

The “MitraBridge” international study

MitraClip procedure as “bridge therapy” for heart transplantation




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Speaker's name : Cosmo Godino

I do not have any potential conflict of interest to declare

Why this study?

- **Increased** prevalence of patients with **advanced/end-stage HF**

- Marked **imbalance** between the demand and supply of donor hearts for heart transplantation (HTx)

- **Expansion** of *waiting lists* and **prolonged** *waiting times* (over 12 months)

- **Difficult management** of patients on «waiting list» with **1-year mortality rate** of **14%** and **20%** up to 3-year (*Eurotransplant waiting list mortality rate 2017*)

How was the study executed?

- ✓ Multicenter registry, case-by-case retrospective review of clinical records
- ✓ Chronic **advanced/end-stage HF** pts **with 3+ or 4+ mitral regurgitation (MR)**
- ✓ **Potential candidates for HTx** treated with MitraClip as a “*bridge strategy*”
- ✓ Started in June 2018 without the support of any external funding
- ✓ A total of **14 centers** from *Europe and Canada*



Italy, 8 centers (69 patients): *Milan* (A. Colombo), *Bologna* (F. Saia), *Catania* (C. Tamburino), *Pavia* (G. Crimi), *Padua* (G. Tarantini), *Trieste* (G. Vitrella), *Pisa* (S. Petronio), *Brescia* (S. Curello)

Spain, 2 centers (17 patients), *Madrid* (R. Estévez-Loureiro), *Barcelona* (E. Peregrina Fernández)

Canada, 2 centers (8 patients): *Toronto* (N. Fam), *Montreal* (A. Asgar)

The Netherlands, 1 center (1 patient): *Rotterdam* (N. Van Mieghem)

Switzerland, 1 center (1 patient): *Zürich* (F. Maisano)

What did we study?

Patients on active HTx list

In list group, “pure bridge”

with low likelihood to receive a donation shortly
(e.g. for body weight or blood group)

Patients waiting for clinical decision

“Bridge to decision”, “BTD” group

including unstable patients during the screening for HTx

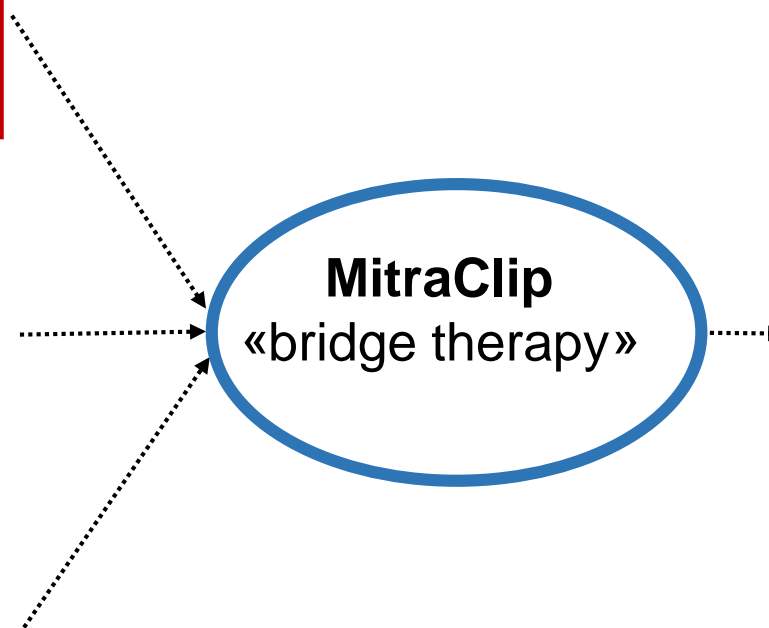
Patients not in list for HTx

Not in list group, “bridge to candidacy”

with *potentially reversible contraindications* to HTx
(severe pulmonary hypertension, elevated pulmonary-vascular-resistance)

MitraClip
«bridge therapy»

Outcome



How was the study executed?

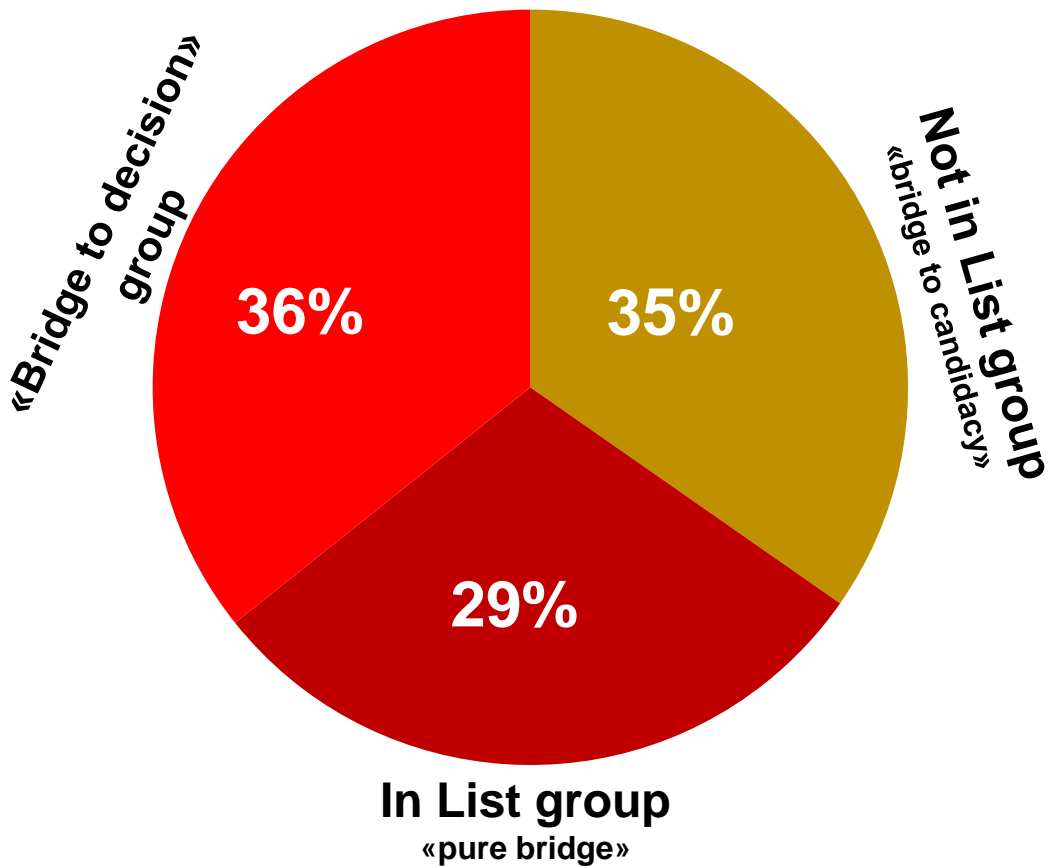
Primary composite end-point: «*success rate of the bridge strategy*»

- Number of patients **going to HTx**
- Number of patients **entering** (or **remaining**) in the HTx list
- Number of patients with **no more indication to HTx**
(significant clinical improvement)

Secondary composite end-point: «1-year adverse events»

- Cardiac mortality rate
- Heart failure hospitalization rate

How was the study executed?



- Severe pulmonary hypertension (n=10)
- Elevated pulmonary-vascular-resistance (n=7)
- Severe CKD (n=3)
- Complicated diabetes (n=2)
- BMI > 35 Kg/m² (n=5)
- Current alcohol, drug or tobacco abuse (n=3)
- Poor social support (n=2)
- New onset neoplasia (n=2)

How was the study executed?

| Clinical Characteristics | Overall population, (n=98) |
|---|----------------------------|
| Age, years | 57 (50-63) |
| Age ≤ 60 years | 57 (58) |
| Male gender | 77 (78.5) |
| BMI, Kg/m ² | 24.9 (22.7-28.6) |
| eGFR, mL/min | 75.75±25 |
| HF hospitalization within previous 6 months | 61 (61) |
| NYHA class III-IV | 94 (96) |
| MR aetiology (functional/secondary) | 94 (96) |
| Ischaemic functional MR | 48 (49) |
| INTERMACS profiles | |
| 1-2 | 3 (3) |
| 3-4 | 27 (27.5) |
| 5-6 | 42 (43) |
| 7 | 15 (15.5) |

How was the study executed?

| Echocardiographic features | Overall population, (n=98) |
|---|----------------------------|
| Mitral Regurgitation grade: Severe (4+) | 89 (91) |
| LVEF, % | 27±7.5 |
| LVEF ≤ 30% | 70 (71.5) |
| LVEDVi, mL/m ^{2§} | 134±41.3 |
| LVESVi, mL/m ^{2§} | 95.6±33.7 |
| LVEDVi >96 mL/m² | 76 (77.6) |
| LAVi, mL/m ^{2§} | 63.3±34.9 |
| sPAP, mmHg | 50.8±15 |
| sPAP ≥ 35 mmHg | 86 (87.8) |
| sPAP ≥ 50 mmHg | 48 (49) |
| Tricuspid Regurgitation > 2 [§] | 21 (21.4) |
| TAPSE, mm [§] | 17.5±3.85 |
| Pulmonary capillary wedge pressure, mmHg [§] | 24.75±9.3 |
| Cardiac Index, L/min/m^{2§} | 2±0.55 |

Procedural results

- No patient died

- MitraClip procedural success rate: **85%** (MVARC definition)

- Number of Clip implanted/patient:

- 1 MitraClip (**36%**)
- **2 MitraClips (50%)**
- 3 or more MitraClips (**14%**)

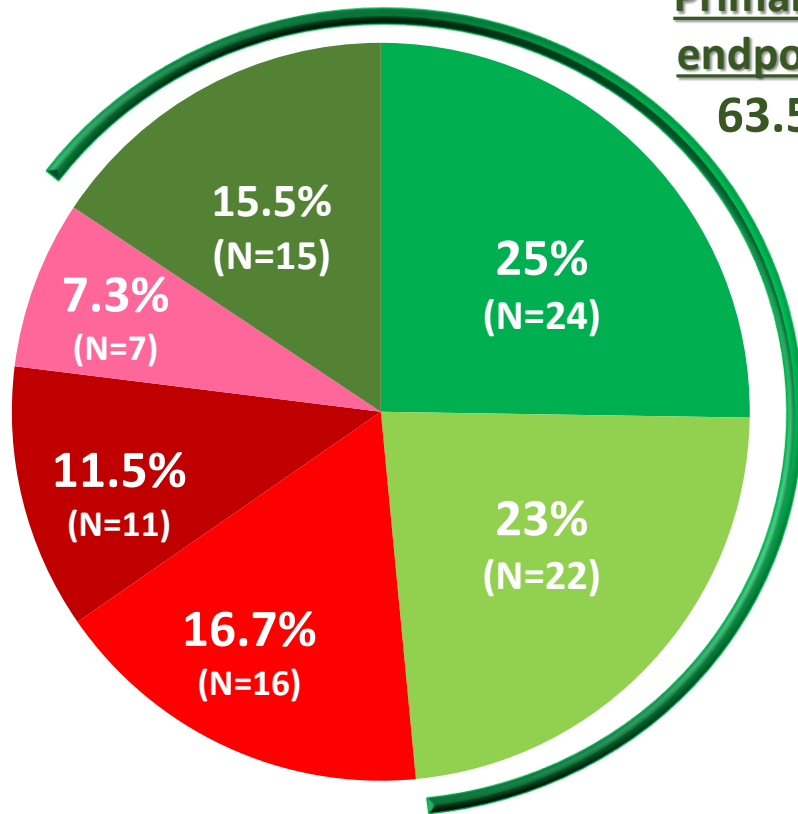
- Residual mitral regurgitation grade:

- ✓ **none/trivial (57%)**
- ✓ mild (**29%**); moderate (**8%**)
- ✓ severe (**6%**)

What are the essential results?

Clinical follow-up available for 95 patients (97%)
Median time of **571 days** (IQR: 230-1089)

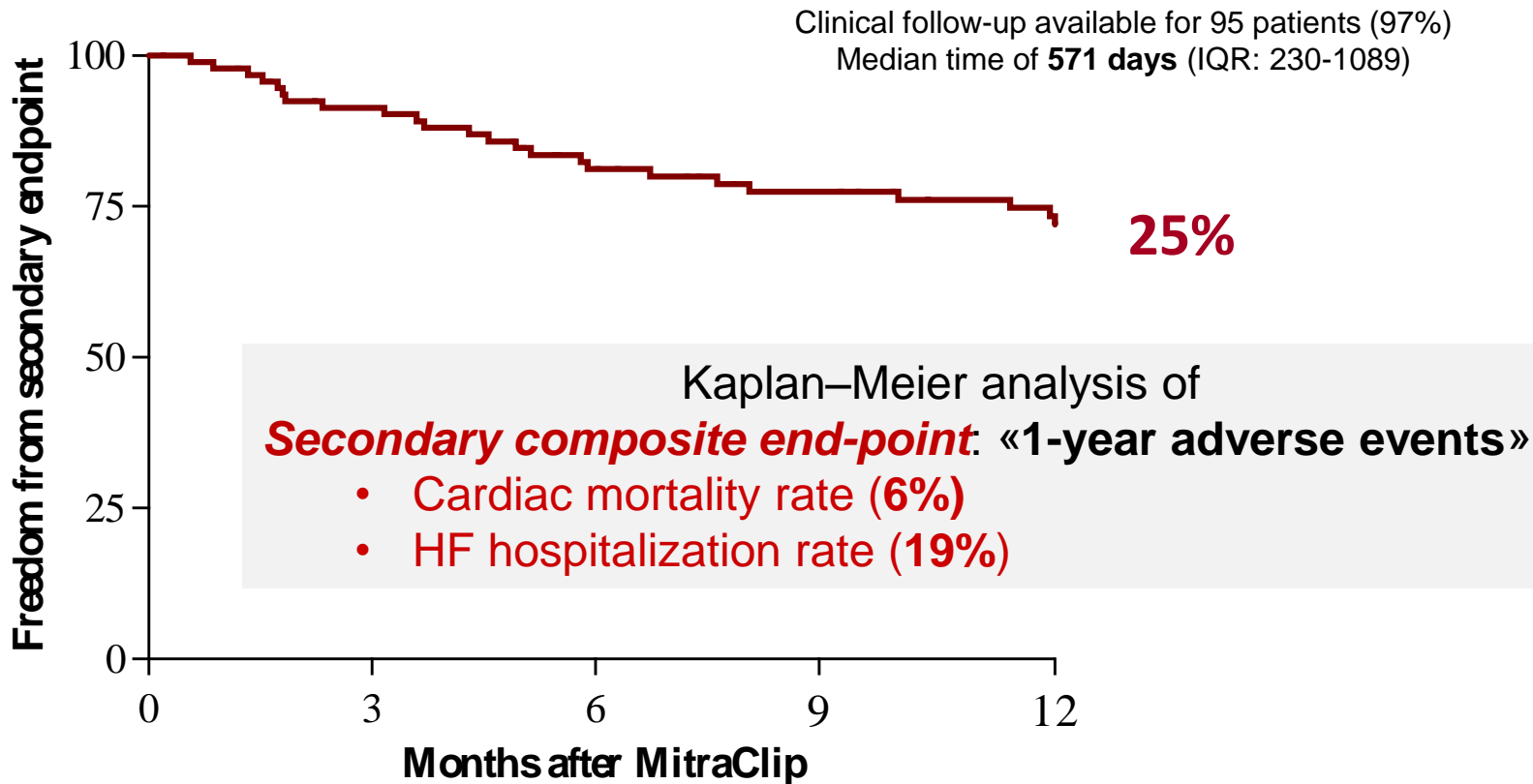
Primary composite endpoint achieved
63.5% (n=61)



- HTx
- Entering (or remained) in the HTx list
- Delisted for clinical improvement

- LVAD
- Still waiting for decision
- Death

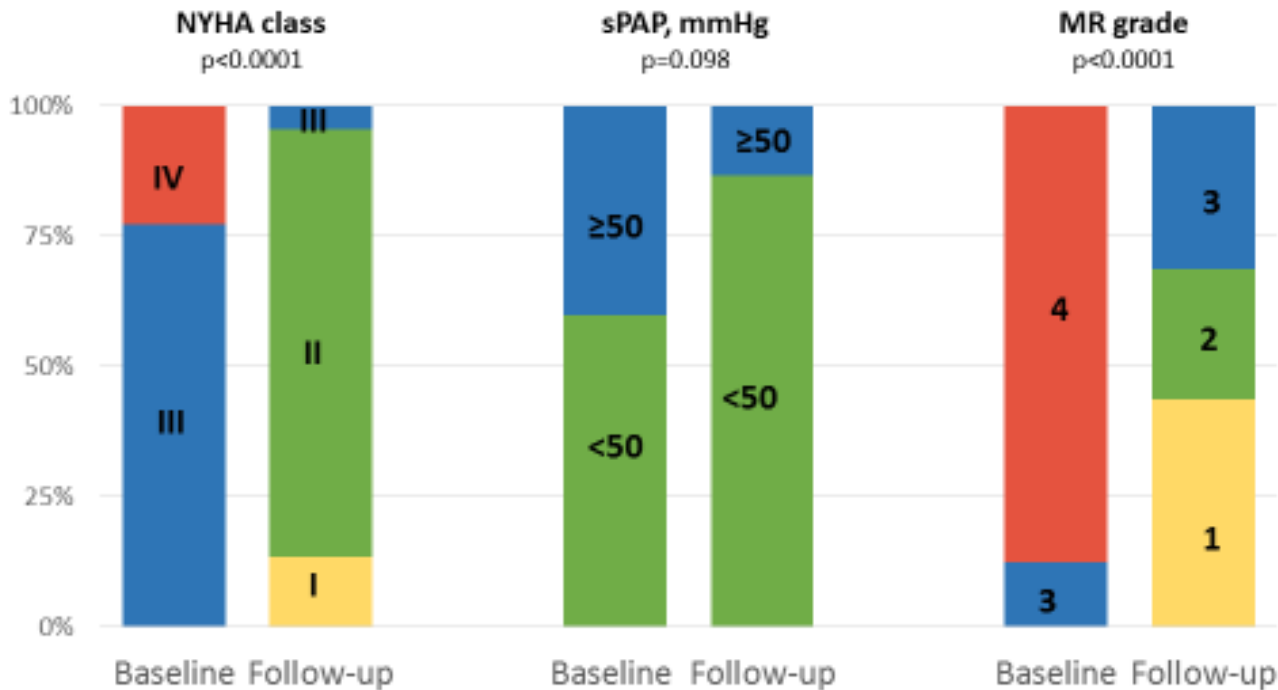
What are the essential results?



What are the essential results?

Delisted patients, N=22 (23%)

Comparison of **NYHA class**, **sPAP** and **MR grade** at baseline vs. follow-up in pts with **clinical improvement** after MitraClip procedure



The “MitraBridge” study

- First multicentre registry reporting data on large series of advanced/end-stage HF patients with significant MR and MitraClip implantation as “bridge-to-transplant strategy”
- **The MitraClip “bridge-strategy” was safe and effective allowing**
 - 1) the *transplant* in **25%** of patients
 - 2) the *eligibility* for transplant in **15%** of patients
 - 3) the *delisting* for clinical improvement in **23%** of patients
- **The conclusions should be considered “*exploratory*” and as *generating hypotheses* and larger data are needed to confirm the present results**