MHIF FEATURED STUDY:  
Half Moon

**CONDITION:** Moderately severe or severe MR  
PI: Paul Sorajja, MD  
RESEARCH CONTACT: Sara Olson  
Sara.Olson@alina.com | 612-863-7801  
SPONSOR: Half Moon Medical

**DESCRIPTION:**  
*Purpose:* to evaluate the safety and performance of the Half Moon Transcatheter Mitral Valve Repair (TMVr) system in patients with severe, symptomatic mitral regurgitation, who are at high risk for conventional mitral valve surgery.  
*Primary endpoint:* survival, free of stroke and any cardiovascular hospitalization at 5 years; MR < mild at 30 days; QOL improvement at 5 years compared to baseline; hospital length of stay; rate of mitral valve replacement at index procedure

**CRITERIA LIST/ QUALIFICATIONS:**  
*Inclusion:* moderately severe or severe MR; symptomatic NHYA class II, III, or IV; high risk for mitral valve surgery; suitable anatomy for transfemoral transeptal access  
*Exclusion:* LVEF <25%; Severe MAC, severe TR, anterior flail or prolapse; valve anatomy which would preclude reducing MR to mild or less; severe RV dysfunction

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MHIF FEATURED STUDY:  
REPAIR-MR

**CONDITION:** Severe primary MR who are at moderate surgical risk  
PI: Paul Sorajja, MD  
RESEARCH CONTACT: Jane Fox  
Jane.fox@alina.com | 612-863-6289  
SPONSOR: Abbott

**DESCRIPTION:**  
*Purpose:* to compare the clinical outcome of MitraClip™ device versus open surgical repair in patients with severe primary MR who are at moderate surgical risk.  
*Primary endpoint:* survival, free of stroke and any cardiovascular hospitalization at 2 years; MR < mild at 30 days; QOL improvement of at least 5 points at 2 years compared to baseline; hospital length of stay; rate of mitral valve replacement at index procedure

**CRITERIA LIST/ QUALIFICATIONS:**  
*Inclusion:* severe primary MR (Grade III or greater mitral regurgitation mixed etiology is acceptable if principal mechanism is a degenerative mitral valve); symptomatic NHYA class II, III, or asymptomatic with EF < 60%, PAS >50 mm HG, or LVESD >40 mm; 75 years or if < 75 years subject with STS predicted risk of mortality repair score >2%, or presence of comorbidities  
*Exclusion:* ischemic or non-ischemic secondary MR; EF <30%; severe TR; severe annular calcification; valve anatomy which would preclude reducing MR to mild or less
MHIF FEATURED STUDY:
TAVR UNLOAD

DESCRIPTION:
A multi-center, randomized, open-label, clinical trial comparing the safety and efficacy of TAVR with the Edwards S3 & S3 Ultra and optimal HF treatment versus optimal HF treatment alone in HF patients with moderate AS.

CRITERIA LIST/ QUALIFICATIONS:
Inclusion: Moderate AS; LVEF <50%; NYHA ≥II; NT-proBNP > 900 pg/ML (or BNP >200 pg/mL) or HF hospitalization within 2 years
Exclusion: EF <20%; severe AI or MR; unicuspid/bicuspid aortic valve; severe RV dysfunction; valve anatomy without minimum calcification necessary
Disclosures

- Consultant / Honorarium / Grants/Advisory board
  - Edwards Lifesciences
  - Medtronic Inc
  - Boston Scientific
  - Abbott St Jude
  - 4C
  - Admedus
  - Cardiomech

Beginnings

King Edward Memorial Hospital, Mumbai
- One of the first heart centers in India
- First heart transplant 1969
- Snake Heart operation
- Rockefeller Foundation collaboration
  1986-1998
  Medical school- General Surgery- CVTS
  12 Publications
  Thesis in Valve replacement in young children <12


Journey – Mechanical valve

Tilting Disc

Bjork-Shiley

Bjork-Shiley Monostrut

Chitra TTK

Medtronic Hall tilting disc
Bileaflet valves

St. Jude Medical

Sorin

On-x

Carbomedics

Edwards-Duromedics

Ideal Heart Valve – Ten Commandments

1. Should not block blood flow
2. Closes promptly and completely
3. Nonthrombogenic
4. Resists infection
5. Chemically inert
6. Does not kill cells
7. Easy to permanently implant
8. Allows healing to occur
9. Pleasing to the patient (noise free)
10. Last for a life time

Does not exist
Canada and UK

- Toronto General Hospital
  1999
  Fellowship in adult and adult congenital

- Guys and St. Thomas' hospital
  2000-2006
  National training in UK

St. Thomas’ Hospital, London - 2007
Heart Valve therapy has to evolve

Changing disease pattern

Valve therapy

Life expectancy

Patient Expectations

TAVR beginnings

Alain Cribier: First Transcatheter Aortic Valve Implantation (TAVI) April 16, 2002

April 16, 2002
8 days post implantation

2019 ACC
TAVR changed the landscape

• Way we think and practice cardiac medicine
• Indications broadened – novel applications
• Options bring challenges!

This affected all of us

• 2007 – Young attending in Guys and St Thomas’ London
• Focus on Aortic Surgery
• TAVR concept was introduced
From PVT to S3........

Percutaneous Valve
Cribier Edwards 2003 - 2004
Edwards Sapien 2005 - 2009
Sapien XT 2010- 2014

Days of Embolisations
Leaks
Vascular complications
Apical ruptures
Arrests on table
Mitral valve injuries
Etc.........
Cardiology Perspective
Very exciting!!

Cardiac Surgery Perspective
Are You Serious!!

Heart Team Selection in 2007, London

- Experienced Cardiologist
- Experienced Surgeons

Include Vinnie as
1. He is young and has lot of energy
2. We need someone to run around to sort out logistics
3. These patients won't survive anyway
Training 2007 December

1. Team
2. Business plan for 20 cases for 2008
3. Training – Cardioskills lab in Frankfurt
4. Cases

Cases-timeline

- I slept very well as I was supposed to assist
- In the morning the Senior Surgeon called to say he wont join!
- Proctor had himself done 4 cases only and was more tense than me!
- The case went well!

- Second case two weeks later the Proctor got stuck in traffic and patient became unstable!
- I did the case independently
- I went ahead to teach the other surgeon in our next 2 TA cases
This was the beginning of an incredible journey

• TCT 2008 Live case TA SAPIEN Ascendra 1

• I got introduced to the leaders in TAVR (Physicians and Industry leadership)

Humbling experience

• New therapy
• Inexperience
• Think on the go!
But I learnt slowly that.....

Surgeons are from MARS

Cardiologist are from VENUS

Cardiology Community doesn’t mind sharing complications!
Innovation and research followed

- TAo approach
- Valve-in-Valve
- Crossing valve without BAV
- Valve Designs
- TMVR
- LVOT obstruction in TMVR
- TAVR in MAC
- Commissural alignment in TAVR
- TTVR

Concept of TAVR proof surgical procedures
**T Ao – case 1**

- 88 years old woman
- Severe kyphoscoliosis
- Poor lung function
- Severe aortic stenosis, Annulus 20mm
- Tortuous Aorta & small calibre iliacs

**Case 7**

- Right Pneumonectomy
- COPD, FEV1 – 1.04
- Severe AS, PG 104mm
- Small caliber femoral
- Surgical turn down
African Safari & Dr. Spencer King

December 2011
South Africa

TAo Zone and Use of CT

Myth of Porcelain and aorta and TAo-TAVR

Distribution of calcium in the ascending aorta in patients undergoing transcatheter aortic valve implantation and its relevance to the transaortic approach

Vinayak N Ilapati, Rizwan Q Attia, Martyn Thomas

PMID: 22626183   DOI: 10.1016/j.jcin.2012.03.006
Trans femoral Delivery

- RF1 – No Nosecone
  Large sheath 24 Fr

Modifications

A

RF2

B

RF3

Novoflex

Sheath Size Comparison

18F

22F

RetroFlex 3

Delivery System

Novaflex

Delivery System

MHIF Cardiovascular Grand Rounds | January 18, 2021

33

34
Commander delivery system for S3

Dual articulation for coaxiality even in challenging anatomies

Ikea Method of using Ascendra 1

Started training other centers

Developed better understanding of Echo sizing, Cathlab working
Surgeon Friendly system!

- Greater hemostatic control
- Single-handed push button operation

Certitude delivery system:
TA and TAo approaches
No BAV 2012-2013

First Live case
No BAV retrograde TF
TCT 2013

Expanding Indications

Optimal SHV design

Valve In Valve

3 decades of no anticoagulation
Why not use it to treat failed surgical valves

- Circular shape
- Perfect anchoring
- Good visualization under Xray

VIV

- Avoids redo operation
  - Less trauma
  - Faster recovery
- Easier Procedure
  - Less/no contrast
  - Near Perfect Implant zone

Early results were hit and miss
Reason for that was simple

Lack of knowledge
Lack of information
Rapidly evolving field

Valve-in-Valve

- Started as a distraction from TAo
- Wall charts and image bank
First publication

Catheterization and Cardiovascular Interventions 00:000–000 (2012)

Original Studies


Vinayak Bapat, Izanne Mydin, Sucharitha Chadalavada, Hassan Tehrani, Rizwan Attia, and Martyn Thomas

Each Surgical valve is unique

Appearance
Sizes
Dimensions
Compatibility
Risk of complications
Second publication

MINI-FOCUS: STRUCTURAL  
State-of-the-Art Paper

Effect of Valve Design on the Stent Internal Diameter of a Bioprosthetic Valve

A Concept of True Internal Diameter and Its Implications for the Valve-in-Valve Procedure

Vinayak N. Bapat, MD, Rizwan Attia, MD, Martyn Thomas, MD

London, United Kingdom
Surgical valve dimensions – confusion!

- To choose the right size of TAVI device

![Diagram of valve dimensions]

**Surgical Valve size**

*Label size does not mean same ID*

<table>
<thead>
<tr>
<th>Valve</th>
<th>Nominal size</th>
<th>Stent ID</th>
<th>True ID</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aspire</td>
<td>25</td>
<td>23</td>
<td>21</td>
</tr>
<tr>
<td>CE Standard</td>
<td>25</td>
<td>23</td>
<td>21</td>
</tr>
<tr>
<td>Mitroflow</td>
<td>25</td>
<td>21</td>
<td>21</td>
</tr>
<tr>
<td>Perimount</td>
<td>25</td>
<td>24</td>
<td>23</td>
</tr>
<tr>
<td>Trifecta</td>
<td>25</td>
<td>23</td>
<td>22</td>
</tr>
</tbody>
</table>

**True ID = Stent ID- reduction due to leaflet tissue**
3 Types of Valves – different dimensions, **True ID**

<table>
<thead>
<tr>
<th>Porcine Leaflets Mounted inside</th>
<th>Pericardial Leaflets Mounted inside</th>
<th>Pericardial Leaflets Mounted outside</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1" alt="Porcine Leaflets" /></td>
<td><img src="image2" alt="Pericardial Leaflets" /></td>
<td><img src="image3" alt="Pericardial Leaflets" /></td>
</tr>
<tr>
<td>True ID = Stent ID – 2mm</td>
<td>True ID = Stent ID – 1mm</td>
<td>Stent ID = True ID</td>
</tr>
</tbody>
</table>

Term now Used in ISO standards

**Issues with non ideal placement**

- Too high: embolise
- Too low: higher gradients and sub optimal function
Third publication

Fluoroscopic Guide to an Ideal Implant Position for Sapien XT and CoreValve During a Valve-in-Valve Procedure

Vinnie N. Bapat, FRCS, Rizwan Q. Attia, MRCS, Fortunata Condemi, MD, Ravi Visagam, MBBS, Maya Guthrie, BSc, Shelina Sunni, BSc, Martyn Thomas, FRCP

London, United Kingdom

Ideal Implant definition

- Position where we get the
  1. Best hemodynamics, and
  2. Secure position
Where is the sewing ring?

• Fluoroscopy
  - Sewing ring marker
  - Stent frame marker
  - No marker

Ideal Position

• With Reference to the Neo-annulus = Sewing ring

Sapien 15%
CoreValve 4mm
Portico 4mm
Is sewing ring is the narrowest diameter?


**Neo-annulus: a reference plane in a surgical heart valve to facilitate a valve-in-valve procedure**

Vinayak Bapat 1, Benjamin Adams, Rizwan Attia, Alia Noorani, Martyn Thomas

Affiliations  + expand

PMID: 24975664  DOI: 10.1002/ccd.25586
Defining the Neo-annulus to optimize ‘Ideal position’

Hancock 2

Biocor/Epic

VIV stentless – first publication

Use of balloon expandable transcatheter valves for valve-in-valve implantation in patients with degenerative stentless aortic bioprostheses: Technical considerations and results

Vinayak Bapat 1, William Davies 2, Rizwan Atta 2, Jane Hancock 2, Kirsty Bolter 2, Christopher Young 2, Simon Redwood 2, Martyn Thomas 2

Affiliations  1 expand

PMID: 25037622  DOI: 10.1016/j.jtcs.2014.06.029
Each Transcatheter Valve is also unique

Dissemination of information ...

- Lacking
- Information was available but not readily

- Charts
- Publications
- Emails
Birth of the Valve in Valve App

App build

- APP
- Material & Flow
- Logo
- Funding
- APP developer
- Content
Funding and challenges

Development cost
Photography
Artwork
Logo and color schemes
Heart Valves**
Time!

APP is free and with unbiased content

Logo!
Current Logo – VIV aortic

3D reconstruction of a CT scan of the Hancock 2 On Osirix

How to use the App to plan the procedure
Valve In Valve
(version 2.0)

How to use the App
- First select TAVI or Surgical valve
- Under each section you will find different valves
- Select the valve you want to know the details about
- This page gives you basic information including manufacturer and fluoroscopic appearance
- Now select the valve size you are interested in
- This takes you to the size specific page
- This page gives you important dimensions of the surgical valve
  - ID
  - True ID
  - Height
- Also gives you TAVI valve size of each TAVI device (based on current clinical evidence)
- If there is size overlap two sizes are shown - use larger size TAVI valve if larger sinuses and regurgitant pathology

VIV Mitral APP

Developed in 14 days
Mitral therapy has different challenges

Sizing?

Deployment and Sizing in Mitral

Delayed migration of Sapien valve following a transcatheter mitral valve-in-valve implantation.

Bapat VV, Khaffel F, Ihleberg L.


PMID: 23784983

We report two cases of delayed migration of the Sapien XT device after a successful mitral valve-in-valve (ViV) implantation. ...We discuss possible mechanisms, which could have resulted in the delayed migration and highlight the difference between ViV procedures in ...

Oversizing is crucial
Parallel vs Conical deployment
Mitral VIR

- Shape - Complete/Incomplete/Bands
- Rigidity - Rigid/Semirigid/Flexible
- Radio opacity- good/Intermediate/ none
  - Edwards – 5 rings
  - Medtronic – 6 rings
  - St Jude – 4 rings
  - Sorin – 6 rings
  - Sizes – 24 to 40

Mitral Valve in Ring

- Shape - Complete/Incomplete/Bands
- Rigidity - Rigid/Semirigid/Flexible
- Radio opacity- good/Intermediate/ none
  - Edwards – 5 rings
  - Medtronic – 6 rings
  - St Jude – 4 rings
  - Sorin – 6 rings
  - Sizes – 24 to 40
Risk of LVOTO

Less Chance if AMA angle is obtuse
Greater Chance if AMA angle is less obtuse
Factors influencing left ventricular outflow tract obstruction following a mitral valve-in-valve or valve-in-ring procedure, part 1

Vinnie Bapat 1, Francesco Pirone 3, Stam Kapetanakis 3, Ronak Rajani 1, Steven Niederer 2

Affiliations + expand
PMID: 26386239 DOI: 10.1002/ccd.25928

Valve In Valve Apps

- Correct Patient
- Correct VIV combination
- Correct position

Downloaded in 130 countries
Free Educational guide
Used by everyone in TAVR field

- Publications: > 40
- Presentations: >100
- Trainees, Medical students and Highschool students have published and presented in national and international meetings
Case in Oman – Pregnant patient with 2 failed valves

Double VIV in Oslo

Pulmonary: Freestyle valve
Tricuspid: Hancock 2
Pulmonary VIV – TF system

RF3 – Sapien XT 26

Ascendra plus Sapien XT 29

Taking TAVR to OR
Hybrid Surgery

11 year old patient
1. DORV repair
2. MV Repair
3. MVR – 21 St Jude Mechanical valve

Presented in Pulmonary oedema within one month with thrombosed valve (INR 4)

Plan
Implant a surgical valve but it would be too small

Use 3D memo ring
Implant Supra-annular (in the atrium)
Implant Sapien 3

Size 28 Ring
Sapien 23
Exploited knowledge of Valve-in-Ring Concept

TAVR in MAC beating heart

78 year old
TAVR and TAVR in MAC
Presented with persistent MR
Heavy MAC
Follow up CT at 3 years

THV in Open surgery

Reported results have been excellent compared to TAVI option
Case Example

Considered for TAVI and Sapien in Mitral

High risk of LVOTO

Open AVR-MVR and CABG

AML Excised
Size now was 33

Mitral sutures cutting through

Physio 32 ring sutured
Sapien3 29 implanted
TCT 2020 live case

• Hybrid Mitral VIV case

CSI TAVR and Difficult cases

• This has been the best reward
• Friendships all over the world
• Learning to solve difficult valve issues and find innovative solutions and also find out what went wrong
Cool cases
TR with no options

68 year old
Two prior surgeries
AVR- Mechanical
MVR- Mechanical
Severe TR
Hepatic pre-coma

Sapien in IVC

97

98
Sapien in IVC

Sapien in IVC
New Technology

Transcatheter Mitral Valve replacement

Abbott
Tendyne

Edwards
CardiAQ

Edwards
Fortis

Medtronic
Twelve

Neovasc

Fortis

Intrepid

2014

2015
What about surgery!

Surgeons feel I am a cardiologist

Cardiologist feel I am a surgeon!
IMPACT ON SURGICAL PRACTICE

Use of CT and advance imaging

• TAVI
• Transcatheter Mitral
• Valve in Valve Aortic
• Valve in valve Mitral
• MAC
• LVOTO

• Aortic Valve replacement
• Aortic surgery
• Unusual pathologies
• Peripheral access
• Redo surgery
• Mitral Surgery?
Team building

- Not to work in isolation
- Work with other stake holders
  - Perfusionist
  - Nursing staff
  - Anaesthetist
  - Cardiologist

ART - AVR

- (Anterior Right thoracotomy)
Hybrid approach: miniAVR + PCI

Developing multiple Strategies for Aortic valve disease


AVR full sternotomy  
AVR + full and Hemi sternotomy  
TAVI

• AVR: full sternotomy  
• AVR: MIS  
• AVR + PCI  
• AVR +CABG  
• TAVI  
• TAVI + PCI
Concept of Lifetime management

Single or no Surgery
No anticoagulation
Minimum morbidity

Age of the patient
Life expectancy
Other issues – Coronary, valves etc

A novel surgical bioprosthesis - INSPIRIS

Designed to enable optimal valve-in-valve, if needed.
Technology has limitations
Technology doesn't always work
New Technology may not work as expected

1. International TAVR-Explant Registry
2. International Cutting-Edge registry
3. Educational videos for explant

Current and future challenges

Sequencing

SAVR → VIV → Surgery
SAVR → VIV
TAVR → SAVR → VIV
TAVR → TAVR in TAVR → Surgery
Fun facts

1,225,466 MILES FLOWN
102 DAYS IN THE AIR
76 CITIES VISITED
41 COUNTRIES VISITED
45.1% AROUND THE EQUATOR
Travelled – all continents except Antartica
Round the world trips 7 times
Snow and dessert storms
Trained the Northern most and probably Southernmost TAVR center in world

Friendship and fun
Some things change but most don’t!

Toronto 1999

Toronto 2014

Lost in translation
MASSAGE AT THIS TIME??

Do you have a message for me

Tale of Two cities

New York  London
‘Chance only favours the prepared mind’
- Louis Pasteur
My role has evolved since 2007

- Open Surgery
- Open and TAVR
- Open, Transcatheter and Innovation

TAVR compatible SAVR designs
TAVR compatible Ring designs
Valve fracture advance projects
AI and commissure alignment

It feels like *STAR TREK*

TAVR Travels Lecture 2009