ACI 2013

THE UK TAVI REGISTRY

MICHAEL MULLEN
THE HEART HOSPITAL, UCLH

ON BEHALF OF
UK TAVI STEERING GROUP
CONFLICT OF INTEREST STATEMENT

Edwards Life Sciences

Medtronic Inc

Direct flow Inc

Keystone heart Inc

Research grant, honoraria for teaching and lectures

Research grant, honoraria for teaching and lectures

Research grant

Research grant
UK TAVI Registry

- 1st UK TAVI case Jan 2007
- CE Mark Edwards Sapien and Corevalve 2007 with gradual increase in number of centres
- Need to collect data on outcomes with this novel procedure identified to guide the introduction and commissioning of TAVI in the UK
- Collaborative program
  - Implanting sites
  - Professional Societies (BCIS and SCTS)
  - Department of Health and Specialist Commissioners
  - NICE
- Data collection via Central Cardiac Audit Database (NICOR)
- 100% of consecutive UK TAVI implants
- Mortality tracking through ONS
  - linkage MRIS Medical Records Information Service
UK TAVI Registry

Steering Group

Chair: Huon Gray

Cardiologists
Andreas Baumbach
Mark de Belder
Tony Gershlick
David Hildick-Smith
Jan Kovac
Peter Ludman
Phil MacCarthy
Michael Mullen
Simon Ray
Martyn Thomas
William Toff

Cardiothoracic surgeons
Neil Moat
Uday Trevidi
Olaf Wendler
Chris Young

Central Cardiac Audit Database (CCAD)
David Cunningham
Roger Boyle
Damien Marlee

Specialist commissioners
Tim Daniel
Su Sethi
Jonathan Howell

NICE
Hannah Patrick
<table>
<thead>
<tr>
<th>Centre</th>
<th>UK TAVI Registry Numbers to Dec 31st 2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Royal Brompton&amp;H/fd</td>
<td>286</td>
</tr>
<tr>
<td>Guys/St Thomas’</td>
<td>256</td>
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<tr>
<td>Leeds</td>
<td>183</td>
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<tr>
<td>Glenfield Hospital</td>
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<td>Royal Sussex County</td>
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<td>King's College</td>
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<tr>
<td>Royal Victoria Belfast</td>
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<tr>
<td>St George's Hospital</td>
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<td>Barts and the London</td>
<td>101</td>
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<tr>
<td>New Cross Hospital</td>
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<tr>
<td>University College</td>
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<tr>
<td>Bristol Royal Infirmary</td>
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<td>Wythenshawe</td>
<td>86</td>
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<tr>
<td>Imperial</td>
<td>83</td>
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<td>James Cook</td>
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<td>Papworth Hospital</td>
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<td>Victoria Hospital</td>
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<td>Liverpool</td>
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<td>John Radcliffe</td>
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<td>Derriford Hospital</td>
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<td>Queen Elizabeth</td>
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<td>Nottingham City</td>
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<tr>
<td>North Staffordshire</td>
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<td>Freeman Hospital</td>
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<td>Southampton</td>
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<td>Manchester Royal</td>
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<td>Univ Hospital Wales</td>
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<td>Morriston Hospital</td>
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<td>London Bridge</td>
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<td>Wellington North</td>
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<td>Harley Street Clinic</td>
<td>8</td>
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<td>Edingborough</td>
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Numbers to Dec 31st 2011
UK TAVI Registry Dataset

• From Jan 2013
• Additional data fields
• Frailty
• Enhanced data on preprocedure risks
• Procedural details and outcomes
• Post procedure stroke scale
• Anti thrombotic medication
• Valve degeneration
UK TAVI Registry Dataset

Transcatheter Aortic Valve Implantation (TAVI) Dataset

<table>
<thead>
<tr>
<th>Order</th>
<th>Domain</th>
<th>CMD Seq</th>
<th>Field Name</th>
<th>Short Code</th>
<th>Long Code</th>
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<td>Patient Identification and Demographics</td>
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<td>Hospital Identifier</td>
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<td>1.02</td>
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<td>3</td>
<td>NHB Number</td>
<td>1.03</td>
<td>NHB Number</td>
<td>1.03</td>
<td>NHB Number</td>
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<td>4</td>
<td>Patient Name (Surname)</td>
<td>1.04</td>
<td>Patient Name (Surname)</td>
<td>1.04</td>
<td>Patient Name (Surname)</td>
</tr>
<tr>
<td>5</td>
<td>Patient Name (Forename)</td>
<td>1.05</td>
<td>Patient Name (Forename)</td>
<td>1.05</td>
<td>Patient Name (Forename)</td>
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<tr>
<td>6</td>
<td>Birth Date</td>
<td>1.06</td>
<td>Birth Date</td>
<td>1.06</td>
<td>Birth Date</td>
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<tr>
<td>7</td>
<td>Sex</td>
<td>1.07</td>
<td>Sex</td>
<td>1.07</td>
<td>Sex</td>
</tr>
</tbody>
</table>

Transcatheter Aortic Valve Implantation (TAVI) Dataset

Pre-Procedural Clinical Status

- Height (m): 1.0
- Weight (kg): 75.1
- Critical pre-operative status: No

CCS angina status
NYHA disponse status
Admission date for procedure (dd/mm/yyyy)
0. No angina
4. Symptoms at rest or minimal activity
18/09/2011

Support
0845 300 0016 Opt 2
IT Support
Clinical Enquiries enquiries.nicor@ucl.ac.uk

NICOR
UK TAVI Registry
Data analysis

2007 2008 2009 2010 2011 2012 2013

Clean

Analyse

Presentation/Publication
UK TAVI Registry
Data analysis

2007  2008  2009  2010  2011  2012  2013

Clean

Analyse

Presentation/Publication
UK TAVI Registry
2007-2010 analysis

EXPEDITED PUBLICATIONS

Long-Term Outcomes After Transcatheter Aortic Valve Implantation in High-Risk Patients With Severe Aortic Stenosis

The U.K. TAVI (United Kingdom Transcatheter Aortic Valve Implantation) Registry

Neil E. Moat, MBBS, MS,* Peter Ludman, MA, MD,† Mark A. de Belder, MA, MD,‡ Ben Bridgewater, PhD,§ Andrew D. Cunningham, PhD,¶¶ Christopher P. Young, MD,¶ Martyn Thomas, MD,¶ Jan Kovac, MD,# Tom Spyt, MD,# Philip A. MacCarthy, BS, PhD,** Olaf Wendler, MD, PhD,*** David Hildick-Smith, MD,†† Simon W. Davies, MBBS, MD,* Uday Trivedi, MBBS,†† Daniel J. Blackman, MD,‡‡ Richard D. Levy, MD,§ Stephen J. D. Brecker, MD,‡§ Andreas Baumbach, MD,¶ Tim Daniel, MB, CHB,¶¶ Huon Gray, MD,‡# Michael J. Mullen, MBBS, MD***

London, Birmingham, Bristol, Middlesbrough, Manchester, Leicester, Brighton, Leeds, and Southampton, United Kingdom

- 870 Patients
- 877 TAVI procedures
- 100% mortality tracking
UK TAVI Registry

Number of TAVI by year

3780 procedures *

* Data for 2013 not yet complete
UK TAVI Registry

100% consecutive UK TAVI procedures 1st Jan 2007 – 31st Dec 2011

30 day mortality by year

<table>
<thead>
<tr>
<th>Year</th>
<th>Mortality Rate</th>
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<tr>
<td>2007</td>
<td>13.9</td>
</tr>
<tr>
<td>2008</td>
<td>8.5</td>
</tr>
<tr>
<td>2009</td>
<td>5.4</td>
</tr>
<tr>
<td>2010</td>
<td>6.2</td>
</tr>
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<td>2011</td>
<td>5.8</td>
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UK TAVI Registry

100% consecutive UK TAVI procedures 1st Jan 2007 – 31st Dec 2011

Edwards (n=1,353)  
Medtronic (n=1,350)  
St Jude (n=13)
UK TAVI Registry

Access route by year

Medtronic CoreValve

Edwards Sapien
## UK TAVI Registry

Demographics by access route

1\(^{\text{st}}\) Jan 2007 – 31\(^{\text{st}}\) Dec 2011

<table>
<thead>
<tr>
<th></th>
<th>Edwards Femoral</th>
<th>CoreValve Femoral</th>
<th>Edwards Apical</th>
<th>CoreValve Subclavian</th>
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</thead>
<tbody>
<tr>
<td>Male, %</td>
<td>49.1</td>
<td>53.3</td>
<td>56.3</td>
<td>71.4</td>
</tr>
<tr>
<td>Age, mean (SD)</td>
<td>81.8 (7.3)</td>
<td>80.7 (7.6)</td>
<td>81.1 (7.7)</td>
<td>80.6 (6.7)</td>
</tr>
<tr>
<td>Diabetes, %</td>
<td>21.1</td>
<td>23.5</td>
<td>21.1</td>
<td>26.3</td>
</tr>
<tr>
<td>Previous MI, %</td>
<td>20.9</td>
<td>22.6</td>
<td>19.5</td>
<td>25.0</td>
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<tr>
<td>Prior cardiac surgery, %</td>
<td>26.8</td>
<td>31.9</td>
<td>42.7</td>
<td>32.3</td>
</tr>
<tr>
<td>PVD, %</td>
<td>15.7</td>
<td>19.3</td>
<td>45.7</td>
<td>55.6</td>
</tr>
</tbody>
</table>
UK TAVI Registry

Log Euroscore by access route

1st Jan 2007 – 31st Dec 2011

Edwards Femoral: 20.35
CoreValve Femoral: 20.8
Edwards Transapical: 23.9
CoreValve Subclavian: 24.8
UK TAVI Registry

30 day survival by valve type and access route

1st Jan 2007 – 31st Dec 2011

- Edwards Femoral: 3.9%
- CoreValve Femoral: 4.5%
- Edwards Transapical: 10.1%
- CoreValve Subclavian: 3.3%

p = ns
p 0.04
UK TAVI Registry

2 year survival by access route
UK TAVI Registry

Ongoing analyses

- Cost-Effectiveness Analysis
- Gender and outcomes
- Outcomes in age > 80
- Does previous Open Heart Surgery affect the outcome of Transcatheter Aortic Valve Replacement (T-AVR)?
- TAVI in patients with concomitant coronary artery disease: A study of patient demographics, management of coronary artery disease and clinical outcomes
- Outcomes by access site
- Ventricular function
- Outcomes by degree of paravalvular aortic regurgitation
- Use of a new surgical risk model applied to the TAVI dataset
- Comparison of UK TAVI and surgical AVR registries
• TAVI in the UK represents the successful introduction of a novel technology into clinical practice
  • evaluative framework
  • collaborative national registry
• >3700 UK cases captured covering all stages of learning curve, valve types and access routes
• Implant rates levelling out
• Reduction in 30 day mortality over time and rates now stabilised
• Proportion of TA cases decreasing with advances in TF technology
• TA 30 day mortality remains high
• Numerous ongoing analyses will help to inform future clinical practice