Infectious complications of new cardiovascular devices

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Disclosure of potential conflicts of interest

Emanuele Durante Mangoni, MD PhD

- My Institution has received research funding for my group from MSD, Pfizer
- I have received personal fees or participated in advisory boards or have been in the speaker’s bureau of Pfizer, MSD, Angelini, Bio-Merieux, Abbvie, Sanofi-Aventis, Medtronic, and DiaSorin.
Heart Failure Epidemic

2% of people affected, worldwide
10% over 70 yrs

Spread of CV risk factors
Better care of Myocardial Infarction
Efficacy of HF drugs

Constant rise in incidence
Increasing placement of Intracardiac Devices

PMK

AICD

CRT-D/P
Increasing placement of new Intracardiac Devices

- TAVI
- MitraClip
- Septal closure devices
- Percutaneous Pulm Valve
- Leadless TPS
- Atrial Appendage Closure devices
Endocarditis on TAVI (transcatheter aortic valve implants)

Less PMK

More PMK

Sapien-Edwards
Balloon-expandible
Funzionamento intra-annulare

Core Valve-Medtronic
Self-expandible
Funzionamento sovra-annulare
Infected endocarditis in patients with an implanted transcatheter aortic valve: Clinical characteristics and outcome of a new entity

Juan M. Pericas \(^a,\)**, Jaume Llopis \(^b\), Carlos Cervera \(^a\)

**Study Design**

- Literature Review: Pubmed search using the words “TAVI”, “TAVR” and endocarditis
- From 2009 to July 2013
- 56 cases (25 from large series and 31 from case reports).
- Statistical analysis of 31 cases:
  - Descriptive analysis
  - Risk factors for acquisition
  - Risk factors for mortality
TAVI Endocarditis: Risk Factors and Clinical Features

Advanced age median 81 yrs (78-85) M/F 1:1

TAVI Endocarditis: Epidemiology

**Acquisition**
- Nosocomial: 39%
- Health-care related: 32%
- Community (late onset): 29%

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TAVI Endocarditis: Clinical Presentation

TAVI Endocarditis: Echocardiography

<table>
<thead>
<tr>
<th>Condition</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Presence of vegetations</td>
<td>52%</td>
</tr>
<tr>
<td>Vegetation size, median</td>
<td>15 mm</td>
</tr>
<tr>
<td>Perivalvular abscess/fistula</td>
<td>45%</td>
</tr>
<tr>
<td>Mitral valve vegetation</td>
<td>13%</td>
</tr>
</tbody>
</table>

18FDG-PET-CT scan: usefulness in TAVI-IE diagnosis

SUV max = 6.5
18FDG-PET-CT scan: usefulness in TAVI-IE diagnosis

SUV max = 4.5
# TAVI Endocarditis: Treatment and Outcome

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Mortality</th>
<th>Antimicrobials alone</th>
<th>Antimicrobials + Surgery</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>35%</td>
<td>68% *</td>
<td>32%</td>
</tr>
</tbody>
</table>

* long-term suppressive in 12%

Prosthetic Valve Endocarditis After Transcatheter Aortic Valve Implantation


18/509 patients with TAVI-PVE during a median follow-up period of 1.4 years

TAVI-PVE was most frequent in the first year after implantation

17 patients (94%) were treated conservatively and 1 with surgery

4 patients (22%) died from endocarditis or complications of treatment

Circ Cardiovasc Interv
Volume 8(4):e001939
April 14, 2015
Kaplan–Meier estimate of overall transcatheter aortic valve implantation (TAVI) prosthetic valve endocarditis (PVE) incidence.

Niels Thue Olsen et al. Circ Cardiovasc Interv. 2015;8:e001939
Kaplan–Meier curves for different procedural risk factors.

Niels Thue Olsen et al. Circ Cardiovasc Interv. 2015;8:e001939
Multicenter registry including 53 pat (mean age, 79±8 years; men, 57%) with TAVI-IE. Mean time from TAVI was 6 months. Self-expandable CoreValve (HR, 3.12; 1.37–7.14; p=0.007) was associated with IE. Microorganisms were CoNS (24%), S. aureus (21%), enterococci (21%). Vegetations present in 77% of patients (valve leaflets, 39%; stent frame, 17%; mitral valve, 21%). At least 1 complication of IE occurred in 87% of patients (heart failure in 68%). Only 11% of patients underwent valve intervention (valve explantation and valve-in-valve procedure in 4 and 2 patients, respectively). The mortality rate in hospital was 47.2% and increased to 66% at the 1-year follow-up. IE complications such as heart failure (p=0.037) and septic shock (p=0.002) were associated with increased in-hospital mortality.
Schematic representation of the location of infective endocarditis (IE) in patients with previous transcatheter aortic valves

**OVERALL** (n=53)

**Self-expandable CoreValve** (n=19)

**Balloon-expandable Edwards valve** (n=34)
Kaplan–Meier survival curves at the 12-month follow-up in patients diagnosed with infective endocarditis (IE) after transcatheter aortic valve implantation (time 0 represents the time of IE diagnosis)

Ignacio J. Amat-Santos et al. Circulation. 2015;131:1566-1574

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MITRACLIP
NEW OPTION FOR INOPERABLE SEVERE MITRAL REGURGITATION
(BOTH PRIMARY AND SECONDARY)
Histo-pathological Healing Response of Explanted MitraClip Devices
Clinical Perspective

Acute response (<30 days)

Subacute response (31 to 90 days)

Chronic response (91 to 300 days)

Long-term response (>300 days)

Fibrin & Platelets

Granulation tissue
Fibrous pannus

Bridges

Collagen rich matrix
Complete encasement

Severe infective endocarditis after MitraClip implantation treated by cardiac surgery
Percutaneous Repair or Surgery for Mitral Regurgitation

<table>
<thead>
<tr>
<th></th>
<th>MITRA CLIP</th>
<th>SURGERY</th>
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</thead>
<tbody>
<tr>
<td>N=184</td>
<td>N=95</td>
<td></td>
</tr>
<tr>
<td>ENDOCARDITIS</td>
<td>2 (1.1%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>GANGRENE</td>
<td>1 (0.5%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>PNEUMONIA</td>
<td>5 (2.7%)</td>
<td>4 (4.2%)</td>
</tr>
<tr>
<td>SEPSIS</td>
<td>1 (0.5%)</td>
<td>1 (1.1%)</td>
</tr>
<tr>
<td>UTI</td>
<td>1 (0.5%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>VIRAL INFECTIONS</td>
<td>1 (0.5%)</td>
<td>0 (0%)</td>
</tr>
</tbody>
</table>

Studies published 2003 to 2017

10 publications, 12 patients with definite IE (median age 76 years, 55% men)

Mean logistic EuroSCORE 41%

IE occurred early (<12 months) in 9 patients (75%); <1 month in 5 patients (42%)

Staphylococcus aureus was the causal microorganism in 60% of cases

Severe mitral regurgitation was present in 11 cases

Surgical MVR was performed in 67% patients

Mortality associated with the IE episode was 42%
ASD & VSD closure devices

Amplatzer

Starflex

Helex
Infective Endocarditis After Device Closure of Atrial Septal Defects: Case Report and Review of the Literature

Pascal Amedro,\textsuperscript{1,2,*} MD, PhD, Camille Soulages,\textsuperscript{1} MD, and Alain Fraisse,\textsuperscript{3} MD, PhD

Endothelialization

<table>
<thead>
<tr>
<th>Description</th>
<th>Count</th>
</tr>
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<tbody>
<tr>
<td>Absent</td>
<td>5</td>
</tr>
<tr>
<td>Incomplete</td>
<td>3</td>
</tr>
<tr>
<td>Present</td>
<td>3</td>
</tr>
<tr>
<td>Not specified</td>
<td>10</td>
</tr>
</tbody>
</table>
ASD closure device-related endocarditis (N=21 cases)

Patient age 1-76 years (median 42 yrs)

From 2 days up to 11 years after device implantation

Mainly Staphylococcus aureus (10 of 21 cases)

Vegetations: LA 10 cases; LA + RA 6 cases

Device surgically removed in 18 pts >> incomplete neo-endothelialization

2 patients died (9.5% - both surgical)
Infective Endocarditis After Device Closure of Atrial Septal Defects: Case Report and Review of the Literature

Pascal Amedro,1,2* MD, PhD, Camille Soulatges,1 MD, and Alain Fraisse,3 MD, PhD

<table>
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<th>Treatment</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Antibiotics only</td>
<td>3</td>
</tr>
<tr>
<td>Surgical removal of device</td>
<td>18</td>
</tr>
</tbody>
</table>
Growing issue

Surgically-/percutaneously corrected Congenital Heart Disease

- Shunts, tubes, closing devices
- Many of these patients are young adults (GUCH)
Percutaneous pulmonary artery valvulated conduits
(for RV efflux disease)

Melody TPV n >5000

Edwards Sapien valves n >300
Mean interval between PPVI and IE was 2.6 ± 2.1 years (range, 5 days to 7.3 years).

15 patients required intravenous antibiotics only.

7 patients had early interventional catheterization to relieve severe RV outflow tract obstruction.

24 patients had surgical valve replacement (six urgently; nine semi-urgently; nine electively).

Staphylococcus aureus IE required surgery in all but 1 patient.

3 pts died before any treatment.

3 additional pts died, for an overall mortality rate of 14%.

PET-CT scan in a ToF patient with pulmonary artery Contegra bioprosthetic valvulated graft
Micra - Leadless Trans-catheter Pacing System
Figure 1: Images demonstrating the miniature size of the Micra™ Transcatheter Pacing System.
the TVP group (123 revisions in 117 patients). TPS revisions occurred 5–430 days postimplant for elevated pacing thresholds, need for alternate therapy, pacemaker syndrome, and prosthetic valve endocarditis; none were due to device dislodgment or device-related infection. TPS was disabled and left in situ in 7 cases, 3 were retrieved percutaneously (range 9–406 days postimplant), and 1 was surgically removed during aortic valve surgery.
TPS implanted in 792 patients
149 implanters
96 centers
20 countries

Study end point:
system or procedure-related major complications
at 30 days post implant

repositioning. Sepsis was reported in 1 patient within 48 hours of the implant procedure and was successfully treated using intravenous antibiotics, without the need for device removal. There was no major complication related to telem-
suspect that the small size, lack of proximity to a cutaneous incision, and late encapsulation will all positively influence a reduced infection rate. Similarly, the rate of device

(Heart Rhythm 2017;14:1375–1379)
Figure 4:
Illustration of the placement of a WATCHMAN® LAA closure device (used with the permission of Atritech, Inc. ©2011).
IE located at the LAAO is an extremely rare complication. Two recent studies about feasibility and safety with the fourth generation watchman LAAOs failed to detect device infection [13]. Only one case of infection associated with atrial appendage occluder, occurring a few days after implantation has been reported (staphylococcus aureus) and was related to lack of sterile conditions during the procedure [9]. IE due to gram-negative bacilli (GNB) represents 4% of all

Transesophageal echocardiographic diagnosis of left atrial appendage occluder device infection

Taiyeb M. Khumri, Joseph B. Thibodeau, and Michael L. Main*
New CVD infectious complications: SUMMARY

- Growing implant rates cause a current steep increase of new CVD infections
- ID physicians should learn the different CVD features and be prepared to recognize their infection
- Tailored preventive measures should be put forward
- Diagnosis of CVD infection may be challenging, Duke University’s criteria may be inaccurate, ESC 2015-based imaging modalities should be exploited
- Prognosis is poor, often worse than traditional prosthetic valve IE
- Therapeutic tools are targeted therapy, CVD removal, long term suppressive rx