Prothèse Lê – VSD: types et sélection des patients

Marc Gewillig
Leuven, Belgium
Disclosure Information

Prothèse Lê – VSD: types et sélection des patients

Marc Gewillig, MD, FSCAI

The following relationships exist related to this presentation:

(G): Grant/Research Support (C): Consultant (SB): Speaker’s Bureau
(AC): Advisory Committee (B): Board Member (O): Other

PFM : SB, proctor
VSD: ideal device for transcatheter closure

- easy to apply
- suitable for all forms of VSD’s
- small sheath preferably via the femoral vein
- reconfigurable
- retrievable
- close the defect completely fast
- not change of surrounding anatomy
  - No AVB, no AR, no TR
- cheap – competitive surgical closure
Nit-Occlud® Lê VSD PFM coil

obstruct the VSD passway
no stenting

2 conical coil layers nitinol
• Left cone:
  • Large stiff ring
  • Polyester fibres
• Right cone:
  • Smaller ring
  • Reversed
  • No fiber

• C€ 2010
Nit-Occlud Lê VSD

Permanent coil for the closure of perimembranous and muscular ventricular septal defects (VSD).

- Content: coil, delivery system, implantation catheter

<table>
<thead>
<tr>
<th>REF</th>
<th>Distal Coil Diameter (D)</th>
<th>Proximal Coil Diameter (P)</th>
<th>Recommended Implantation Sheath</th>
<th>Implantation Catheter Length</th>
</tr>
</thead>
<tbody>
<tr>
<td>149086</td>
<td>8 mm</td>
<td>6 mm</td>
<td>6 F</td>
<td>105 cm</td>
</tr>
<tr>
<td>149106</td>
<td>10 mm</td>
<td>6 mm</td>
<td>6 F</td>
<td>105 cm</td>
</tr>
<tr>
<td>149126</td>
<td>12 mm</td>
<td>6 mm</td>
<td>6 F</td>
<td>105 cm</td>
</tr>
<tr>
<td>149128</td>
<td>12 mm</td>
<td>8 mm</td>
<td>7 F</td>
<td>105 cm</td>
</tr>
<tr>
<td>149148</td>
<td>14 mm</td>
<td>8 mm</td>
<td>7 F</td>
<td>105 cm</td>
</tr>
<tr>
<td>149168</td>
<td>16 mm</td>
<td>8 mm</td>
<td>7 F</td>
<td>105 cm</td>
</tr>
</tbody>
</table>
from left to right:

Nit-Occlud® Lê VSD Coil:

Y-connector:

Markers:

bp = baseline point
M1 = four windings outside the implantation catheter
M2 = only two windings remain within the implantation catheter
M3 = whole of coil outside implantation catheter

Implantation catheter with fitted coil:

Single-hand insertion device:

Delivery system (with markings):

Single-use handle:
Nit-Occlud Lê VSD

Patient selection

• VSD
  • PM or muscular
  • Shunt important
  • Effective VSD < 8 mm (cf max size 16 mm)
• Ao rim > 3mm unless coil in aneurysm
• > 12 months 6 – 7 F

• Device selection
  • Left disk > 0 - 2 mm left side VSD (echo 5Ch)
  • Left disk > 2x right side VSD (color Doppler)
  • Right disk > right side VSD
Nit-Occlud Lê VSD

Echo: apical 5Ch view
Nit-Occlud Lê VSD

Echo: apical 5Ch view

Choice of coil:
• LV size + 1-2 mm
• RV size X 2
 Lê VSD coil

5F Ri Judkins; snare in PA (free of TriV)
Lê VSD coil

8/6 PFM coil through 6F sheath
Lê VSD coil

8/6 PFM coil through 6F sheath
Lê VSD coil
Lê VSD coil

10/6 PFM coil through 6F sheath
Lê VSD coil

10/6 PFM coil through 6F sheath
Lê VSD coil

10/6 PFM coil through 6F sheath
Lê VSD coil

10/6 PFM coil in VSD
Le VSD coil: results

Retrospective European Registry for VSD Closure using the Nit-Occlud® Le-VSD-Coil EUREVECO

<table>
<thead>
<tr>
<th><strong>Attempted ITT</strong></th>
<th><strong>110</strong></th>
<th>18 centers, 2010-13</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
<td>8.4 years</td>
<td>0.7–67 years</td>
</tr>
<tr>
<td><strong>Weight</strong></td>
<td>28.8 kg</td>
<td>7.2 - 109 kg</td>
</tr>
<tr>
<td><strong>VSD PM</strong></td>
<td>85</td>
<td>48 aneurysm, 20 multiple exits</td>
</tr>
<tr>
<td><strong>Musc</strong></td>
<td>25</td>
<td></td>
</tr>
</tbody>
</table>

| **Deployed** | **101** |                     |
| **Closed**   | **100**  |                     |
| **Embolised**| 1        |                     |

N Haas et al, submitted
EUREVECO participating centers

- Bad Oeynhausen, Hannover, Bonn, Berlin, Duisburg, Mainz, Munich, Germany
- Leiden, Utrecht, Netherlands
- Gent, Leuven, Belgium
- Kiev, Ukraine
- Kemerovo, Russia
- Zurich, Switzerland
- Padova, Italy
- Rome, Vatican
Lê VSD coil: results EUREVECO

VSD closure 1 shot 87

Failed deployment 9 / 110
  • Sheath not advanced 1
  • VSD too large 1
  • AVBlock with sheath 1
  • AoV dysfunction 2
  • Large residual shunt 2
  • Poor position 2

N Haas et al, submitted
Lê VSD coil: results

101 pts

Results

• Discharge:
  • complete closure 49 48.5%
  • trivial shunt 51 50.0%

Complete closure

• 3 months 90%
• 6 months 95%
• 12 months 97%
• 36 months 99%

• Embolisation 1
• Surgical closure 1

N Haas et al, submitted
Lê VSD coil: results EUREVECO

Complications:

<table>
<thead>
<tr>
<th>Complication</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemolysis</td>
<td>4</td>
</tr>
<tr>
<td>Transient &lt; 48 h</td>
<td>2</td>
</tr>
<tr>
<td>2nd device after 2w</td>
<td>1</td>
</tr>
<tr>
<td>Surgical closure after 2y</td>
<td>1</td>
</tr>
<tr>
<td>Embolization &lt; 24h</td>
<td>1</td>
</tr>
<tr>
<td>AV-block: RBBB &lt; AVB D 5-8 &lt; RBBB</td>
<td>1</td>
</tr>
<tr>
<td>RBBB</td>
<td>6</td>
</tr>
<tr>
<td>TR &gt; 2/4</td>
<td>5</td>
</tr>
<tr>
<td>Device fracture at 1 y</td>
<td>1</td>
</tr>
<tr>
<td>Death</td>
<td>0</td>
</tr>
<tr>
<td>New AR</td>
<td>0</td>
</tr>
<tr>
<td>AVB</td>
<td>0</td>
</tr>
</tbody>
</table>

N Haas et al, submitted
Lê VSD coil: retrieval before release
Recover after release

Multi-Snare® VSD-Loop Set
Specially designed to support the implantation of Nit-Occlud® Lê VSD.
› Content: snare, guide wire, 2 clips

<table>
<thead>
<tr>
<th>REF</th>
<th>Diameter loop</th>
<th>Catheter Length</th>
<th>Recommended Catheter</th>
</tr>
</thead>
<tbody>
<tr>
<td>147015</td>
<td>15 mm (15–20)</td>
<td>145 cm</td>
<td>5 F</td>
</tr>
</tbody>
</table>

The set features a 260 cm hydrophilic-coated crossover wire (0.035 inch with 60° angled tip), and 2 metal clips. The Multi-Snare VSD Loop-Set is only available without a sling catheter.
Nit-Occlud® Lê VSD Occlusion System

- Interventional closure is
  - feasible
  - large variety of patients
  - different VSD morphologies

- Safe

- Small risk of severe side effects

- FU needed for long-term effects and safety
Prothèse Lê – VSD: types et sélection des patients

Marc Gewillig
Leuven, Belgium