The “MitraBridge” international study

*MitraClip procedure as “bridge therapy” for heart transplantation*

Cosmo Godino,
Potential conflicts of interest

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
In List group «pure bridge»

36%

35%

29%

Not in List group «bridge to candidacy»

«Bridge to decision»

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)
### Clinical Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Overall population, (n=98)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td>57 (50-63)</td>
</tr>
<tr>
<td>Age ≤ 60 years</td>
<td>57 (58)</td>
</tr>
<tr>
<td>Male gender</td>
<td>77 (78.5)</td>
</tr>
<tr>
<td>BMI, Kg/m²</td>
<td>24.9 (22.7-28.6)</td>
</tr>
<tr>
<td>eGFR, mL/min</td>
<td>75.75±25</td>
</tr>
<tr>
<td>HF hospitalization within previous 6 months</td>
<td>61 (61)</td>
</tr>
<tr>
<td>NYHA class III-IV</td>
<td>94 (96)</td>
</tr>
<tr>
<td>MR aetiology (functional/secondary)</td>
<td>94 (96)</td>
</tr>
<tr>
<td>Ischaemic functional MR</td>
<td>48 (49)</td>
</tr>
</tbody>
</table>

### INTERMACS profiles

<table>
<thead>
<tr>
<th>Profile</th>
<th>Count (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-2</td>
<td>3 (3)</td>
</tr>
<tr>
<td>3-4</td>
<td>27 (27.5)</td>
</tr>
<tr>
<td>5-6</td>
<td>42 (43)</td>
</tr>
<tr>
<td>7</td>
<td>15 (15.5)</td>
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</table>
## Echocardiographic features

<table>
<thead>
<tr>
<th>Feature</th>
<th>Overall population, (n=98)</th>
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<tbody>
<tr>
<td>Mitral Regurgitation grade:</td>
<td></td>
</tr>
<tr>
<td>Severe (4+)</td>
<td>89 (91)</td>
</tr>
<tr>
<td>LVEF, %</td>
<td>27±7.5</td>
</tr>
<tr>
<td>LVEF ≤ 30%</td>
<td>70 (71.5)</td>
</tr>
<tr>
<td>LVEDVi, mL/m²</td>
<td>134±41.3</td>
</tr>
<tr>
<td>LVESVi, mL/m²</td>
<td>95.6±33.7</td>
</tr>
<tr>
<td>LVEDVi &gt; 96 mL/m²</td>
<td>76 (77.6)</td>
</tr>
<tr>
<td>LAVi, mL/m²</td>
<td>63.3±34.9</td>
</tr>
<tr>
<td>sPAP, mmHg</td>
<td>50.8±15</td>
</tr>
<tr>
<td>sPAP ≥ 35 mmHg</td>
<td>86 (87.8)</td>
</tr>
<tr>
<td>sPAP ≥ 50 mmHg</td>
<td>48 (49)</td>
</tr>
<tr>
<td>Tricuspid Regurgitation &gt; 2</td>
<td>21 (21.4)</td>
</tr>
<tr>
<td>TAPSE, mm</td>
<td>17.5±3.85</td>
</tr>
<tr>
<td>Pulmonary capillary wedge pressure, mmHg</td>
<td>24.75±9.3</td>
</tr>
<tr>
<td>Cardiac Index, L/min/m²</td>
<td>2±0.55</td>
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**How was the study executed?**
What are the essential results?

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

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

- LVAD
- Still waiting for decision
- Death

Primary composite endpoint achieved 63.5% (n=61)
What are the essential results?

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

Kaplan–Meier analysis of

Secondary composite end-point: «1-year adverse events»
- Cardiac mortality rate (6%)
- HF hospitalization rate (19%)
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 essentials to remember

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