TCTAP 2022

The TAVI Patient Journey from Admission to Discharge

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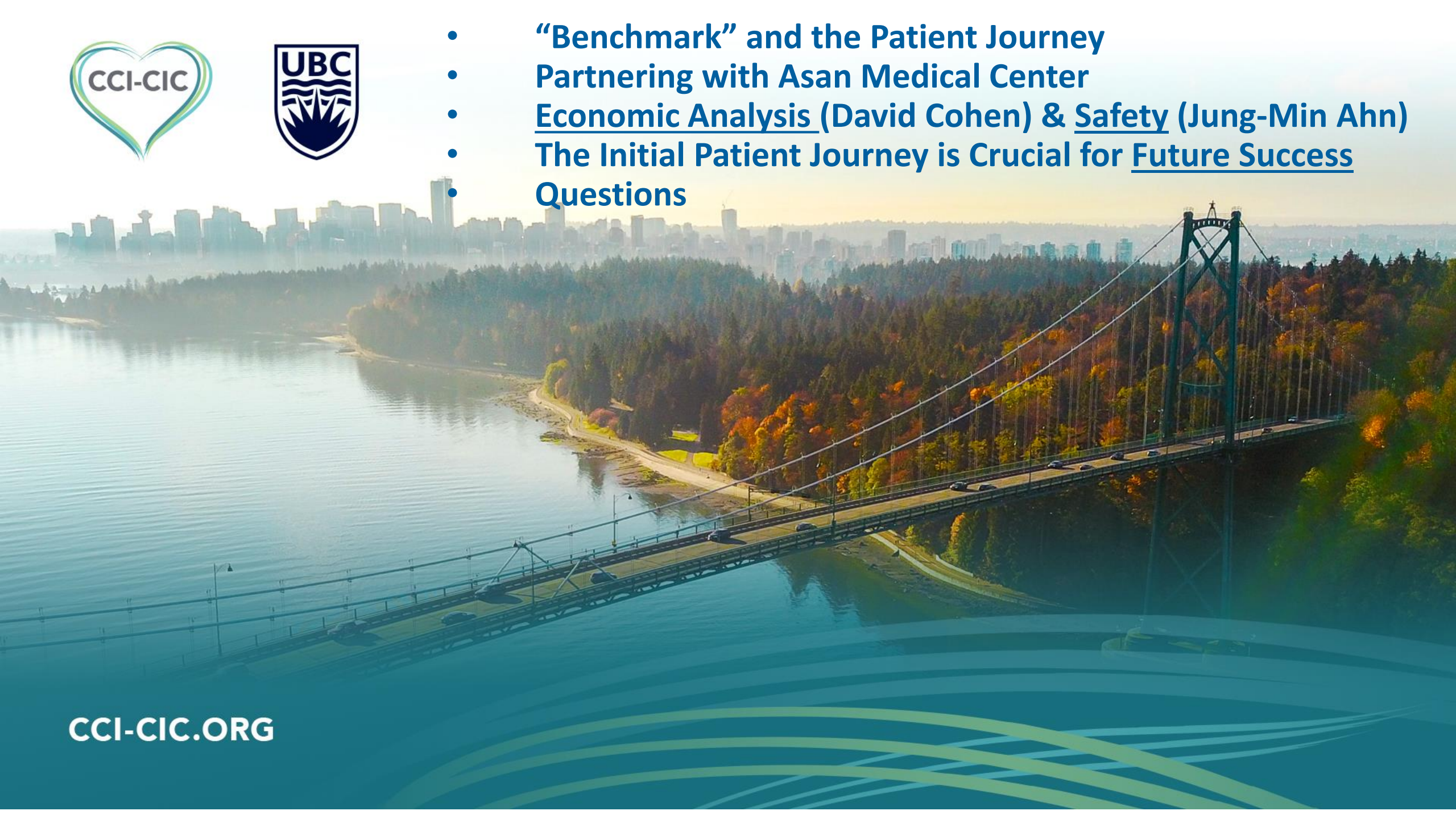
Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest, arrangement or affiliation with the organization(s) listed below.

- Dr. Wood is a consultant to Edwards Lifesciences, Medtronic, Boston Scientific, and Abbott and has received unrestricted grant support from Edwards Lifesciences, Medtronic and Abbott.

- "Benchmark" and the Patient Journey
- Partnering with Asan Medical Center
- Economic Analysis (David Cohen) & Safety (Jung-Min Ahn)
- The Initial Patient Journey is Crucial for Future Success
- Questions



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Benchmark

Transcatheter Valve Care Pathway

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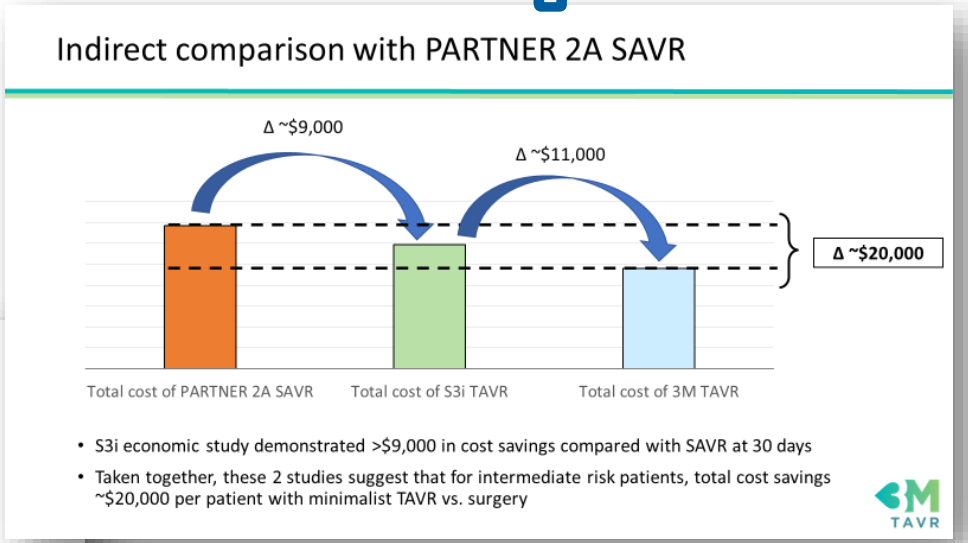
Safety/Efficacy

QOL

Cost Savings



› Cardiovasc Revasc Med. 2020 Dec;21(12):1573-1578. doi: 10.1016/j.carrev.2020.05.044. Epub 2020 Jun 3.

Very Early Changes in Quality of Life After Transcatheter Aortic Valve Replacement: Results From the 3M TAVR Trial

Sandra B Lauck [1], Suzanne V Arnold [2], Britt Borregaard [3], Janarthanan Sathananthan [4], Karin H Humphries [5], Suzanne J Baron [6], Harindra C Wijeysundera [7], Anita Asgar [8], Robert Welsh [9], James L Velianou [10], John G Webb [11], David A Wood [4], David J Cohen [12], 3M TAVR Investigators

The Vancouver 3M (Multidisciplinary, Multimodality, But Minimalist) Clinical Pathway Facilitates Safe Next-Day Discharge Home at Low-, Medium-, and High-Volume Transfemoral Transcatheter Aortic Valve Replacement Centers: The 3M TAVR Study

Focus On Transcatheter Aortic Valve Replacement And Vascular Access

David A. Wood, Sandra B. Lauck, John A. Cairns, Karin H. Humphries, Richard Cook, Robert Welsh, Jonathon Leipsic, Philippe Genereux, Robert Moss, John Jue, Philipp Blanke, Anson Cheung, Jian Ye, Danny Dvir, Hamed Umedaly, Rael Klein, Kevin Rondi, Rohan Poulter, Dion Stub, Marco Barbanti, Peter Fahmy, Nay Htun, Dale Murdoch, Roshan Prakash, Madeleine Barker, Kevin Nickel, Jay Thakkar, Janarthanan Sathananthan, Ben Tyrell, Faisal Al-Qoofi, James L. Velianou, Madhu K. Natarajan, Harindra C. Wijeysundera, Sam Radhakrishnan, Eric Horlick, Mark Osten, Christopher Buller, Mark Peterson, Anita Asgar, Donald Palisaitis, Jean-Bernard Masson, Susheel Kodali, Tamim Nazif, Vinod Thourani, Vasilis C. Babaliaros, David J. Cohen, Julie E. Park, Martin B. Leon, and John G. Webb SEE FEWER AUTHORS

J Am Coll Cardiol Intv. 2019 Mar, 12 (5) 459–469

By utilizing the full set of Best Practices, excellent patient outcomes can be achieved:

TARGET

1%	1%	1.5%	6%	4%	80%
30-day Mortality[2]	30-day Stroke[2]	30-day Major Vascular Complications[1]	30-day Permanent Pacemaker[3]	30-day Cardiovascular Readmissions[2]	Next Day Discharge Home[3]

Benchmark Update

US

65 US Faculty

73 Centres

Tremendous teamwork and collaboration

OUS

> 100 Centres with 28 Centres in the Benchmark Registry

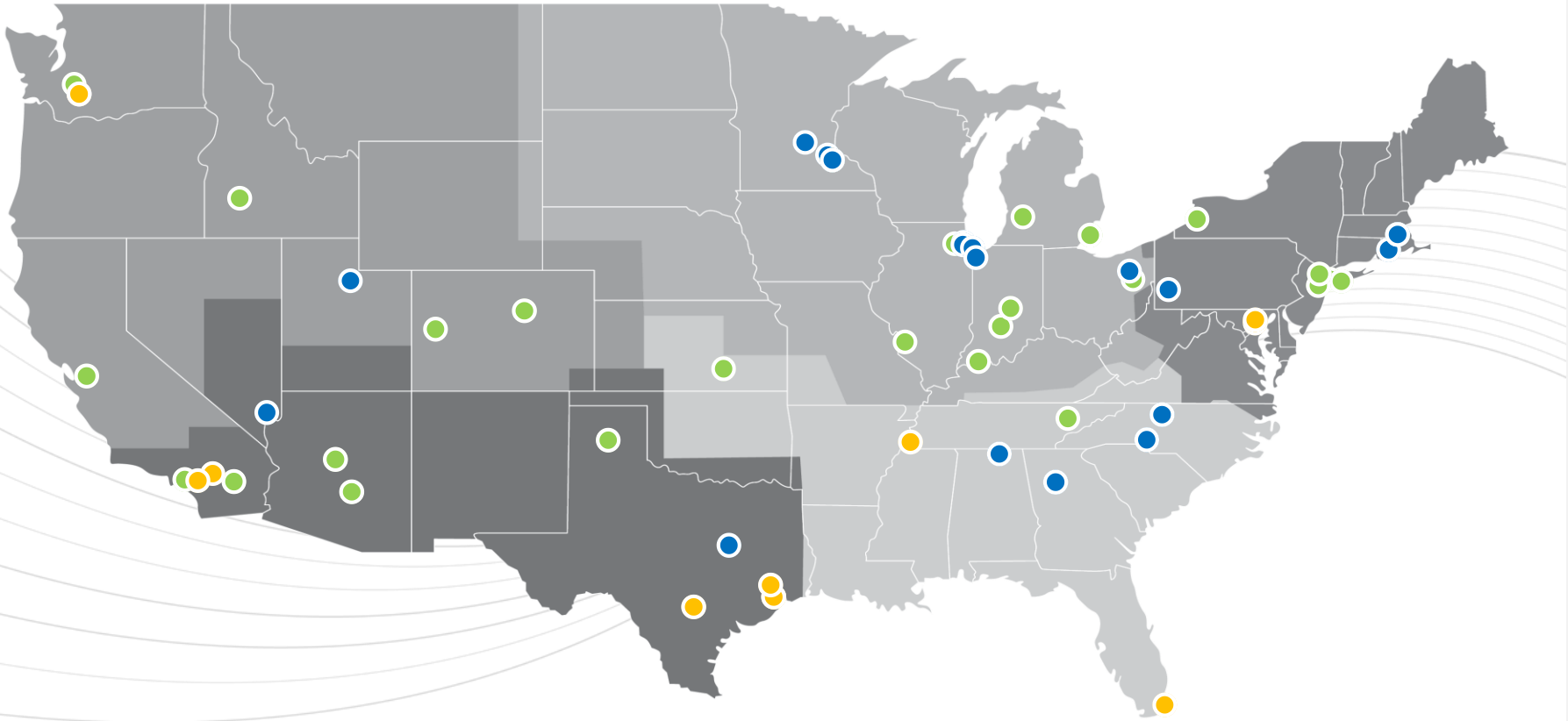
Fabulous collaboration and momentum

CCI-CIC

Centre for Cardiovascular Innovation

Centre d'Innovation Cardiovasculaire

US – Edwards Benchmark Program



Accounts per Area

- Pipeline
- Active
- Complete

30 Active Accounts in Varying Degrees of Deployment
+
10 Pipeline Accounts
+
22 Complete Accounts
=
62 Total Accounts

ACTIVE (30)
Aultman Hospital
Ascension St. John Medical Ctr. (Detroit)
Baptist Memorial Hospital
Barnes Jewish Hospital
BSA – Amarillo
Deaconess Gateway
Eisenhower Hospital
Indiana University Health
Methodist West
Munson Medical
Northwell Health – Lenox Hill
Northwell Health – North Shore
Northwell Health – South Shore
Northwell Health – Staten Island
Northwest Community Healthcare
Sherman Hospital
Stanford Health
St. Anthony Hospital
St. Bernardine
St. Joseph Medical Ctr.(Tacoma)
St. Joseph Hospital-Orange (Orange, CA)
St. Michael Medical Ctr.
Torrance Hospital
University of Maryland Med Ctr.
University of Maryland-St. Joseph's
University of Tennessee at Knoxville
University of Utah
The Valley Hospital
Via Christi
Yavapai Regional Medical Center

PIPELINE (10)
Memorial Hermann Memorial City Hospital
St. Luke's Woodlands
Westmorland Hospital
UHS San Antonio
Memorial Regional (Florida)
Loma Linda University Medical Ctr.
St. Mary's Medical Center
UMass Memorial Healthcare
Tacoma General
Orlando Regional Medical Center

Microsoft Teams

31:30

Request control

Leave

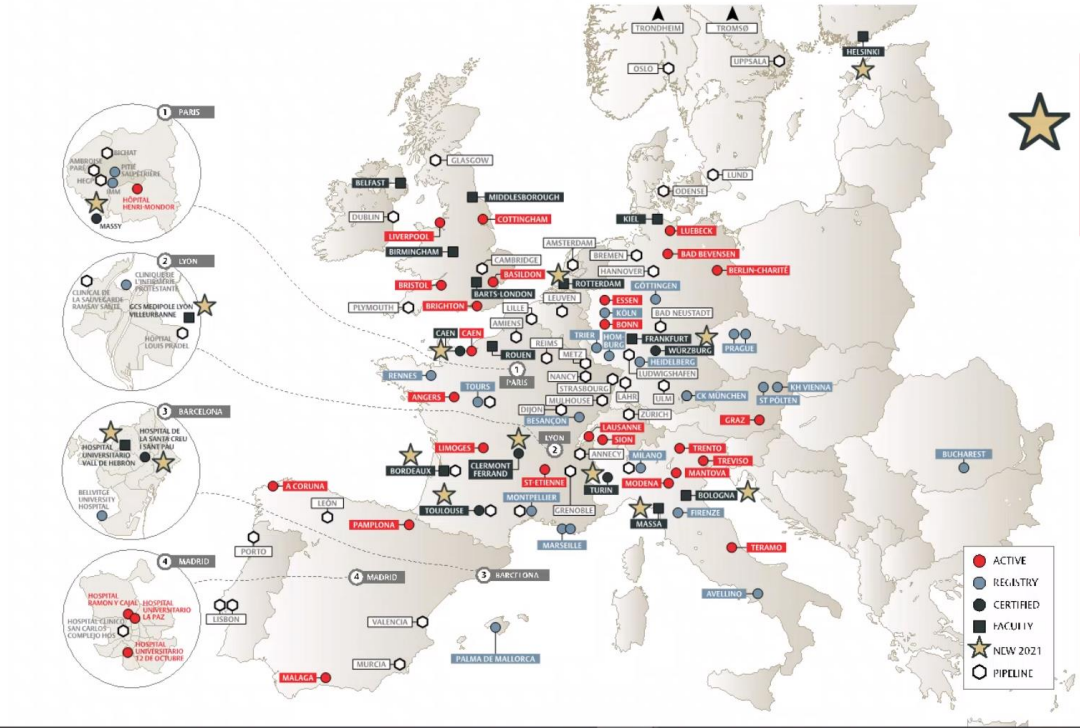
SL

Sandra Lauc...

+15

Edwards Lifesciences

Benchmark Program Deployment YTD



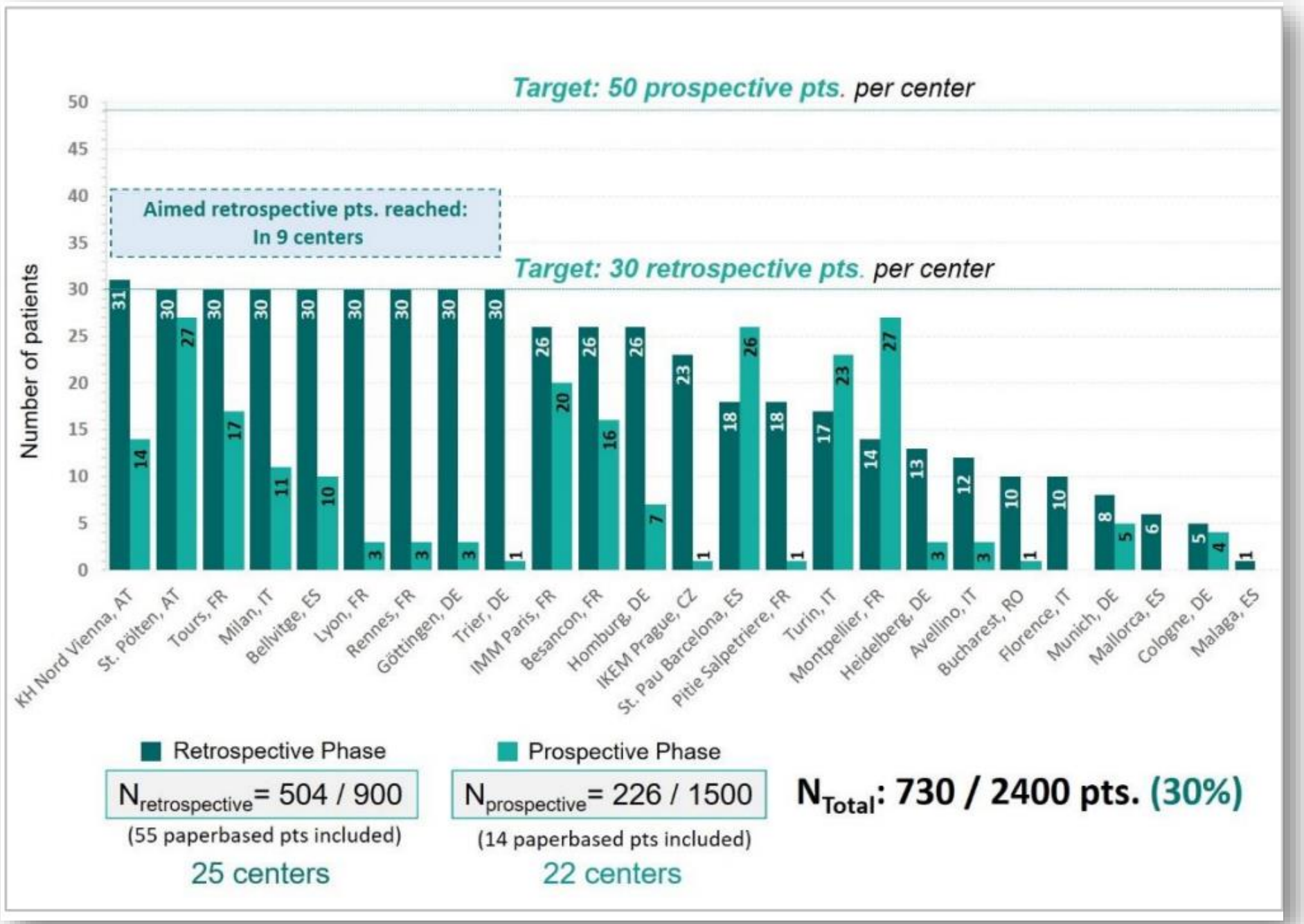
Latest certified centers :

- Vall de Hebron – Barcelona (Faculty)
- Torino (Registry)
- San-Pau- Barcelona (Registry)
- Würzburg
- Erasmus, Rotterdam (Faculty)

21 completed centers
Went through the full program

54 active centers
Confirmed registry centers or active on the digital platform

51 pipeline centers
Targeted and not yet on the platform / confirmed


Target: 50 prospective pts. per center
Aimed retrospective pts. reached:
In 9 centers
Target: 30 retrospective pts. per center
Number of patients
0
5
10
15
20
25
30
35
40
45
50
31
14
30
27
30
17
30
11
30
10
30
3
30
3
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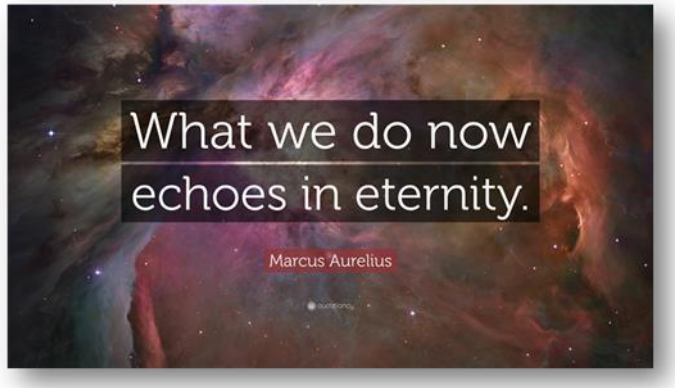
26
18
1
17
23
14
27
13
3
12
3
10
1
10
8
5
6
5
4
1
KH Nord Vienna, AT
St. Pölten, AT
Tours, FR
Milan, IT
Bellvitge, ES
Lyon, FR
Rennes, FR
Göttingen, DE
Trier, DE
IMM Paris, FR
Besancon, FR
Homburg, DE
IKEM Prague, CZ
St. Pau Barcelona, ES
Pitie Salpetriere, FR
Turin, IT
Montpellier, FR
Heidelberg, DE
Avellino, IT
Bucharest, RO
Florence, IT
Munich, DE
Mallorca, ES
Cologne, DE
Malaga, ES
Retrospective Phase
Prospective Phase
N retrospective = 504 / 900
(55 paperbased pts included)
25 centers
N prospective = 226 / 1500
(14 paperbased pts included)
22 centers
N Total: 730 / 2400 pts. (30%)

The Initial Patient Journey is Crucial for Future Success

- THV in THV likely 30,000 – 50,000 cases per year by 2032
- Lifetime management of severe symptomatic AS and when/if to treat concomitant CAD and when/if to perform repeat TAVR are both crucial unresolved questions in SHD



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Centre d'Innovation Cardiovasculaire

UBC

Prospective Data…

COMPLETE TAVR

ClinicalTrials.gov Identifier NCT04634240

DISCORDANCE TAVR

ClinicalTrials.gov Identifier NCT04827238

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- John A Cairns MD (SCC)
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- John G Webb MD (Co-PI)
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- Shamir Mehta MD
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- Azeem Latib MD
- Amr Abbas MD
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SYMPTOMATIC AS PATIENTS with at least 1 coronary artery lesion in a native segment that is **≥ 2.5 mm** in diameter with a **≥ 70%** visual angiographic* stenosis AND Heart Team Consensus they are suitable for transfemoral TAVR and would receive a bypass if they were undergoing elective SAVR

*CT, Echo, Hemodynamic, and Angiographic Core Labs

COMPLETE TAVR

SUCCESSFUL TF TAVR WITH A BALLOON EXPANDABLE THV
STANDARDIZED INVASIVE HEMODYNAMICS (SIH) WITH ON-TABLE TTE

RANDOMIZATION within 96 hours
and Stratified for Intended Timing of PCI and Requirement for OAC:

COMPLETE REVASCULARIZATION	**MEDICAL THERAPY**
Staged PCI of all lesions (1 – 45 days post TAVR)	Guideline-directed medical therapy alone
Goal of complete revascularization of all qualifying lesions	No revascularization
N=2000	N=2000
Antithrombotic Therapy	
DAPT for 1-6 months (ASA + clopidogrel preferred), then SAPT lifelong (ASA preferred)	SAPT lifelong (ASA preferred)
If Requirement for OAC (usually AF)	
Guideline-directed DOAC † + SAPT for 1-6 months then guideline-directed DOAC therapy alone lifelong	Guideline-directed DOAC therapy † lifelong

†See supplementary antithrombotic guidance document

MEDIAN FOLLOW-UP: 3.5 YEARS
(REPEAT SIH WITH ON-TABLE TTE IF ≥ MODERATE VARC-3 HEMODYNAMIC VALVE DETERIORATION **OR** MG ≥ 20 MMHG ON ANY FOLLOW-UP TTE > 1 MONTH POST TAVR

PRIMARY OUTCOME: Composite of CV Death, New MI, Ischemia-Driven Revascularization, or Hospitalization for Unstable Angina or for Heart Failure
KEY SECONDARY OUTCOMES: CV death or new MI, Transaortic gradients post TAVR (echocardiographically-derived vs. direct invasive measurement)
SECONDARY OUTCOMES: Hemodynamic variables obtained with SIH and TTE, Each component of the primary outcome, Angina Status, All-cause Mortality, Stroke, Cost-effectiveness, QOL, Bleeding, Contrast Associated Acute Kidney Injury, Fluoroscopic Time/Contrast Utilization for Staged PCI

2021 PCR london valves

Standardized Invasive Hemodynamics for Monitoring Acute and Long-term Valve Performance: The **DISCORDANCE TAVR** Study

David Wood MD (PI) and Amr Abbas MD (Co-PI)

on behalf of the DISCORDANCE TAVR Investigators

(Clinicaltrials.gov NCT04827238)

Late Breaking Trial

Nov 21, 2021

9:08 – 9:16 am GMT

Simultaneous Publication
Circulation Cardiovascular Interventions Nov 21, 2021

Circulation: Cardiovascular Interventions

RESEARCH LETTER

Standardized Invasive Hemodynamics for Management of Patients With Elevated Echocardiographic Gradients Post-Transcatheter Aortic Valve Replacement at Midterm Follow-Up

Madeleine Barker, MD; Amr E. Abbas, MD; John G. Webb, MD; Philippe Pibarot, MD; Janarthanan Sathananthan, MBChB, MPH; Nathan Brunner, MD; Dee Dee Wang, MD; Jia Wang, MSc; Martin B. Leon, MD; David A. Wood, MD

The Valve Academic Research Consortium-3 (VARC-3) proposes a multiparameter echocardiographic-derived approach for structural valve degeneration of transcatheter heart valves (THVs).[1] In clinical practice, physicians may be guided by mean gradient (MG) alone to suspect structural valve degeneration.[1,2] Several reports have demonstrated discordance between echocardiography-derived and direct invasive measurement of MG immediately post-TAVR, with lower gradients observed with invasive measures, attributed to limitations of the Bernoulli equation and impact of pressure recovery.[3] The role of invasive hemodynamics for the assessment of elevated echocardiography-derived MGs at midterm follow-up post-TAVR is unknown and may have important implications.

This prospective pilot study compared echocardiographic and invasive transaortic MGs in patients who met the VARC-3 criteria for ≥stage 2 (moderate) hemodynamic valve deterioration (HVD) or a MG ≥20 mm Hg on any follow-up transthoracic echocardiogram (TTE) >1 month post-TAVR. All eligible patients underwent standardized invasive hemodynamic (SIH) testing with a simultaneous on-table TTE. Before SIH, all patients had computed tomography to exclude hypoattenuated leaflet thickening or thrombosis. This study was approved by the institutional review board, and procedures followed were in accordance with institutional guidelines. The data to support the findings of this study are available from the corresponding author upon reasonable request.

SIH is performed as follows: two 6F pigtail catheters were positioned in the ascending aorta to assess for pressure tracings quality and difference. One pigtail catheter was then advanced across the THV and positioned as deep in the left ventricular cavity. The proximal pigtail catheter was positioned at the origin of the transverse arch to obtain a gradient across the aortic valve and eliminate the impact of pressure recovery (average of 3 measurements). An on-table TTE was done concurrently. All hemodynamic tracings were reviewed by 2 independent readers at the CCI-CIC Hemodynamic Core Lab using the Mac-Lab software (GE Healthcare).

Between July 2020 and January 2021, 13 patients with an echocardiographic MG ≥20 mm Hg on follow-up post-TAVR (2–39 months; median, 19.2 months) and 5 of whom with ≥stage-2 VARC-3 HVD underwent SIH and simultaneous on-table TTE. All 13 patients had Sapien 3 THVs, and 4 patients had undergone valve-in-valve TAVR in failed surgical bioprostheses. Mean (SD) difference between on-table echocardiographic and invasive MG was 6.1±5.6 mm Hg (P=0.002; paired t test). When compared with invasive MG, the follow-up TTE MG was also significantly higher with mean (SD) difference of 11.5±8.4 mm Hg (P<0.001, paired t test). The Bland-Altman plot demonstrates a wide limit of agreement, indicating that echocardiography and direct invasive MG measurements are not interchangeable with no detectable trend between the difference and magnitude of the measured

Key Words: echocardiography ■ follow-up studies ■ heart valves ■ physicians ■ transcatheter aortic valve replacement

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For Sources of Funding and Disclosures, see page XXX.

Circulation: Cardiovascular Interventions is available at www.ahajournals.org/journal/circinterventions

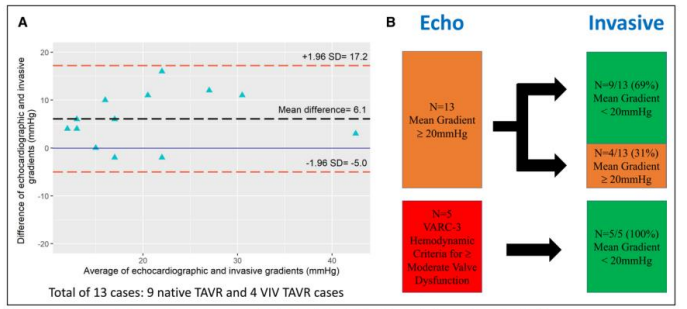

Figure. Discordance between echocardiography (echo) and standardized invasive hemodynamics (SIH).
A, Bland-Altman plot between echo-derived and direct invasive measures of transaortic valve gradients post-transcatheter aortic valve replacement (TAVR). A positive value indicates a higher gradient using on-table transthoracic echocardiogram compared with SIH. **B**, Using SIH instead of echo-derived gradients, 9 (69.2%) patients now had a mean transaortic gradient <20 mm Hg. All 5 patients who met Valve Academic Research Consortium-3 (VARC-3) hemodynamic criteria for ≥moderate valve dysfunction were not found to have hemodynamic valve deterioration (HVD) by invasive measurement. VIV indicates valve-in-valve.

value (Figure [A]). SIH is an additive tool in the setting of elevated echocardiography-derived MG on follow-up after TAVR, 9 (69.2%) patients had an MG <20 mm Hg, and all 5 patients who met the VARC-3 criteria for ≥stage 2 HVD had an invasive MG <20 mm Hg (Figure [B]).

This is the first hemodynamic core laboratory adjudicated prospective study using a standardized, reproducible protocol to measure invasive MG, which demonstrated a significant discordance between echocardiographic and invasive MGs at follow-up after TAVR. Importantly, all patients who met the VARC-3 criteria for ≥stage 2 HVD by echocardiography were not found to have HVD by invasive measurement, thus possibly avoiding unnecessary valvular reintervention. This study demonstrates the additive role of SIH in patients with echocardiographic structural valve degeneration post-TAVR and may help guide the assessment of THV function. The role of invasive hemodynamics and a comparison of echocardiography-calculated and invasively measured pressure recovery, defined by the difference between MG 1 cm above the THV frame and at the origin of the transverse arch, will be further investigated in the larger prospective multicenter DISCORDANCE TAVR study (Standardized Invasive Hemodynamics for Monitoring Acute and Long-Term Valve Performance in Patients With Elevated Gradients Post-Transcatheter Aortic Valve Replacement: The DISCORDANCE TAVR Study; https://www.clinicaltrials.gov; unique identifier: NCT04827238) in patients who meet the VARC-3 criteria for ≥stage 2 HVD.

ARTICLE INFORMATION

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None.

Disclosures
Drs Abbas and Brunner are consultants to Edwards Lifesciences. Dr Abbas has received research grants from Edwards Lifesciences. J. Sathananthan, Dr Webb, and Dr Wood are consultants to and receive unrestricted grant support from Edwards Lifesciences, Abbott, and Medtronic. The other authors report no conflicts.

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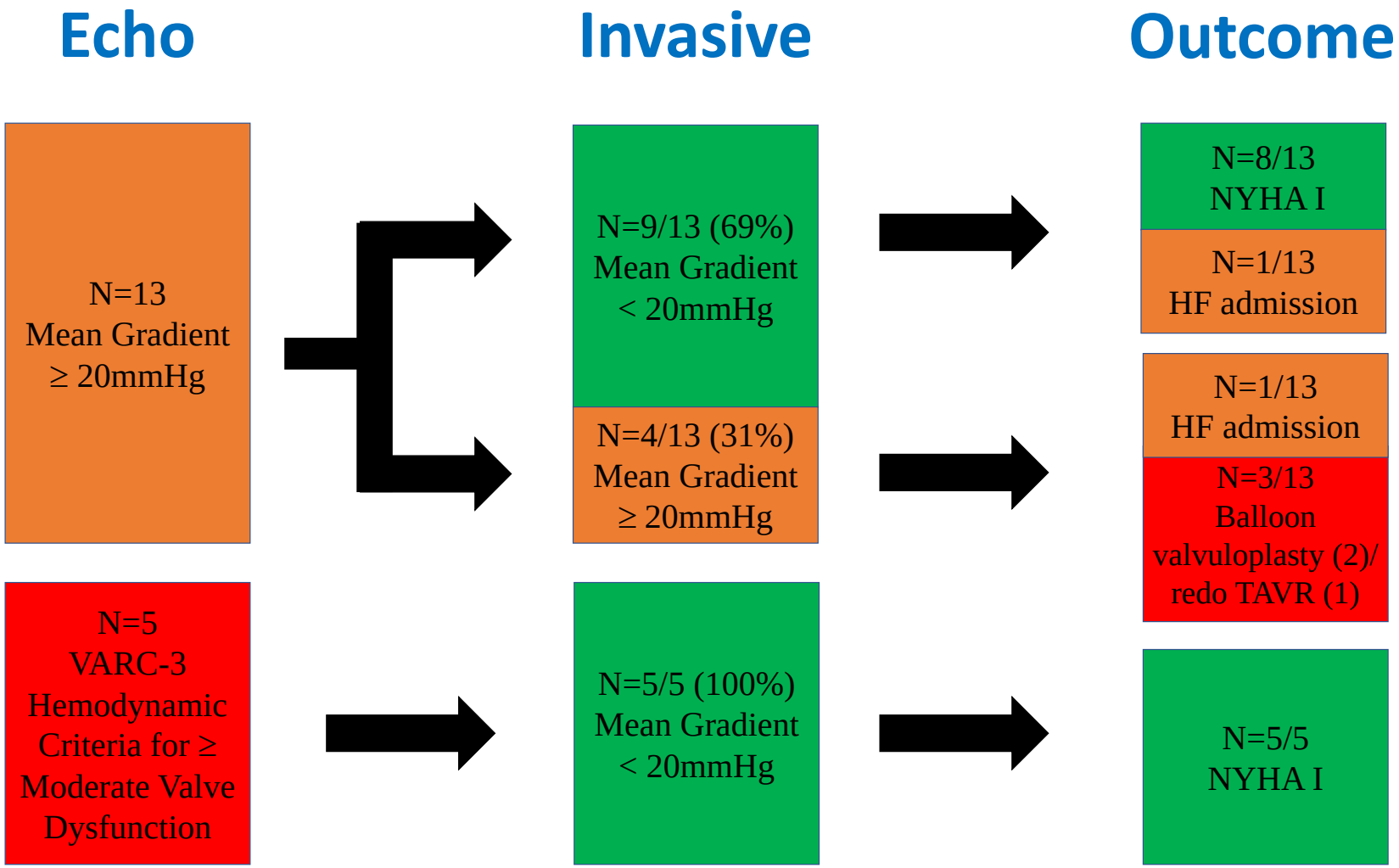
2. Abbas AE, Mando R, Hanzel G, Gallagher M, Safian R, Hanson I, Almany S, Pibarot P, Dalal P, Vivacqua A, et al. Invasive versus echocardiographic evaluation of transvalvular gradients immediately post-transcatheter aortic valve replacement. *Circ Cardiovasc Interv*. 2019;12:e007973. doi: 10.1161/CIRCINTERVENTIONS.119.007973
3. Abbas AE, Mando R, Hanzel G, Goldstein J, Shannon F, Pibarot P. Hemodynamic principles of prosthetic aortic valve evaluation in the transcatheter aortic valve replacement era. *Echocardiography*. 2020;37:738–757. doi: 10.1111/echo.14663

Barker et al. Circulation Cardiovascular Interventions. Nov 21, 2021.

Post SIH Outcomes



Conclusions

- Summarize the most important points of your lecture (24pt / Arial)

Thank You!

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