# Narrowing of the Coronary Sinus for the Treatment of Refractory Angina Pectoris:
# A multicentre prospective observational open-label clinical study (REDUCER-I),
# Analysis of the first 207 patients

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# Potential conflicts of interest

Stefan Verheye

**Speaker's name : Stefan Verheye**

☑ I have the following potential conflicts of interest to declare:

Receipt of honoraria or consultation fees: Biotronik, Elixir Medical, Neovasc

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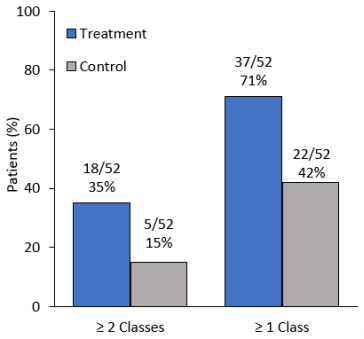
# Why this study?

- Refractory angina is a common disabling condition, which is highly correlated with increased healthcare costs
- Patients suffering from refractory angina have poor quality of life but their overall prognosis is similar to that of patients with stable CAD
- The coronary sinus (CS) Reducer is a device-based therapy for the treatment of refractory angina
- The Reducer is designed to improve quality of life and functional capacity by reducing ischemic burden




**COSIRA Trial**

*Verheye S, Jolicoeur EM, Behan MW, et al. Efficacy of a device to narrow the coronary sinus in refractory angina. N Engl J Med 2015; 372: 519-527*

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# What did we study and how was it executed?

- Multi-center, international, three-arm prospective and retrospective observational study
- Enrollment up to 400 subjects; 241 as of 12 March 2020
- Follow-up through 5 years post implant (Baseline, implant, 30 day, 6 and 12 month, annual)
- Primary endpoints:
  - Reduction in CCS grade at 6 months as compared to baseline
  - Rate of occurrence of device and/or procedure related periprocedural SAEs
  - MACE: composite of cardiac death, major stroke, and MI through 30 days post-implant

**REDUCER-I Study Design**

| Arm 1<br>(N=191 enrolled,<br>N= 180 implanted) | Arm 2<br>COSIRA Follow-up Arm<br>*Enrollment Completed (N=11)* | Arm 3<br>CE Mark Follow-up Arm<br>*Enrollment Completed (N=39)* |
|---|---|---|
| • Subjects are enrolled prior to receiving the Reducer<br>• Prospective | • Subjects from the treatment arm of the COSIRA study<br>• Retrospective collection of follow-up data occurring after completion of the COSIRA study but prior to enrollment into REDUCER-I | • Patients implanted under CE Mark<br>• Retrospective collection of existing data from subjects implanted with Reducer under CE mark prior to enrollment into REDUCER-I |

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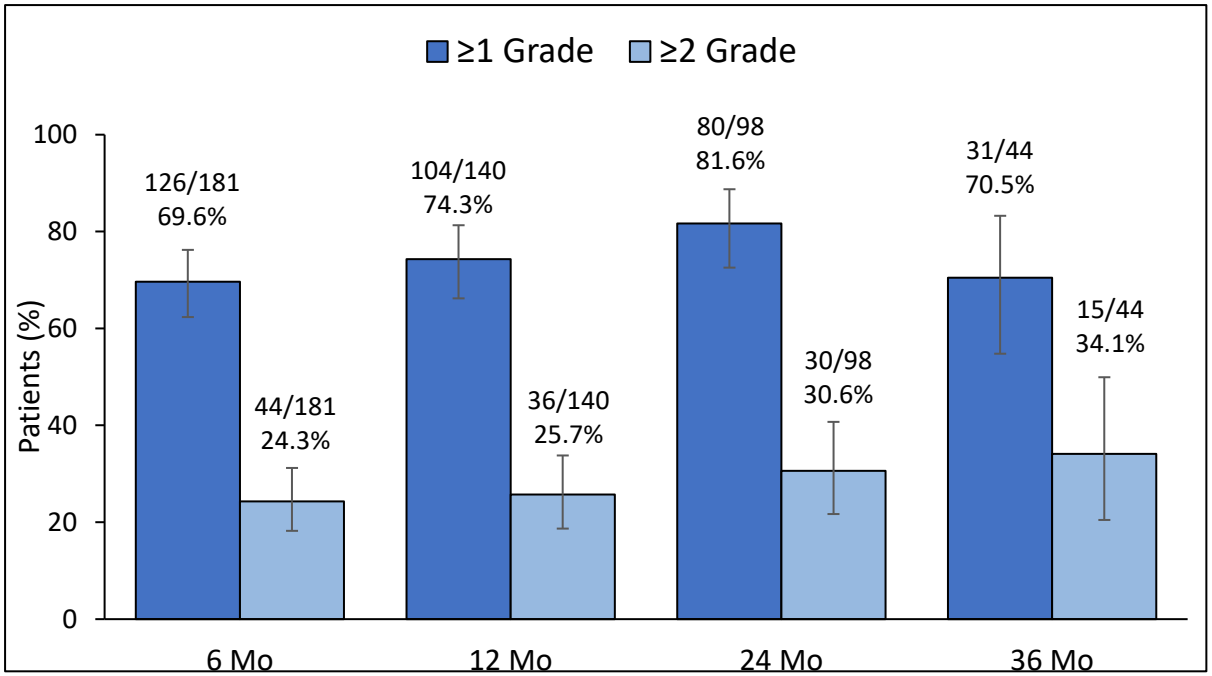
# What are the essential results?

## Primary Endpoint: Reduction in CCS Grade




Includes data through analysis lock on 12 March 2020 and is 90% monitored; on file at Neovasc

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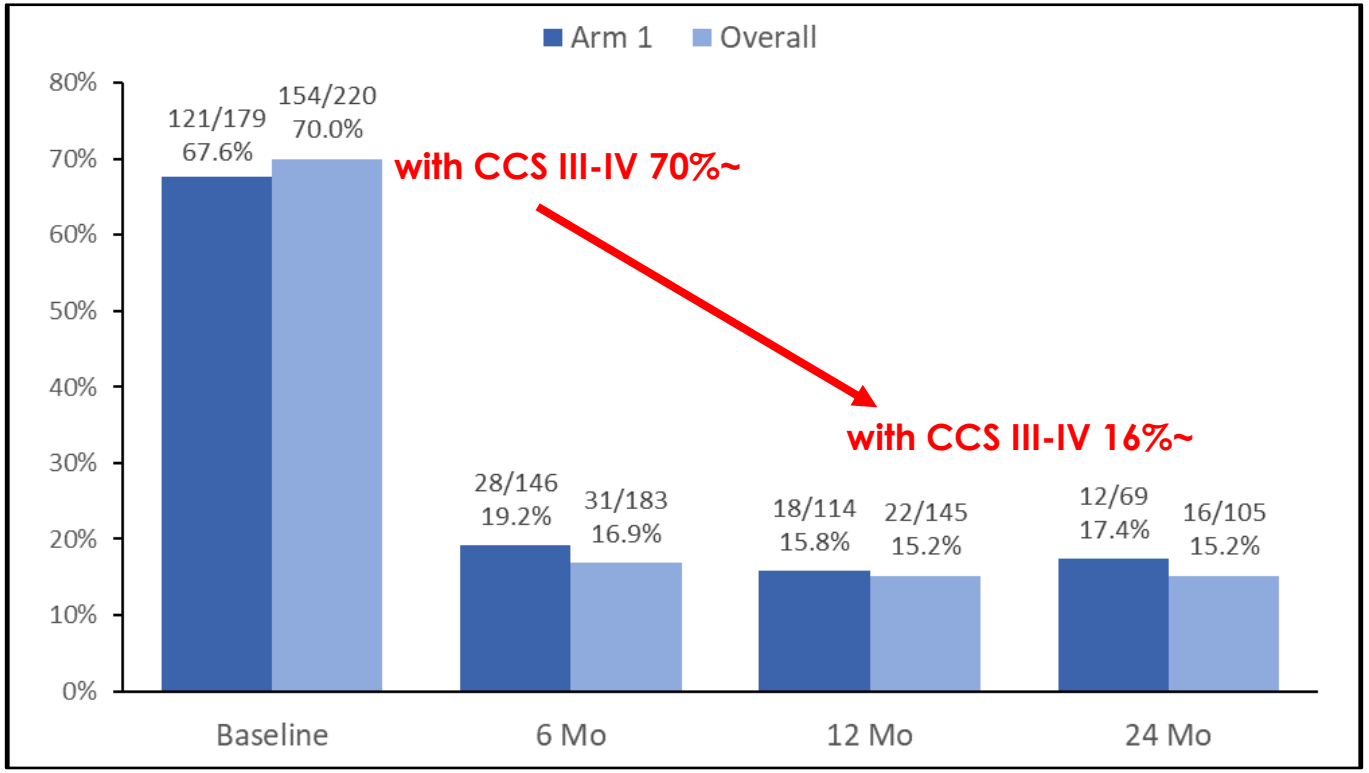
# What are the essential results?

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# Why is this important?

32 MACE reported in 228 subjects that proceeded to the implant procedure

- One MI occurring in one subject (0.4%) was adjudicated as procedure and device related

| Event | Events n/N (%) | Subjects n/N (%) | *Subjects with procedure-related events n/N (%)* | *Subjects with device-related events n/N (%)* |
|---|---|---|---|---|
| **Cardiac Death** | 6/32 (18.8%) | 6/228 (2.6%) | *0/228 (0.0%)* | *0/228 (0.0%)* |
| **Major Stroke** | 5/32 (15.6%) | 4/228 (1.8%) | *0/228 (0.0%)* | *0/228 (0.0%)* |
| **Myocardial Infarction** | 21/32 (65.6%) | 16/228 (7.0%) | *1/228 (0.4%)*[2] | *1/228 (0.4%)*[2] |
| **Total** | | 23/228 (10.1%) | *1/228 (0.4%)* | *1/228 (0.4%)* |

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# What are the essential results?

| | COSIRA[1] | REDUCER-I[2] | |
|---|---|---|---|
| **SAQ Subscale** | **Change from Baseline to 6M N=51 (SD)** | **Change from Baseline to 6M N= 144 (SD)** | **P-value** |
| **Physical Limitations** | 9.2 (20.2) | 12.2[3] (23.0) | <0.0001 |
| **Anginal Stability** | 18.1 (32.4) | 15.5 (34.9) | <0.0001 |
| **Angina Frequency** | 15.3 (28.9) | 19.3 (28.1) | <0.0001 |
| **Treatment Satisfaction** | 2.9 (16.6) | 6.2 (17.4) | <0.0001 |
| **Quality of Life** | 17.6 (26.2) | 25.6 (26.9) | <0.0001 |

A change in score of 10 points in any of the subscales is considered to be clinically important.[4]

[1] *Verheye S, Jolicoeur EM, Behan MW, etal. Efficacy of a device to narrow the coronary sinus in refractory angina. N Engl J Med 2015; 372:519-527*

[2] Includes data through analysis lock on 12 March 2020 and is 90% monitored; on file at Neovasc

[3] N=133

[4] *Spertus JA, Winder JA, et al., J Am Coll Cardiol. 1995 Feb; 25(2):333-41. Development and evaluation of the Seattle Angina Questionnaire: a new functional status measure for coronary artery disease*

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# What are the essential results?

Number of Documented Emergency Department Visits Due to Angina in the Past 12 Months

| ED Visits | Baseline | 12 Months |
|---|---|---|
| **Subjects with at least 1 ED visit in the last 12 months[2]** | 41.6% (47/113) | 13.3% (15/113) |
| **Sum of ED visits across all subjects** | 78 | 22 |
| **Average number of ED visits in the previous 12 months including subjects with 0 visits[3]** | 0.69 ± 1.06 (113) [0, 5] | 0.19 ± 0.60 (113) [0, 4] |
| **P-value for change in number of visits** | NA | <0.0001 |
| **Decrease in the number of ED visits or 0 visits at Baseline and 12 months** | NA | **91.2%** (103/113) |

[1] Based on ARM 1 Subjects with Baseline and 12 Month Visits; Excluding subject with 15 ED days at baseline
[2] Data are presented as % (n/N)
[3] Data are presented as mean ± SD (N) [min, max]

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# The essentials to remember

- **REDUCER-I** “real-world” data is **consistent** with the COSIRA randomized double-blind, sham controlled study data
- Reducer has a positive clinical effect on patients with refractory angina
- A reduction in ED visits by 91.2%
- Reducer provides a **safe treatment option** for patients
- **Positive clinical effects are maintained long-term**


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