In-vitro investigation of valve-in-valve procedure in mitral position.

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Valve-in-valve an alternative to surgery

Mitral valve surgery:
- Mitral valve repair
- Mitral valve replacement
  - Bioprosthetic
  - Mechanical prosthesis

Prosthesis failure:
- Re-surgery
- Valve-in-valve

In mitral position:
More and more clinical cases
Lowering of criteria
But still no FDA approval
⇒ And no in-vitro testing in heart valve normalization process
Valve-in-valve implantation

Failed bioprosthesis of different manufacturers
No specific design for valve-in-valve procedure:
Transcatheter valves used for aortic

Tested prostheses: Assemblies

- 5 models - 3 manufacturers
- 2 SAPIEN sizes: 23 and 26mm

Test protocols:

- SAPIEN alone
- Surgical valve alone
- Assemblies

Problematics:

Which size of SAPIEN in which surgical valve?
Influence of bioprosthesis design?
⇒ What does the hemodynamic say?
Methods: in-vitro test system

Pulsed duplicator

Pressure-volume loop validation.


Duplicator specificity:

- Anatomically shaped LA
- Double activation
In-vitro test system
In-vitro acquisitions

Testing conditions:

- Stroke volume: 70 and 90 mL
- E/A ratio: 0.5, 1.0 and 1.5
- Heart rate: 45, 70 and 120 bpm
- Pao mean: 40, 100 and 180 mmHg
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Acquisition:
- Electromagnetic flowmeter
- Millar pressure catheter
- Philips HDI 5000 echographic system
- CCD camera calibrated
**In-vitro acquisitions**

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**Regurgitant volumes:**
- Closing volume (CV)
- Leakage volume (LV)
- Regurgitant fraction (RF)

\[ RF = \frac{CV + LV}{SV} \]
Valve-in-valve: Protocole

Bioprosthetic design type:

- Coaptation
- Sewing ring
- Commisures
- Leaflets
- Posts
- Suture ring
- Internal diameter
- External diameter

Internal diameter measurements:

<table>
<thead>
<tr>
<th>Location</th>
<th>Measurement</th>
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<tbody>
<tr>
<td>A</td>
<td>20.5mm</td>
</tr>
<tr>
<td>B</td>
<td>23.32mm</td>
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<tr>
<td>C: ID</td>
<td>25mm</td>
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Edwards Magna 7000

Transcatheter prosthesis size:

- SAPIEN 23: 22mm > 20mm
- SAPIEN 26: 25mm > 23mm
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Porcine vs pericardic:

Testing configurations:

- Prosthesis orientation
- Prosthesis location
- Deployment: 8 bar

GIBoc
Aix-Marseille University
M. EVIN October 9, 2013
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Testing configurations:
Mitral bioprosthesis assessment

Doppler echocardiography:
- Continuous wave
- Pulsed wave

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Valve-in-valve: SAPIEN 23 vs 26

SAPIEN 23 vs 26:
- Epic 27 and 29mm
- Mosaïc 27 and 29mm

Results RF: Decreases
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Results TPG: Constant or decreases
Results EOA: Constant or increase

Consequences:
- Benefic for Epic and Mosaic 29mm
- Negative for Epic 27mm
Valve-in-valve: Model Design

Regurgitation:
- Min Magna 25mm
- Max Epic 29mm
Valve-in-valve: Model Design

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Edwards Magna 25mm
St Jude Epic 29mm
Medtronic Mosaïc 29mm

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Valve-in-valve: Model Design

![Image showing valve-in-valve model designs and data distributions for Edwards Magna 25mm, St Jude Epic 29mm, and Medtronic Mosaïc 29mm. The graph illustrates EOA (cm²) with box plots and a comparison of regurgitation for Min Magna 25mm and Max Epic 29mm.]
Valve-in-valve: Model Design

- Edwards Magna 25mm
- St Jude Epic 29mm
- Medtronic Mosaïc 29mm

Regurgitation:
- Min Magna 25mm
- Max Epic 29mm

EOA:
- Min Mosaïc 29mm
Conclusion & perspectives

Influences of hemodynamics results:

- Surgical valve design
- Central or peri-valvular regurgitations
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Recommendations for VinV assemblies:

- Adjusted size: Real diameter or -10% manufacturer diam.
- Oversize carefully
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Specific design for VinV:

- Optimize coaptation + suppress regurgitations
  ⇒ More diameter + coat
- Radio-opac mark
- For all designs of prosthesis
- Solve presence of calcifications
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Recommendations for VinV assemblies:
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Clinical consequences:
- Reference values for assessment
- Careful overestimation
- SAPIEN size selection
- Bioprosthesis choice for future VinV

Specific design for VinV:
- Optimize coaptation + suppress regurgitations
  ⇒ More diameter + coat
- Radio-opac mark
- For all designs of prosthesis
- Solve presence of calcifications
Thank you for your time!

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Mitral bioprostheses assessment

Effective orifice area (EOA):

- Area formed by the flow after the available orifice of the prosthesis.

EOA by continuity equation:

\[
\int_{\text{diast}} \frac{V_{\text{Vol.GOA}}}{V_{\text{it.Fluide}}} = \frac{SV}{VTT}
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Indexed EOA
\[ EOAi = \frac{EOA}{BSA} \]

BSA: body surface area
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Patient-prosthesis mismatch

EOA reference values
Mitral bioprostheses assessment

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EOA reference values

Transvalvular pressure gradient (TPG):
- Bernoulli equation simplified at each point of selected VTI
\[ p_1 - p_2 = \frac{1}{2} \rho (v_2^2 - v_1^2) \]
- Averaged on diastole
Valve-in-valve: Regurgitation

RF for SAPIEN 23:
- SAPIEN alone
- Bioprosthesis alone
- Assemblies
Valve-in-valve: Regurgitation

RF for SAPIEN 23:
- SAPIEN alone
- Bioprosthesis alone
- Assemblies

RF for SAPIEN 23:
- St Jude Epic 29mm
- Not only IOA
Valve-in-valve: Regurgitation

RF for SAPIEN 23:
- SAPIEN alone
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RF for SAPIEN 26:
- Pericardic: CEP
- Porcine: Epic
Valve-in-valve: EOAi

EOAi for SAPIEN 23:
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Valve-in-valve: EOAi

EOAi for SAPIEN 23:
- SAPIEN alone
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EOAi for SAPIEN 23:
- St Jude Epic 25mm
- Raise of EOAi

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EOAi for SAPIEN 26:
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Valve-in-valve: EOAi

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EOAi for SAPIEN 23:
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EOAi for SAPIEN 26:
- Same results
- SAPIEN alone

EOAi for SAPIEN 23:
- SAPIEN alone

EOAi for SAPIEN 23:
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- Raise of EOAi

EOAi for SAPIEN 26:
- Same results
- SAPIEN alone
Valve-in-valve: TPG

TPG SAPIEN 23:
- TPG SAPIEN
- TPG surgical prosthesis
- TPG assemblies
Valve-in-valve: TPG

TPG SAPIEN 23:
- TPG SAPIEN
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- TPG assemblies

Results SAPIEN 23:
- Slightly decreases
- Leaflet opening
- 5mmHg threshold
Valve-in-valve: TPG

TPG SAPIEN 23:
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- TPG surgical prosthesis
- TPG assemblies

Results SAPIEN 23:
- Slightly decreases
- Leaflet opening
- 5mmHg threshold

⇒ TPG SAPIEN 26:
- No critical values
- Same results except
  - Epic 27mm