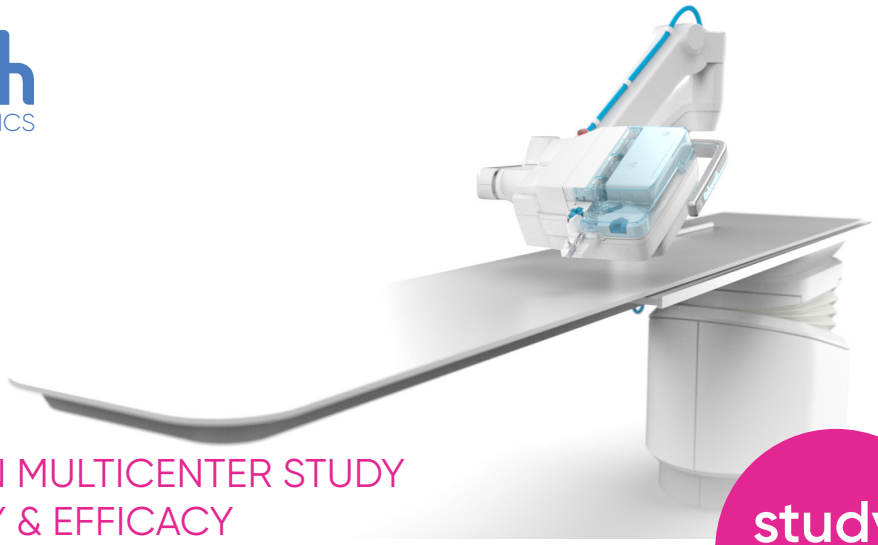
Robocath
INTUITIVE VASCULAR ROBOTICS



R-EVOLUTION EUROPEAN MULTICENTER STUDY TO EVALUATE THE SAFETY & EFFICACY OF THE R-ONE™ SYSTEM IN PERCUTANEOUS CORONARY INTERVENTIONS

study summary

Eric Durand, PhD, on behalf of all the investigators of the R-Evolution study

STUDY DESIGN

- Design: prospective, multicenter, single arm
- Population: 62 patients (64 lesions)
- Centers: 6 (the University Hospitals in Rouen and Caen with Prof. Durand and Prof. Sabatier, the Clinique Pasteur in Toulouse with Dr. Fajadet, all based in France; the ZNA Middelheim hospital in Antwerp, Belgium, with Prof. Verheye; the Maasstad clinic in Rotterdam, Netherlands, with Prof. Smits and Dr. Van Der Ent; and the National Interventional Cardiac Surgery Institute in Luxembourg with Dr Pereira and Dr Muller)
- Indication: de novo, up to 2 lesions in a single procedure (1 lesion per vessel)
- Exclusion criteria: length > 38mm, diameter > 4.00mm, severe calcification and tortuosity, bifurcations, ostial lesions, restenosis, LM, SVGs
- Follow-up: 1 month
- **Primary endpoints:**
  - Clinical Success: absence of major complication at 30 days follow-up
  - Technical Success: robotic PCI without total manual conversion

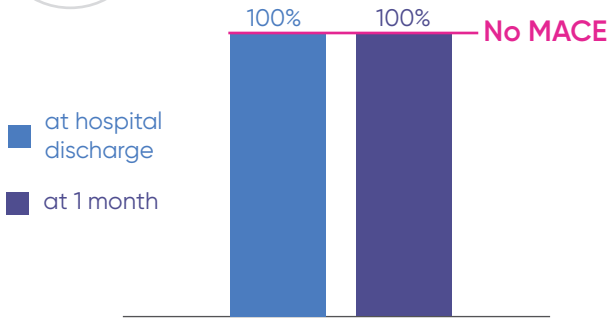
CLINICAL & ANGIO CHARACTERISTICS

Variables	Overall population (N=62)
Age, years	65.4 ± 10.1
Male, N (%)	50 (80.6)
BMI, Kg/m^2	27.2 ± 4.7
Clinical presentation, N (%)	
Silent ischemia	23 (37.1)
Stable angina	26 (41.9)
Unstable angina	6 (9.7)
NSTEMI	7 (11.3)

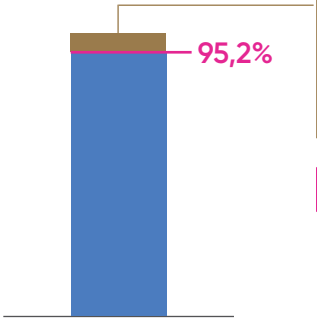
Variables	Overall population (N=62)
Radial artery (Left or right), N (%)	60 (96,8%)
Lesion location, N (%)	
LAD	22 (34.4)
LCX	21 (32.8)
RCA	17 (26.5)
B2/C lesions, N (%)	16 (25,0)
Pre-dilatation, N (%)	38 (59.4)
Stent per lesion	1.05 ± 0.28
Stent diameter, mm	3.0 ± 0.4
Stent length, mm	19.5 ± 6.5
Post-dilatation, N (%)	24 (37.5)

STUDY RESULTS

CLINICAL SUCCESS



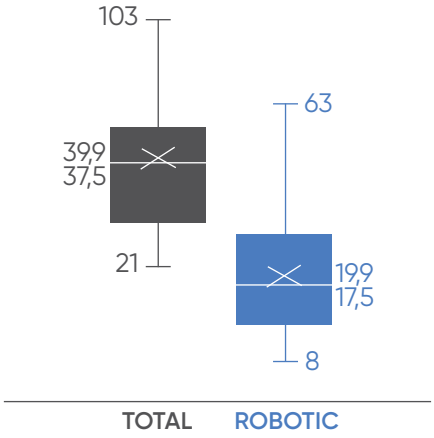
TECHNICAL SUCCESS



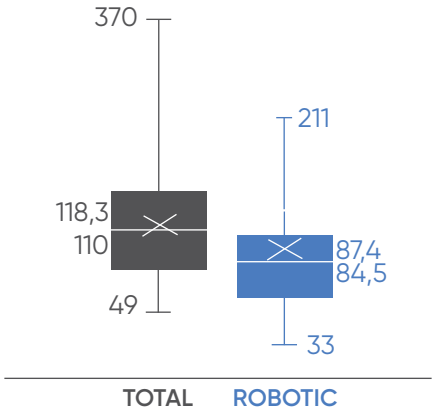
- Inability to cross the lesion with the balloon due to a lack of support (1/3)
- Software error due to wrong adjustment of the guidewire into the pads of the robot (2/3)
- a non-occlusive coronary dissection (NHLBI type B) non-related to the robot (3/3)

2/3 of manual conversions were not related to the robot

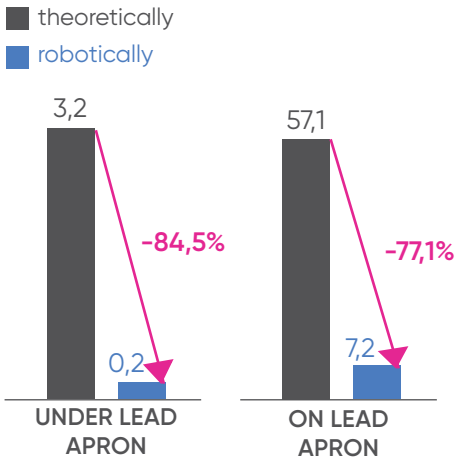
PROCEDURE DURATION (min)



CONTRAST VOLUME (mL)



RADIATION EXPOSURE (µSv)



KEY FINDINGS

1. >95% technical success: 59 of the 62 robotic procedures were performed completely robotically and 25% of the lesions were complex *(ACC AHA classification)*
2. 100% clinical success: no major intra-procedural and 30-day complications reported
3. Only one permanent manual conversion was a robotic failure
4. The 3 permanent manual conversions occurred in early experienced centers*
5. - 84,5% of radiation exposure to the operator

* For each early experienced center, 5 robotic PCI were performed before patient enrollment in the study

For more information:
sales@robocath.com

or visit:
www.robocath.com

Robocath Headquarters
19, rue Marie Curie
76000 Rouen
France

CE 2797
BSI, CE n°690387

The R-One robotic platform is a Class IIb medical device.
The R-One consumable kit is a Class Is medical device.
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