Results of the MELODY REGISTRY – an international multicenter study of transcatheter pulmonary valve implantation

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MELODY Registry – Contributing Centers

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Geneva, University Hospital
Ghent, University Hospital
Giessen, University Hospital
Goettingen, University Hospital
Graz, University Hospital
Helsinki, University Hospital
Leiden, Leiden University Medical Center
Leipzig, University Hospital
Leuven, University Hospital
Lille, CHU Lille
Linz, Children`s Hospital
Lisbon, Hospital De Santa Marta
London, Evelina Children`s Hospital
London, Royal Brompton Hospital
Manchester, Royal Infirmary
Massa, Heart Hospital
Milan, San Donato Milanese
Muenster, University Hospital
Munich, DHM
Nantes, CHU Nantes
Oslo, Rikshospitalet
Padova, Azienda Ospedaliera di PADOVA
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Rotterdam, Thoraxcentrum ErasmusMC
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Toronto, Sick Kids
Tuebingen, University Hospital
Vienna, KHZ University Hospital
Vienna, AKH University Hospital
Zurich, University Hospital
Zurich, Children`s Hospital
MELODY Registry – Key Facts

- **Aim:** To assess the acute and One-Year clinical outcomes of transcatheter pulmonary valve implantation (TPVI) in a multicenter registry (MELODY Registry)

- Inclusion of **1,003 pts.** after TPVI, of which **694 pts.** had One-Year Follow-Up

- Inclusion: when Melody opened: all-comers population → `real-world cohort` of patients

- Implantation dates: 2006 to 2013

- Participation of **41 centers**
  - Europe, n= 39
  - Saudi-Arabia, n=1
  - Canada, n=1
MELODY Registry – Patient characteristics

- **Mean age:** 21.5 ± 11.4 (3.4 to 81.6) years
- **Diagnoses:**
  - 50% Tetralogy of Fallot and variants
  - 10% TGA / VSD
  - 19% s/p Ross-Operation (i.e. primary aortic lesion)
- **RVOT lesion:**
  - 54% predominant pulmonary stenosis (PS)
  - 21% predominant pulmonary insufficiency (PI)
  - 25% mixed lesion
MELODY Registry – Technical procedural details

- **Size of Delivery Systems used:**
  - 18 mm, \( n = 173 \) (~ 18%)
  - 20 mm, \( n = 265 \) (~ 28%)
  - 22 mm, \( n = 514 \) (~ 54%)

- **Pre-Stenting with a bare metal stent prior to TPVI:**

![Bar charts showing the number of patients with pre-stenting and the number of pre-stents.](image-url)

- **Patients with pre-stenting [%]:**
  - Yes: 85.9%
  - No: 14.1%

- **Number of pre-stents:**
  - 1: 80
  - 2: 40
  - 3: 20
  - 4: 10
Primary outcome:

- freedom from death / reoperation / reintervention at One-Year
Secondary Outcomes – Safety / Complications

- **Procedural safety:**
  - Death (coronary compression, ECMO/LVAD) \( n=2 \) 0.2%
  - Surgical intervention required \( n=13 \) 1.3%
  - Transcatheter intervention required \( n=32 \) 3.2%

- **Rate of endocarditis at One-Year:**
  - Overall incidence \( n=19 \) 2.7%
  - With positive blood culture findings \( n=5 \) 0.7%

- **Rate of stent fractures at One-Year:**
  - Major (= Type II) \( n=8 \) 1.5%
  - Minor (= Type I) \( n=53 \) 9.7%
Melody: stent fractures
Secondary Outcomes – Haemodynamic performance

![Graph showing RVOT velocity on echo (m/s) and PI grade on echo (% of total)]
Secondary Outcomes – Functional performance

NYHA-class

% of each grade of NYHA-class

pre (n=667)  post (n=487)  1 year (n=438)

I

II

III

IV

0 50 100 100

10 50 100

I

II

III

IV
Overall conclusions

- confirm the safety and effectiveness of TPVI in a `real-world cohort` of patients
- The MELODY Registry represents the largest patient series after TPVI to date
- … and offers the great potential to assess the long-term utility of TPVI
  - stent fractures
  - endocarditis

Conclusions related to technical aspects of the TPVI procedure:

- Pre-Stenting: standard technique, used in 85.9% of procedures
- TPVI is increasingly used in patients after the Ross-Operation (i.e. primary aortic lesions)
Melody: evolution RVOT0

Leuven 2006-2014
n = 107
Melody: evolution PR

n = 107
Melody: freedom stent fracture
Leuven 2006-14: Melody® IE

Follow-up (Years)

Patient number

N = 107
Melody: freedom IE

Leuven 2006-2014
n = 107
Characteristics of patients IE Melody®

- Incidence: 8 / 107 (7.5%)
- Avoidable factors: 7/8
  - oral infections 5
  - poor hygiene 2
  - PM retardation 4

  vs 9/99

- Fever at presentation: 7/8
  - Septic lung emboli 2
  - Septic shock 1
Melody IE: PET-CT
Melody: IE 2006 – 2014

Outcome:

- Explantation < 30d 2
- Obstruction
  - Overstented & re-revalvation 1
  - Overstented 1
- Remaining
  - PS < 30 mmHg 4
  - PR < 2/4 4

Leuven 2006-2014
n = 107
Melody in RVOT

- Europe: first 1000 implantations with FU up to 1y

- Leuven: first 107 implantations with FU up to 7y