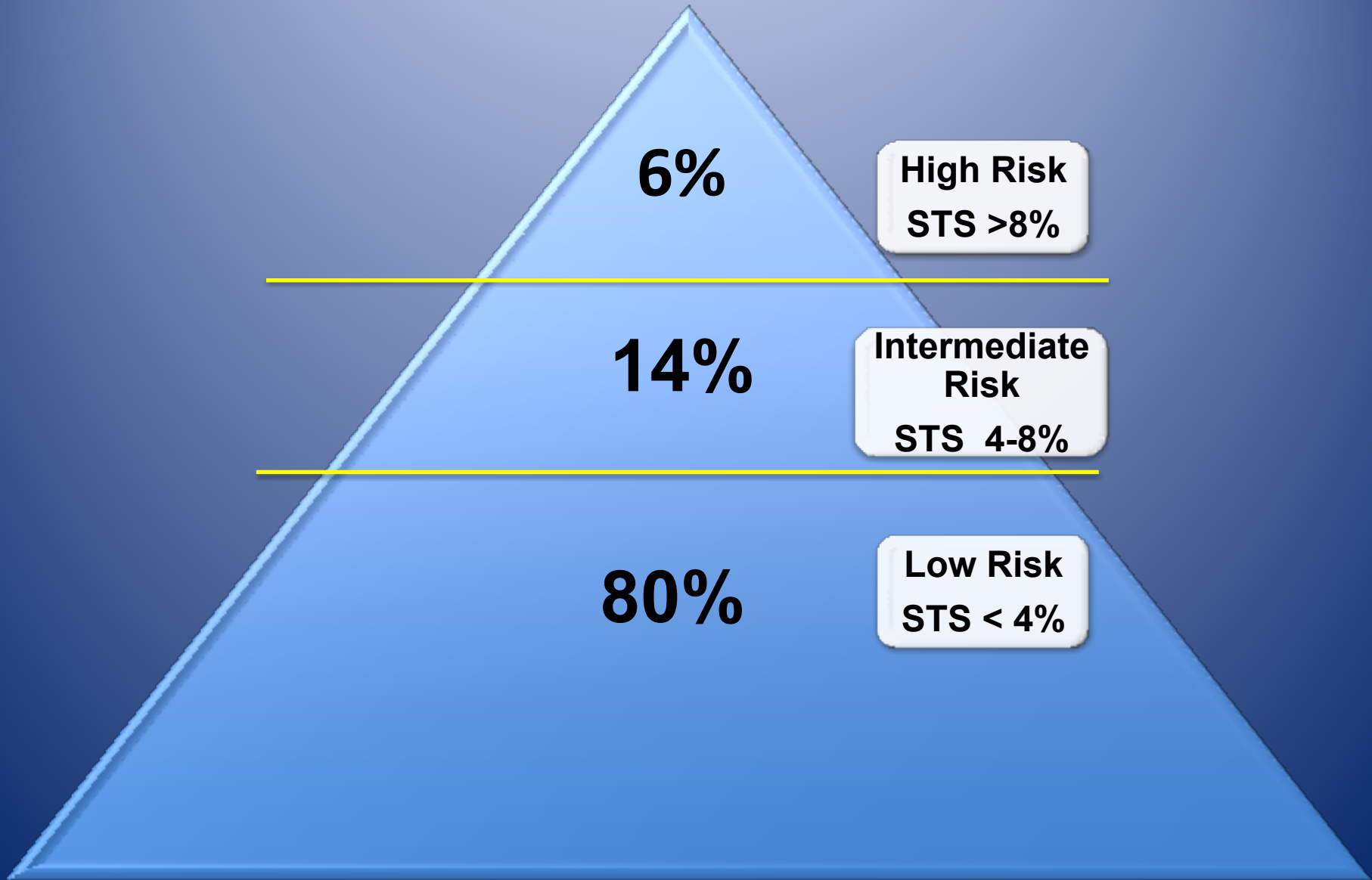


**This House believes SAVR is the
treatment of choice for aortic
stenosis in patients predicted to have
good surgical outcome and good life
expectancy**

Marjan Jahangiri
Professor of Cardiac Surgery
St. George's Hospital, London

All trials have concentrated on risk stratification



Estimated surgical risk no longer dictates the choice between SAVR and TAVI

- **Primary considerations should be given to:**

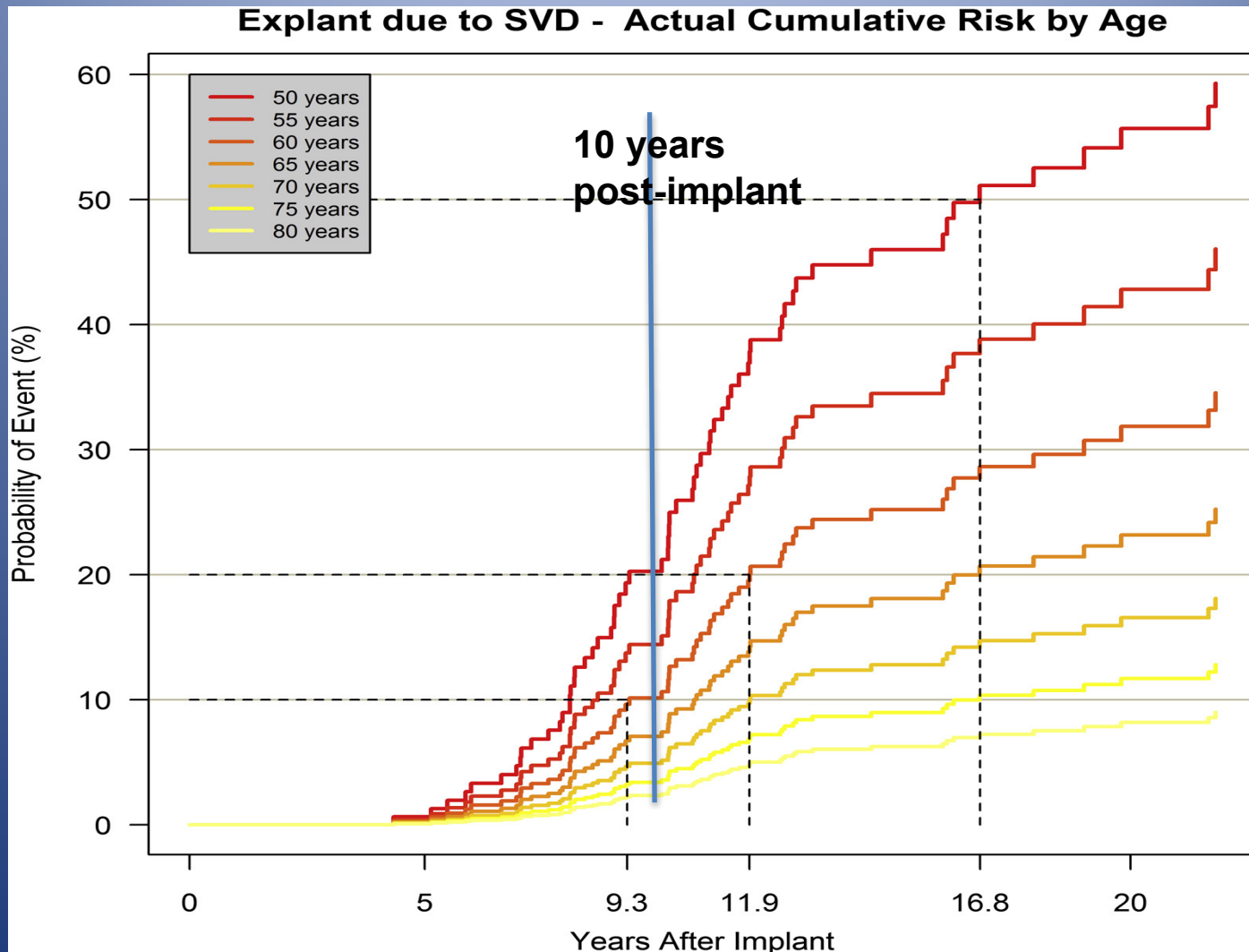
1. Life expectancy
2. Valve durability

- **Both related to patients age**

50 yr old female life expectancy = 34 yrs

70 yr old male life expectancy = 14 yrs

Durability of bioprosthetic valves is inversely proportional to age



15-yr risk of re-operation

Age	Risk of re-op
70 yrs	5%
50 yrs	30%

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OCTOBER 21, 2010

VOL. 363 NO. 17

Transcatheter Aortic-Valve Implantation for Aortic Stenosis in Patients Who Cannot Undergo Surgery

Martin B. Leon, M.D., Craig R. Smith, M.D., Michael Mack, M.D., D. Craig Miller, M.D., Jeffrey W. Moses, M.D., Lars G. Svensson, M.D., Ph.D., E. Murat Tuzcu, M.D., John G. Webb, M.D., Gregory P. Fontana, M.D., Raj R. Makkar, M.D., David L. Brown, M.D., Peter C. Block, M.D., Robert A. Guyton, M.D.,

M.D., Pamela S. Douglas, M.D.,
, Duolao Wang, Ph.D.,
Investigators*

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Transcatheter versus Surgical Aortic-Valve Replacement in High-Risk Patients

Craig R. Smith, M.D., Martin B. Leon, M.D., Michael J. Mack, M.D., D. Craig Miller, M.D., Jeffrey W. Moses, M.D., Lars G. Svensson, M.D., Ph.D., E. Murat Tuzcu, M.D., John G. Webb, M.D., Gregory P. Fontana, M.D., Raj R. Makkar, M.D., Mathew Williams, M.D., Todd Dewey, M.D., Samir Kapadia, M.D., Vasilis Babaliaros, M.D., Vinod H. Thourani, M.D., Paul Corso, M.D., Augusto D. Pichard, M.D., Joseph E. Bavaria, M.D., Howard C. Herrmann, M.D., Jodi J. Akin, M.S., William N. Anderson, Ph.D., Duolao Wang, Ph.D., and Stuart J. Pocock, Ph.D., for the PARTNER Trial Investigators*



The NEW ENGLAND
JOURNAL of MEDICINE

ORIGINAL ARTICLE

Transcatheter or Surgical Aortic-Valve Replacement in Intermediate-Risk Patients

Martin B. Leon, M.D., Craig R. Smith, M.D., Michael J. Mack, M.D., Raj R. Makkar, M.D., Lars G. Svensson, M.D., Ph.D., Susheel K. Kodali, M.D., Vinod H. Thourani, M.D., E. Murat Tuzcu, M.D., D. Craig Miller, M.D., Howard C. Herrmann, M.D., Darshan Doshi, M.D., David J. Cohen, M.D., Augusto D. Pichard, M.D., Samir Kapadia, M.D., Todd Dewey, M.D., Vasilis Babaliaros, M.D., Wilson Y. Szeto, M.D., Mathew R. Williams, M.D.,

The NEW ENGLAND JOURNAL of MEDICINE

Transcatheter aortic valve replacement versus surgical valve replacement in intermediate-risk patients: a propensity score analysis



Vinod H Thourani, Susheel Kodali, Raj R Makkar, Howard C Herrmann, Mathew Williams, Vasilis Babaliaros, Richard Smalling, Scott Lim, S Chris Malaisrie, Samir Kapadia, Wilson Y Szeto, Kevin L Greason, Dean Kereiakes, Gorav Ailawadi, Brian K Whisenant, Chandan Devireddy, Jonathon Leipsic, Rebecca T Hahn, Philippe Pibarot, Neil J Weissman, Wael A Jaber, David J Cohen, Rakesh Suri, E Murat Tuzcu, Lars G Svensson, John G Webb, Jeffrey W Moses, Michael J Mack, D Craig Miller, Craig R Smith, Maria C Aki, Rupa Parvataneni, Ralph B D'Agostino Jr, Martin B Leon

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Two-Year Outcomes after Transcatheter or Surgical Aortic-Valve Replacement

Susheel K. Kodali, M.D., Mathew R. Williams, M.D., Craig R. Smith, M.D., Lars G. Svensson, M.D., Ph.D., John G. Webb, M.D., Raj R. Makkar, M.D., Gregory P. Fontana, M.D., Todd M. Dewey, M.D., Vinod H. Thourani, M.D., Augusto D. Pichard, M.D., Michael Fischbein, M.D., Ph.D., Wilson Y. Szeto, M.D., Scott Lim, M.D., Kevin L. Greason, M.D., Paul S. Teirstein, M.D., S. Chris Malaisrie, M.D., Pamela S. Douglas, M.D., Rebecca T. Hahn, M.D., Brian Whisenant, M.D., Alan Zajarias, M.D., Duolao Wang, Ph.D., Jodi J. Akin, M.S., William N. Anderson, Ph.D., and Martin B. Leon, M.D., for the PARTNER Trial Investigators*

THELANCET-D-15-00795

S0140-6736(15)60308-7

Embargo: [add date when known]

5-year outcomes of transcatheter aortic valve replacement or surgical aortic valve replacement for high surgical risk patients with aortic stenosis (PARTNER 1): a randomised controlled trial

Michael J Mack, Martin B Leon, Craig R Smith, D Craig Miller, Jeffrey W Moses, E Murat Tuzcu, John G Webb, Pamela S Douglas, William N Anderson*, Eugene H Blackstone, Susheel K Kodali, Raj R Makkar, Gregory P Fontana, Samir Kapadia, Joseph Bavaria, Rebecca T Hahn, Vinod H Thourani, Vasilis Babaliaros, Augusto Pichard, Howard C Herrmann, David L Brown, Mathew Williams, Jodi Akin*, Michael J Davidsont, Lars G Svensson, for the PARTNER 1 trial investigators

Transcatheter Aortic-Valve Replacement with a Self-Expanding Prosthesis

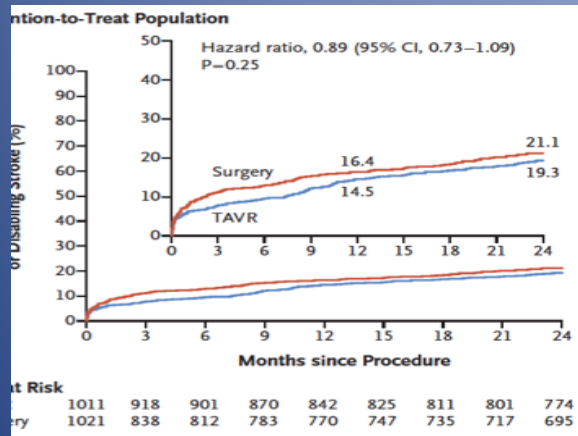
Adams, M.D., Jeffrey J. Popma, M.D., Michael J. Reardon, M.D., Yakubov, M.D., Joseph S. Coselli, M.D., G. Michael Deeb, M.D., Gleason, M.D., Maurice Buchbinder, M.D., James Hermiller, Jr., M.D., Ian, M.D., Stan Chetcuti, M.D., John Heiser, M.D., William Merhi, D.O., George Zorn, M.D., Peter Tadros, M.D., Newell Robinson, M.D., Petrossian, M.D., G. Chad Hughes, M.D., J. Kevin Harrison, M.D., Monte, M.D., Brijeshwar Maini, M.D., Mubashir Mumtaz, M.D., Sharla Chenoweth, M.S., and Jae K. Oh, M.D., for the U.S. CoreValve Clinical Investigators*

Trials exclusion criteria

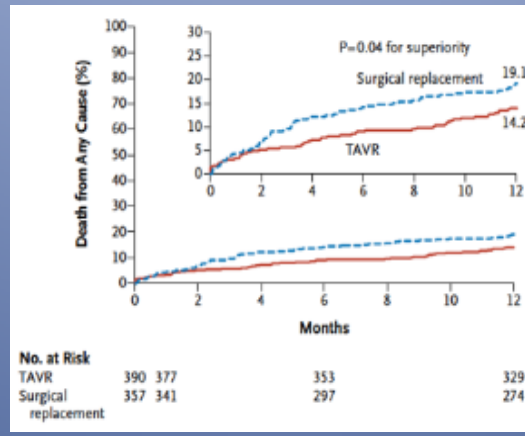
- Bicuspid aortic valve
- Aortopathy
- Heavy left ventricular outflow tract obstruction
- Complex coronary artery disease
- Moderate-severe MR
- Moderate-severe TR

Difficult for clinicians to interpret data from multiple studies

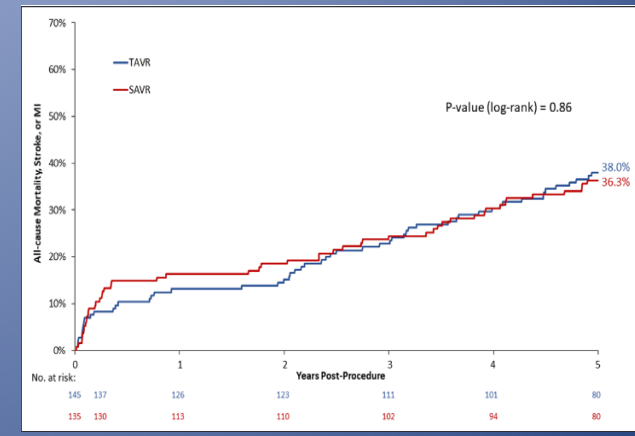
PARTNER 2A



Pivotal



NOTION



1. Do these reflect real world practice?
2. Should observational and registry data be considered?
3. Can the data in different studies be combined?
4. Is the design accurate? e.g. Comparing AVR+CABG vs TAVI
5. Is the evidence strong enough to change practice?
6. Volume-outcome relationship

Non-inferiority cardiovascular trials in high impact journals

- Non-inferiority CV trials are increasingly being published by the highest impact journals

1990-2016 111 CV non-inferiority trials

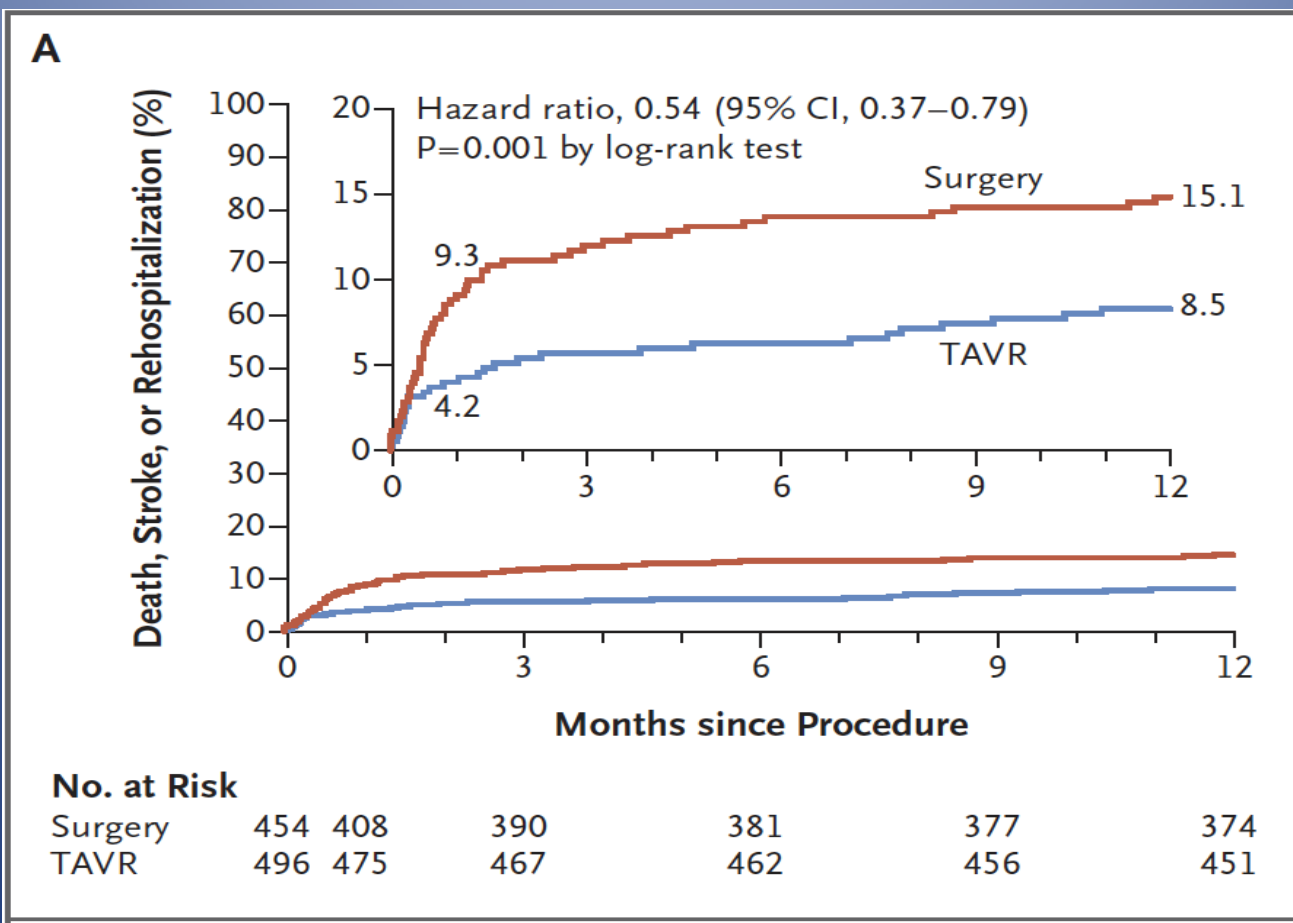
- Most (80%) of the trials concluded the tested interventions were non-inferior to the compared therapy
- Many trials had methodological or reporting limitations
 1. Failure to report both intention-to-treat and per-protocol/as treated cohorts
 2. Not justifying the inferiority margin
 3. Exclusion or loss of >10% of the cohort

PARTNER 3 trial

SAVR=454 TAVI=496

STS score = 1.9

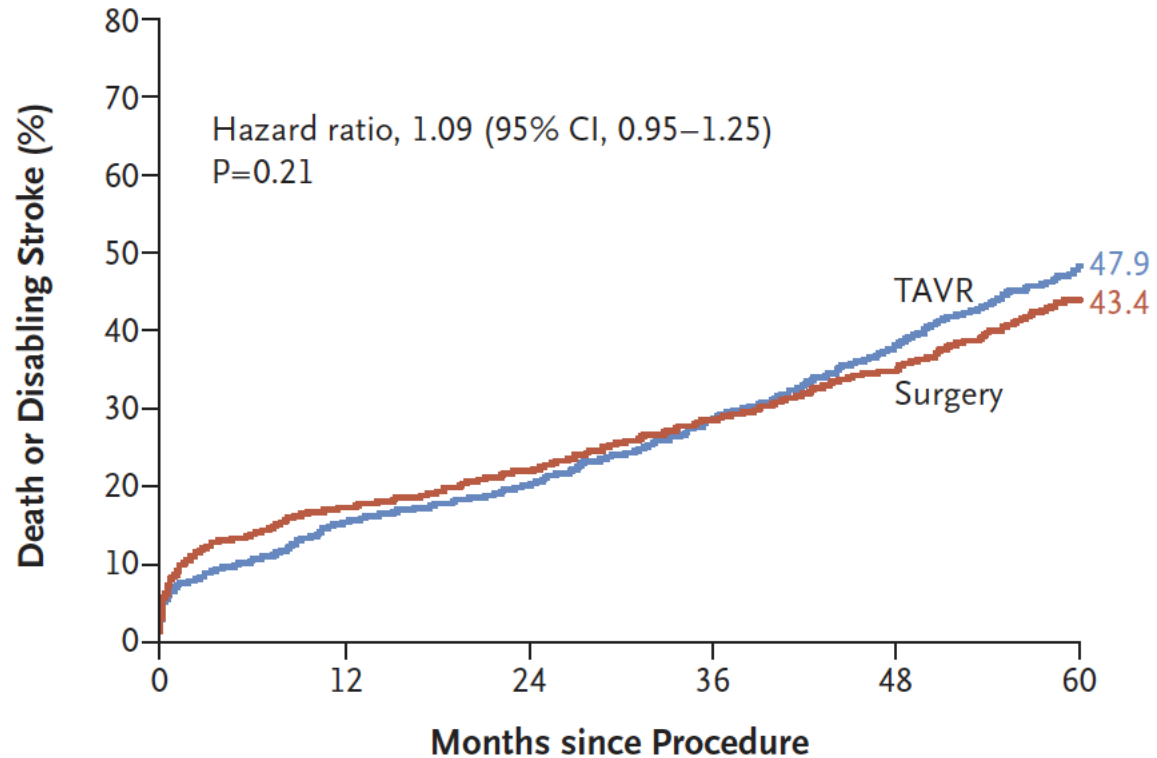
Euroscore II = 1.5



5-year outcomes of PARTNER 2

SAVR=1021 TAVI=1011

STS score = 5.8



No. at Risk

TAVR	1011	843	785	687	581	474
Surgery	1021	771	704	625	547	440

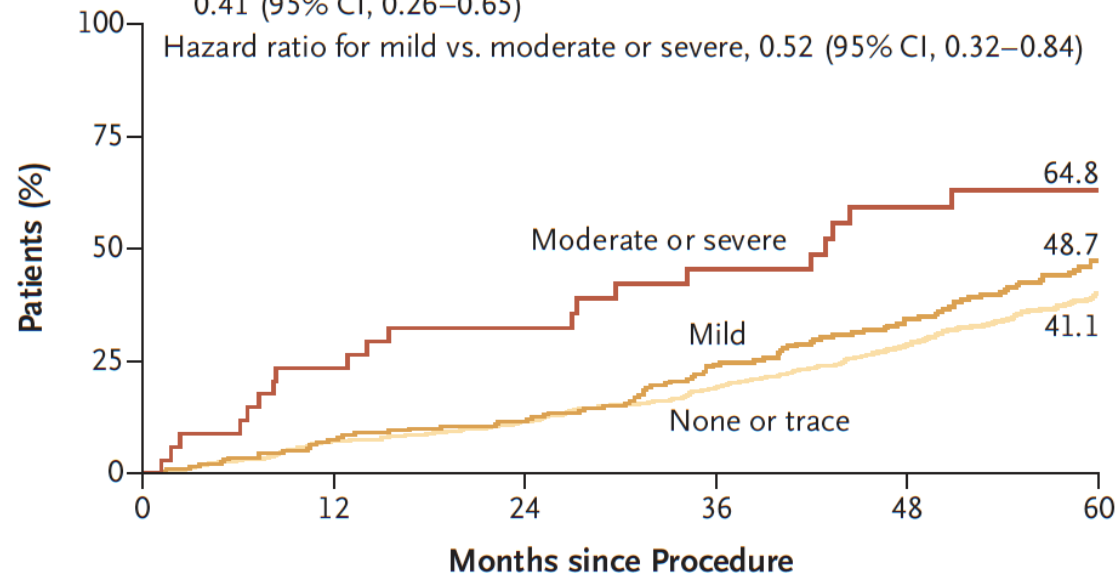
5-year outcomes of PARTNER 2

D Death from Any Cause, According to Severity of Paravalvular Aortic Regurgitation

Hazard ratio for none or trace vs. mild, 0.80 (95% CI, 0.63–1.02)

Hazard ratio for none or trace vs. moderate or severe, 0.41 (95% CI, 0.26–0.65)

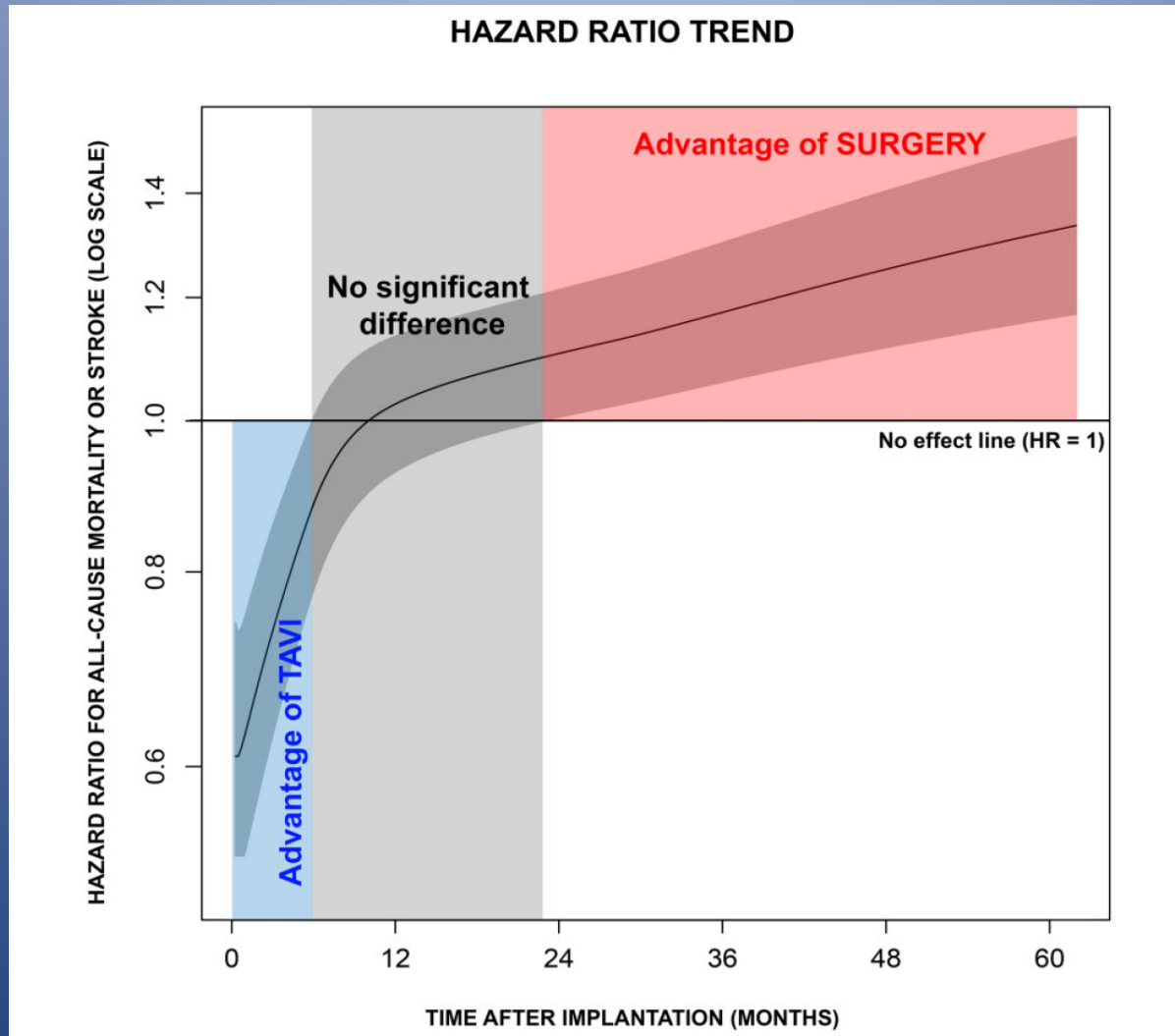
Hazard ratio for mild vs. moderate or severe, 0.52 (95% CI, 0.32–0.84)



No. at Risk

Moderate or severe	33	25	20	16	11	5
Mild	196	178	170	143	120	63
None or trace	643	592	557	495	427	225

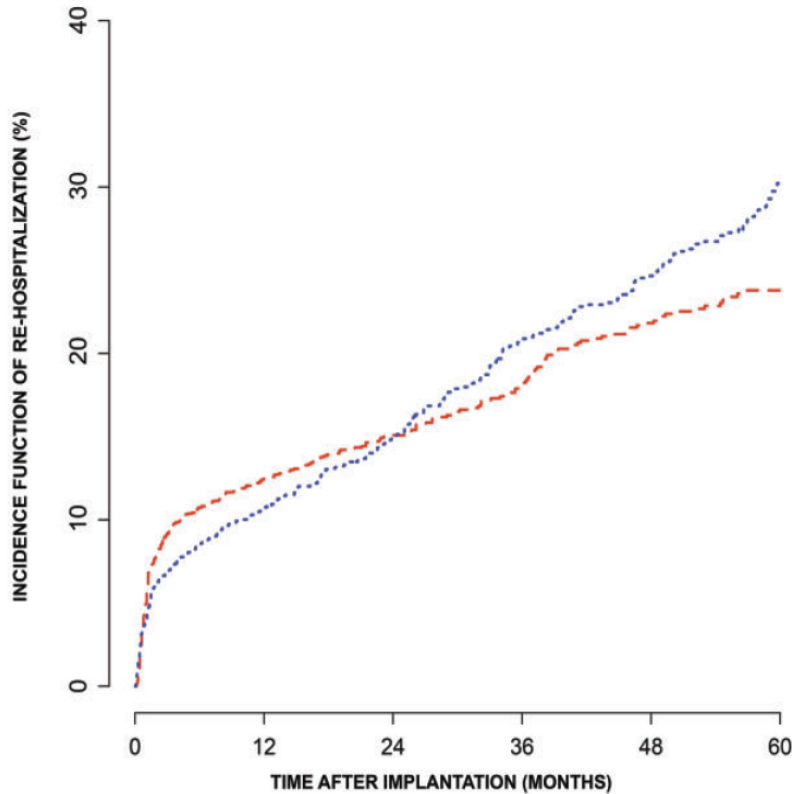
Meta-analysis of time to event over 5 years



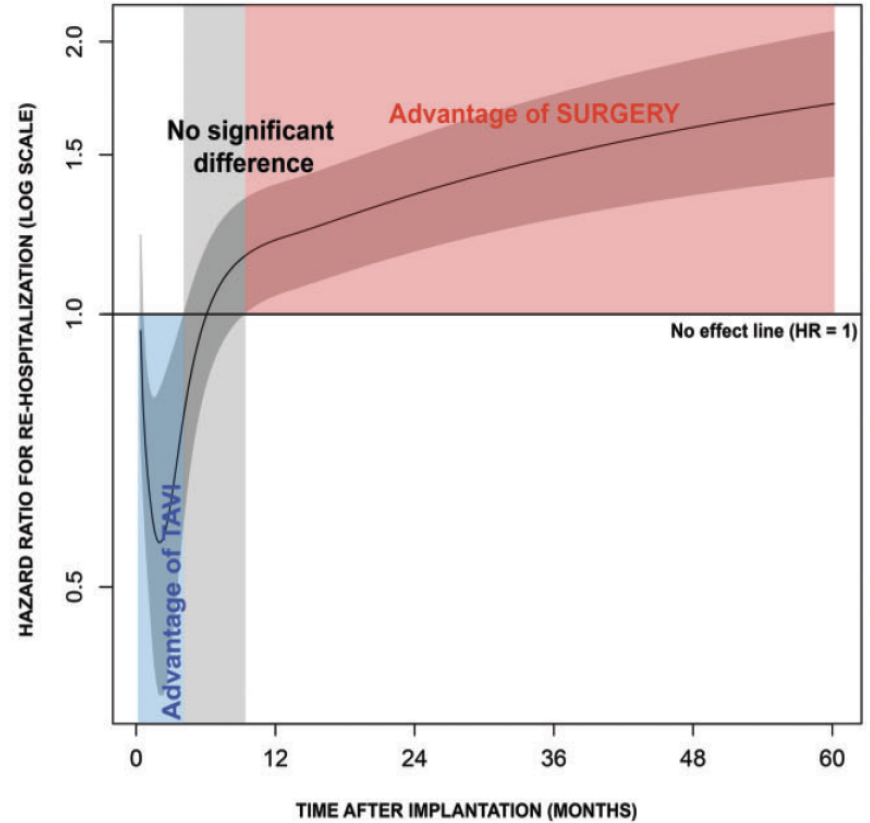
Meta-analysis of time to event over 5 years

RE-HOSPITALIZATION

Incidence Function



Hazard Ratio Trend



SAVR	2504	1638	1114	694	576	308
TAVI	2580	1855	1284	722	594	291

Reasons for meta-analysis findings

Surgery fares worse, because:

- Perioperative complications of cardiac surgery in general, only meaningful during the initial perioperative period

TAVI fares worse, because:

- Paravalvular regurgitation
- Leaflet degeneration
- Need for permanent pacemaker
- Features of the AVR rather than the mode of treatment
- They influence long term prognosis, irrespective of age at implantation

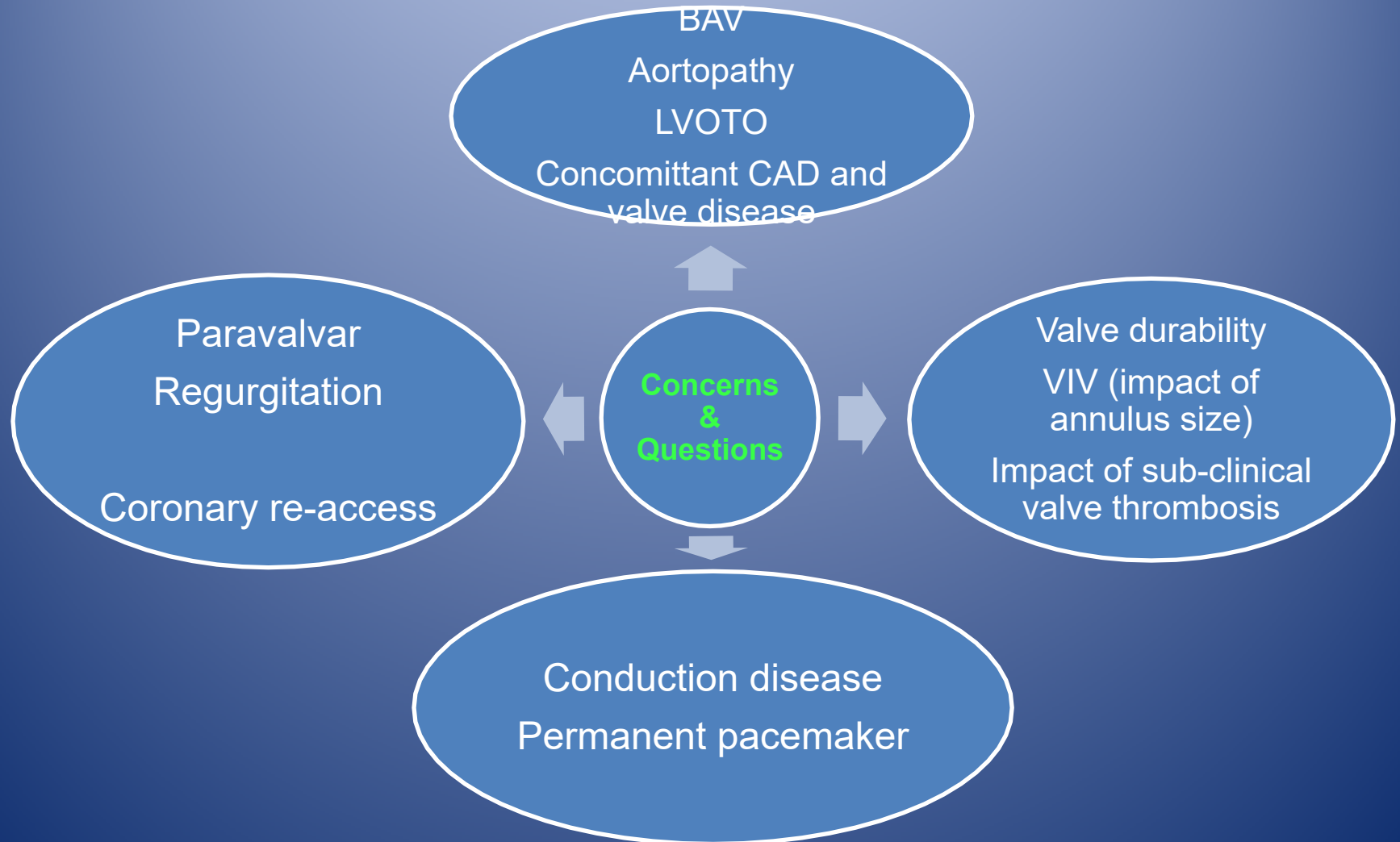
UK National Database

BMJ Open Surgical aortic valve replacement in the era of transcatheter aortic valve implantation: a review of the UK national database

Marjan Jahangiri ,¹ Rajdeep Bilkhu,² Andrew Embleton-Thirsk,³ Hakim-Moulay Dehbi,³ Krishna Mani,¹ Jon Anderson,⁴ Vassilios Avlonitis,² Max Baghai,⁵ Inderpaul Birdi,⁶ Karen Booth,⁷ Amal Bose,⁸ Norman Briffa,⁹ Keith Buchan,¹⁰ Sunil Bhudia,¹¹ Alex Cale,¹² Indu Deglurkar,¹³ Shakil Farid,¹⁴ Leonidas Hadjinikolaou,¹⁵ Martin Jarvis,¹⁶ Seyed Hossein Javadpour,¹⁷ Reubendra Jeganathan,¹⁸ Manoj Kuduvalli,¹⁹ Kulvinder Lall,²⁰ Jorge Mascaro,²¹ Dheeraj Mehta,¹³ Sunil Ohri,²² Prakash Punjabi,⁴ Rajamiyer Venkateswaran,²³ Paul Ridley,²⁴ Christopher Satur,²⁴ Serban Stoica,²⁵ Uday Trivedi,²⁶ Afzal Zaidi,²⁷ Patrick Yiu,²⁸ Narain Moorjani,²⁹ Simon Kendall,³⁰ Nick Freemantle³¹

- 2013-2018
- N= 31277
- All SAVR and SAVR+CABG, consecutive
- Elective, urgent and emergency operations
- **Overall SAVR mortality = 1.9%**
- **SAVR + CABG mortality = 2.4%**

Expansion of TAVI to low risk younger patients



Universal adoption of TAVI to intermediate-low risk patients?

- **Increase in TAVI activity to deal with NHS back log**

BMJ Open. Jun 16 2022;12(6)

- There is **NO** mid or long term follow-up in the UK
- FDA in US collecting data up to 10 years after TAVI
- Must consider mechanical valve

Thank you for your attention

