Doraya: First-in-man clinical study
Concept and initial results

Dr. R. Dierckx, FESC
Cardiovascular center
OLV Hospital, Aalst, Belgium
☑️ I do not have any potential conflict of interest to declare
Background: diuretic resistance

<table>
<thead>
<tr>
<th>TRIAL</th>
<th>METRIC</th>
<th>PREVALENCE</th>
<th>Outcome</th>
</tr>
</thead>
</table>
| ASCEND-HF (n= 4379) | Weight loss  
Urine output             | 15%        | ↑ 30 d death or HF readmissions  
↑ 30 d death or HF readmissions, ↑180 d death |
| PROTECT (n= 1745)   | Weight loss            | 20%        | ↑ 180 d death, ↑ 60 d death or renal or CV readmission, ↑ 60 d HF readmission |
| RELAX-HF (= 1097)  | Weight loss            | 33%        | ↑ 60 d CV death or readmission for HF or renal failure                  |
| VMAC (n= 475)     | Net fluid loss  
Urine output             | 25%        | ↑ 180 d death  
↑180 d death                                                                 |
Doraya catheter

- **CVP port**
  - Over-the-wire insertion

- **Adjustment knob**
  - Adjust the obstruction degree

- **Heparin port**

- **Peripheral pressure port**

- **Polyurethane coating**
  - Varying degree of flow obstruction
  - Anti-thrombotic Hydrogel coating

- **Nitinol frame**
  - Conforms to vessel anatomy
  - Support device shape
Gradual relief of AHF congestion

Reduction of central venous pressure and cardiac preload

Diuretic efficiency improved

Organ function regained
Inclusion criteria

- Evidence of fluid overload as indicated by 2 or more of the following criteria:
  - peripheral edema ≥2+
  - jugular venous distension ≥7 cm H2O
  - radiographic pulmonary edema or pleural effusion
  - enlarged liver or ascites
  - pulmonary rales or paroxysmal nocturnal dyspnea, or orthopnea

- Subject insufficiently responds to standard diuretic therapy, based on metrics of weight and/or urine output and one of the following:
  - >80 mg furosemide per day or an equivalent, or;
  - >1.5X of the subject chronic baseline diuretic level

- BNP ≥ 400 pg/ml or NTproBNP ≥ 1600 pg/ml

- CVP > 12 mmHg prior to the catheterization procedure
<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safety</td>
<td>Device or procedure related Serious Adverse Event (SAE) rate through 30 days post index procedure as adjudicated by a Clinical Events Committee (CEC)</td>
</tr>
<tr>
<td>Feasibility</td>
<td>Ability to position the device below the renal veins, to regulate the flow in the IVC using the device by creating a gradient pressure of at least 2 mmHg, and to withdraw the device</td>
</tr>
<tr>
<td>Observational</td>
<td>Congestion, renal function, circulatory system hemodynamics</td>
</tr>
</tbody>
</table>
Urine output during treatment

![Graph showing urine output in ml/hr over time](image)

- **Urine output ml/hr**
- **Procedure time**
- **Diuretics**
- **Day (-1)**

Legend:
- Orange line: BL02
- Gray line: BL03
- Yellow line: PL01
Urine output during treatment
Hemodynamic improvement

SBP, mmHg

Baseline  | Min   | End
---       | ---   | ---
120       | 110   | 100
100       | 90    | 80
80        | 70    | 60

RAP (CVP), mmHg

Baseline  | End
---       | ---
25        | 15
20        | 10
15        | 5

PCWP, mmHg

Baseline  | End
---       | ---
35        | 25
30        | 20
25        | 15
20        | 10

PAP, mmHg

Baseline  | End
---       | ---
70        | 60
60        | 50
50        | 40
40        | 30
30        | 20
Natriuresis

![Graph showing Natriuresis levels for BLO2, BLO3, and PLO1 with comparison between Baseline and End.](image-url)
• The Doraya catheter appears to be safe and can help overcome diuretic resistance in patients admitted with acute heart failure

• Ongoing FIM will further determine the safety profile and provide insights into hemodynamic effect and renal function
• Cardiology team, OLV Hospital, Aalst, Belgium
• Dr. Robert Zymlinski and cardiology team, University Clinical Hospital Wroclaw, Poland