th></th>
<th>2015-16</th>
<th>2016-17</th>
<th>Canada 2013-2014</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Referral to Heart Team Decision</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median (25&lt;sup&gt;e&lt;/sup&gt; - 75&lt;sup&gt;e&lt;/sup&gt; percentile)</td>
<td>61 days (18 - 114)</td>
<td>44 days (15 - 99)</td>
<td>58 days (26 - 110)</td>
</tr>
<tr>
<td><strong>Procedure Wait Time : Decision to TAVI</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median (25&lt;sup&gt;e&lt;/sup&gt; - 75&lt;sup&gt;e&lt;/sup&gt; percentile)</td>
<td>40 days (12 - 77)</td>
<td>42 days (14 - 89)</td>
<td>37 days (16 - 70)</td>
</tr>
</tbody>
</table>
Canada 2013-14: 4.2%
Conclusions

- A collaborative effort to measure quality of care:
  - has been associated with improvements in processes of care and declining rates of adverse outcomes
  - has shown a lack of standardized documentation concerning the selection process for TAVI patients
Conclusions (2)

Other projects using this evaluation framework:

• Acute care of ST-elevation myocardial infarction
• Acute care of ischemic stroke (thrombectomy)
• Replacement / deactivation of ICD
• Use of long term left ventricular assist devices
Merci !

Questions ?

laurie.lambert@INESSS.qc.ca
Distribution of the STS Score: Predicted risk of operative mortality at 30 days

<table>
<thead>
<tr>
<th></th>
<th>2013 - 14</th>
<th>2014 - 15</th>
<th>2015 -16</th>
<th>2016-17</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median</td>
<td>6%</td>
<td>7%</td>
<td>4%</td>
<td>5%</td>
</tr>
<tr>
<td>(25th - 75th percentile)</td>
<td>(4 - 9)</td>
<td>(4 - 9)</td>
<td>(3 - 7)</td>
<td>(4 - 7)</td>
</tr>
</tbody>
</table>

**STS PROM**

<table>
<thead>
<tr>
<th></th>
<th>Low Risk</th>
<th>Intermediate Risk</th>
<th>High Risk</th>
<th>Prohibitive Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>STS PROM</strong></td>
<td>&lt;4%</td>
<td>4% to 8%</td>
<td>&gt;8%</td>
<td>Predicted risk with surgery of death or major morbidity (all-cause) &gt;50% at 1 y</td>
</tr>
</tbody>
</table>