SAVI TF REGISTRY

CLINICAL RESULTS EuroPCR 2016

LATEST RESULTS AT EuroPCR 2016. 1000 PATIENTS ENROLLED @ 30 DAYS.
NO COMPROMISE

1000 PATIENTS

8.2% PPM°

4.1% PVL°° ≥ 2

1.3% ACM°°°

* PPM : Permanent Pace-Maker
** PVL : Para-Valvular Leak @ 7 days
*** ACM : All-Cause Mortality
NEW PERMANENT PM
1000 PATIENTS ENROLLED. DATA UP TO 30 DAYS*

NO N EED TO COM PROMISE PPM & PVL

LOWEST NEW PPM°° RATE

8.2%

DEVICE PERFORMANCE
1000 PATIENTS ENROLLED. DATA UP TO 30 DAYS°

PVL°° ≥ GRADE 2

4.1%

** PVL : Para-Valvular Leak @ 7 days

PERFORMANCE @ 7 DAYS

<table>
<thead>
<tr>
<th>Population [n]</th>
<th>999</th>
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<tbody>
<tr>
<td>Mean ΔP gradient [mmHg, mean ± SD]</td>
<td>8.3 ± 4.0</td>
</tr>
<tr>
<td>Mean EOA [cm², mean ± SD]</td>
<td>1.81 ± 0.5</td>
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</table>

PVL Grade

≤ Grade 1 (none to mild) [n/%] | 926 / 95.9 |
Grade 2 (moderate) [n/%] | 39 / 4.0 |
> Grade 2 [n/%] | 1 / 0.1 |

** PVL : Para-Valvular Leak @ 7 days

MACCE @ 30 DAYS

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<th>Population [n]</th>
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<td>All-cause mortality [n/%]</td>
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<td>Stroke [n/%]</td>
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<td>MI [n/%]</td>
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<td>Re-intervention post-DC [n/%]</td>
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<td>Freedom from MACCE [n/%]</td>
<td>959/ 96.5</td>
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New pacemaker implantation [n/%] | 82 / 8.2 |

¹ one patient withdrew consent after treatment, 5 patients lost to follow-up

* Symetis SAVI TF registry presented by Prof. Moellmann at EuroPCR 2016, LBCT, 17 May 2016.
** PPM : Permanent Pace-Maker
* Medtronic Evolut R data from the IDE trial presented at ACC 2016
** SJM PORTICO data from the PORTICO I registry presented at EuroPCR 2016
*** Boston Lotus data from the RESPOND registry presented at EuroPCR 2016
**** EDW. SAPIEN 3 data from the European SOURCE 3 registry presented at EuroPCR 2016

Data presented side by side for illustration

8.3

Mean gradient (mmHg)

1.81

Mean EOA (cm²)

MEAN GRADIENT @ 7 DAYS (mmHg)

EFFECTIVE ORIFICE AREA (EOA) @ 7 DAYS (cm²)

* Symetis SAVI TF registry presented by Prof. Moellmann at EuroPCR 2016, LBCT, 17 May 2016.
** PVL : Para-Valvular Leak @ 7 days
ALL-CAUSE MORTALITY
1000 PATIENTS ENROLLED. DATA UP TO 30 DAYS°

1.3%
LOWEST ACM°° RATE

NYHA FUNCTIONAL CLASS @ 30D
1000 PATIENTS ENROLLED. DATA UP TO 30 DAYS°

SIGNIFICANT REDUCTION
OF THE NYHA FUNCTIONAL CLASS
BETWEEN BASELINE & 30D

81.2% TO 9.6%

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** ACM: All-Cause Mortality
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Data presented side by side for illustration

MACCE @ 30 DAYS

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° One patient withdrew consent after treatment, 5 patients lost to follow-up
CONCLUSION
1000 PATIENTS ENROLLED. DATA UP TO 30 DAYS

NO COMPROMISE

** 8.2% PPM°**

** 4.1% PVL ≥ 2°°**

** 1.3% ACM°°°**

- Results show outstanding outcomes at 30 days
- Anatomic fit of ACURATE neo, top-down deployment technology and stability during positioning promise a high rate of procedure success, a minimal PVL & abbreviated device usage times
- Excellent survival rates in this all-comers population
- NO COMPROMISE with the best PPM & PVL combination

* PPM : Permanent Pace-Maker
** PVL : Para-Valvular Leak @ 7 days
*** ACM : All-Cause Mortality
DETAILS & ENDPOINTS

1000 PATIENTS ENROLLED. DATA UP TO 30 DAYS°

• European Post-Market Registry to collect safety and performance data after CE mark was obtained in June 2014

• Symetis ACURATE neo™ Valve Implantation using TransFemoral Access (SAVI TF) Registry
  • Recruitment performed in 25 sites in 6 EU countries
  • 1000 patients enrolled between Oct. 2014 and Apr. 2016 up to 30 days°°

• Primary Endpoints
  • All-Cause Mortality (ACM) @ 30 days

• Secondary Endpoints
  • Procedure success post-implant
  • Device performance @ 7 days and 12 months
  • VARC 2 safety @ 30 days and 12 months
  • NYHA class @ 30 days and 12 months

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<tr>
<td>Female [n/%]</td>
</tr>
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<td>Log. EuroSCORE I [%], mean ± SD</td>
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<td>Log. EuroSCORE II [%], mean ± SD</td>
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<td>STS Score [%], mean ± SD</td>
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<tr>
<td>ΔP [n/mmHg, mean ± SD]</td>
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<td>AVA [cm², mean ± SD]</td>
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<td>NYHA Class III/IV [%]</td>
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** PVL : Para-Valvular Leak @ 7 days.
intuitive at heart

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