Short-term outcomes of a novel self-expanding device: ITAL-neo Registry

Andrea Buono[1], MD; Riccardo Gorla[2], MD; Ottavia Cozzi[3], MD; Alfonso Ielasi[4], MD; Matteo Montorfano[5], MD; Jacopo Oreglia[6], MD; Erica Ferrara[7], MD; Fausto Castriota[8], MD; Farncesco Giannini[8], MD; Diego Maffeo[1], MD

[1]Fondazione Poliambulanza Istituto Ospedalierp, Brescia, Italy
2IRCCSPoliclinico San Donato, San Donato Milanese, Italy
[3]Humanitas Rozzano Hospital, Milan, Italy
[4]Istituto Clinico Sant'Ambrogio, Gruppo Ospedaliero San Donato, Milan, Italy.
[5]San Raffaele Hospital, Milan, Italy
[6]Ospedale Niguarda, Milan, Italy
[7] ASST Ovest Milanese, Ospedale Civile di Legnano, Legnano, Italy
[8]Humanitas Gavazzeni, Bergamo, Italy
[8]GVM Maria Cecilia Hospital, Cotignola, Italy

Why this study?

1st generation device

Acurate *neo*
(Boston Scientific)

STUDY	Incidence	Competitor	Competitor's incidence
Safy TF Registry	4.1% (procedural)	-	-
MORENA Registry	**4.8% (30-d)**	Sapien 3 (Edwards)	**1.8% (30-d)**
SCOPE I RCT	**9% (30-d)**	Sapien 3 (Edwards)	**3% (30-d)**
Mauri V et al. (small annuli)	**4.5% (30-d)**	Sapien 3 (Edwards)	**3.6% (30-d)**
NEOPRO Registry	**10.9% (30-d)**	Evolut PRO (Medtronic)	**8.7% (30-d)**
SCOPE II RCT	**10% (30-d)**	CoreValve/Evolut (Medtronic)	**3% (30-d)**

Not negligile more-than-mild PVL incidence

New 2nd generation device

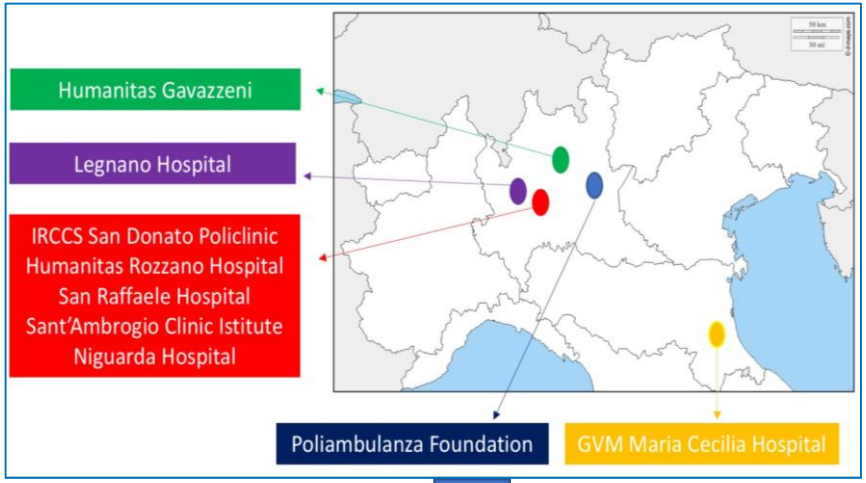
Acurate *neo2*
(Boston Scientific)

Active Pvseal™ technology

Taller external skirt

What did we study?

From the 30th September 2020 to 21th March 2021 in 9 Italian Centers



95 patients with *severe native aortic valve stenosis* underwent TAVR, implanting Acurate *neo* 2 (no pre-selection was performed)

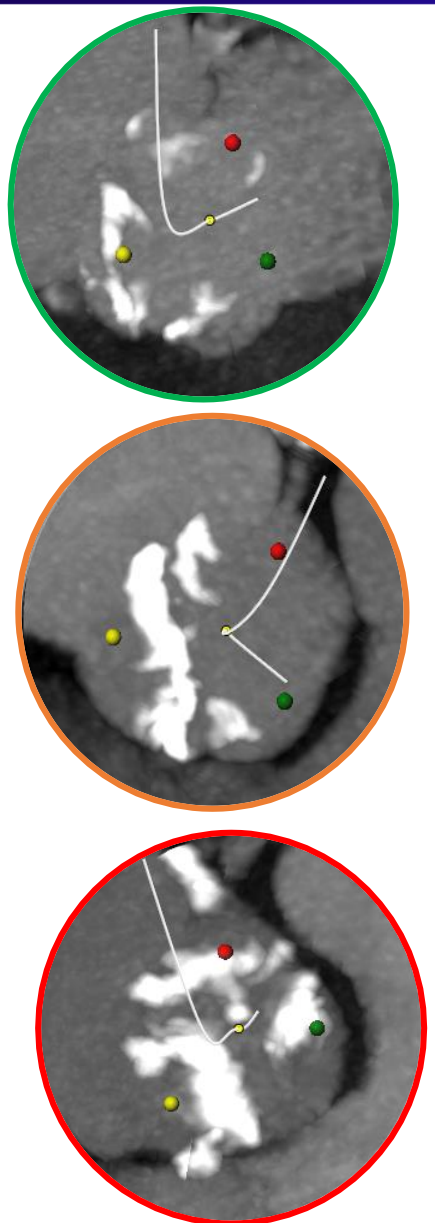
Baseline Characteristics	
Age (years), mean±SD	81.9±4.6
Female sex, n(%)	**69(72.6)**
BMI kg/m^2, mean±SD	26.8±5.4
Arterial hypertension, n(%)	82(86.3)
Diabetes mellitus, n(%)	24(25.2)
Dyslipidemia, n(%)	54(56.8)
Smoking history, n(%)	15(15.8)
Active malignancy, n(%)	6(6.3)
Glomerular Filtration Rate (ml/min), mean±SD	56.2±22.8
Significant coronary artery disease, n(%) • Previous PCI, n(%) • Previous CABG, n(%)	33(34.7) 28(29.5) 3(3.2)
Previous permanent pacemaker, n(%)	**6(6.3)**
Significant peripheral vascular disease, n(%)	10(10.5)
Significant carotid artery disease, n(%)	8(8.4)
History of atrial fibrillation, n(%)	33(34.7)
Previous stroke or TIA, n(%)	11(11.6)
COPD, n(%)	10(10.5)
NYHA class >1, n(%)	**95(100)**
STS-mortality score (%), mean±SD	**4.59±3.16**

How was the study executed?

Baseline ECGraphic and Echocardiographic characteristics	
Sinus rhythm, n(%)	69(72.6)
First-degree atrioventricular block in SR pts, n(%)	**14(20.2)**
Intraventricular conduction disturbances in pts w/o PM, n(%)	**17 [19% (9% RBBB - 10% LBBB)]**
LVEF (%), mean±SD	57.2±8.9
Tricuspid valve, n(%) Bicuspid valve, n(%)	92(96.8) 3(3.2)
Aortic valve area (cm^2), mean±SD	**0.70±0.14**
Transaortic mean gradient (mmHg), mean±SD	**42.2±12.5**
Concomitant aortic regurgitation, n(%): • Mild, n(%) • Moderate, n(%) • Severe, n(%)	68(71.5) 50(52.6) 17(17.9) 1(1)
Concomitant mitral regurgitation, n(%): • Mild, n(%) • Moderate, n(%) • Severe, n(%)	82(86.3) 62(65.2) 18(18.9) 2(2.1)

How was the study executed?

Computed Tomography analysis	
Annulus area (mm^2), mean±SD	429.2±57.8
Annulus perimeter (mm), mean±SD	74.5±5.0
SOV mean diameter (mm), mean±SD	30.9±2.8
STJ mean diameter (mm), mean±SD	28.2±2.8
LVOT mean diameter (mm), mean±SD	23.0±1.8
Left main height (mm), mean±SD	13.6±2.9
Right coronary artery height (mm), mean±SD	16.5±3.2
Aortic angle (°), mean±SD	49.7±9.8
Degree of leaflet calcification:	
• **Mild, n(%)**	**46(48.4)**
• **Moderate, n(%)**	**31(32.6)**
• **Severe, n(%)**	**18(19)**
Degree of annulus calcification:	
• None, n(%)	61(64.2)
• Mild, n(%)	26(27.4)
• Moderate, n(%)	5(5.2)
• Severe, n(%)	3(3.2)
Degree of LVOT calcification:	
• None, n(%)	77(81)
• Mild, n(%)	15(15.8)
• Moderate, n(%)	3(3.2)



How was the study executed?

All the assessed endpoints are in-hospital

Primary endpoint

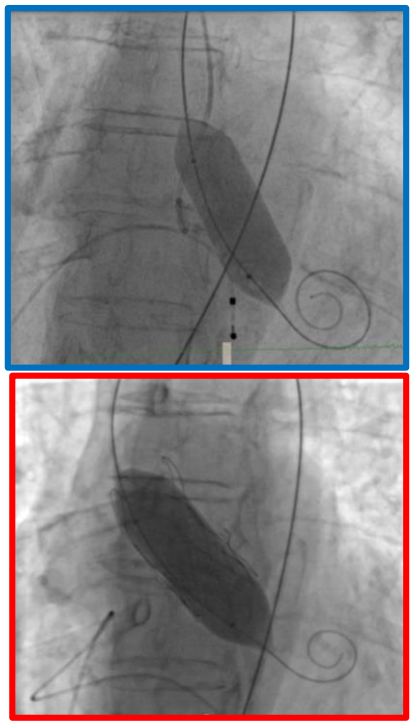
Device success (according VARC-2 criteria)

Secondary endpoints:

- More-than-mild post-procedural paravalvular leak incidence at pre-discharge echocardiogram
- Bleedings incidence (according BARC-2 criteria)
- Vascular complication incidence (according VARC-2 criteria)
- Rate of post-procedural permanent pacemaker implantation
- Hospitalization length

What are the essential results?

Procedural Results	
Access route: • **Trans-femoral, n(%)** • Trans-subclavian, n(%)	 **94(99.1)** 1(0.9)
Acurate *neo* 2 size • *S*, n(%) • *M*, n(%) • *L*, n(%)	 23(24.2) 42(44.2) 30(31.6)
Valve pre-dilatation, n(%)	**80(84.2)**
THV post-dilatation, n(%)	**28(29.5)**
Implantation depth (mm), mean±SD	4.51±1.62
Concomitant angio and/or PCI, n(%)	36(37.9)
Procedure length (min), mean±SD	96.2±33.5
Fluoroscopy time (min), mean±SD	23.5±9.5
Contrast dye amount (ml), mean±SD	126.3±60.3
Antithrombotic therapy • Single antiplatelet, n(%) • Dual antiplatelet, n(%) • Oral anticoagulant, (%) • Single antiplatelet plus anticoagulant, n(%) • Dual antiplatelet plus anticoagulant, n(%)	 36(37.9) 23(24.2) 27(28.4) 8(8.4) 1(1.1)



Primary endpoint

97.9% DEVICE SUCCESS

2.1% of valve embolization, successfully managed with 2° valve implantation

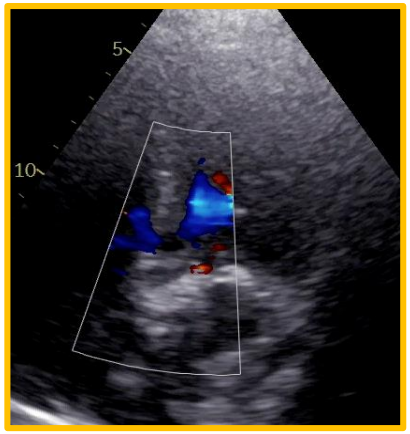
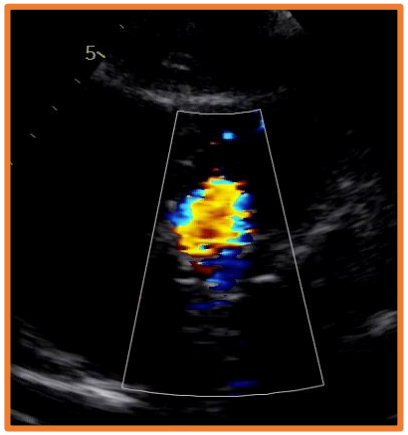
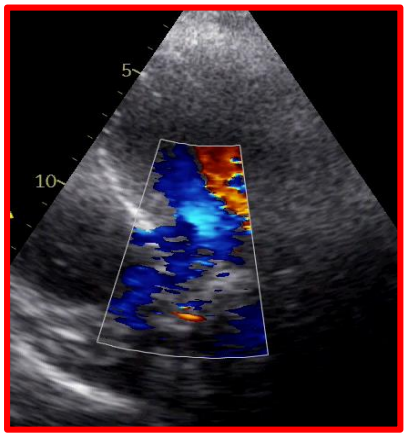
What are the essential results?

In-Hospital Outcomes	
All-cause death, n(%)	**0(0)**
Peri-procedural myocardial infarction, n(%)	**0(0)**
Development of new advanced AVB or BBB in pts w/o PPM, n(%): • *Spontaneous regression of new-developed, n(%)* • **New permanent pacemaker implantation, n(%)**	25(28.1) 9(36) **10(11.2)**
Bleeding (BARC-2): • None, n(%) • Minor (1;2; 3a requiring 1 blood unit), n(%) • **Major** (3a requiring >1 unit; 3b; 3c; 5a-b), n(%)	 88(92.6) 4(4.2) **3(3.2)**
Vascular complication (VARC-2): • None, (%): • Minor, n(%) • **Major, n(%)**	 87(91.6) 7(7.3) **1(1.1)**
Stroke/TIA, n(%): • Disabling, n(% of total stroke) • Not-disabling, n(%)	**1(1.1)** 1(100) 0(0)
Other complications, n(%): • Ventricular perforation with cardiac tamponade, n(%) • Iatrogenic ventricular septal defect, n(%)	2(2.1%) 1(1.05%) 1(1.05%)
Renal Failure, n(%)	3(3.2)
Intensive care unit stay (days), median[IQR]	1[1;2]
Hospital stay (days), median[IQR]	**6[5;9.5]**

80% full AVB
20% AF with advanced AVB

What are the essential results?

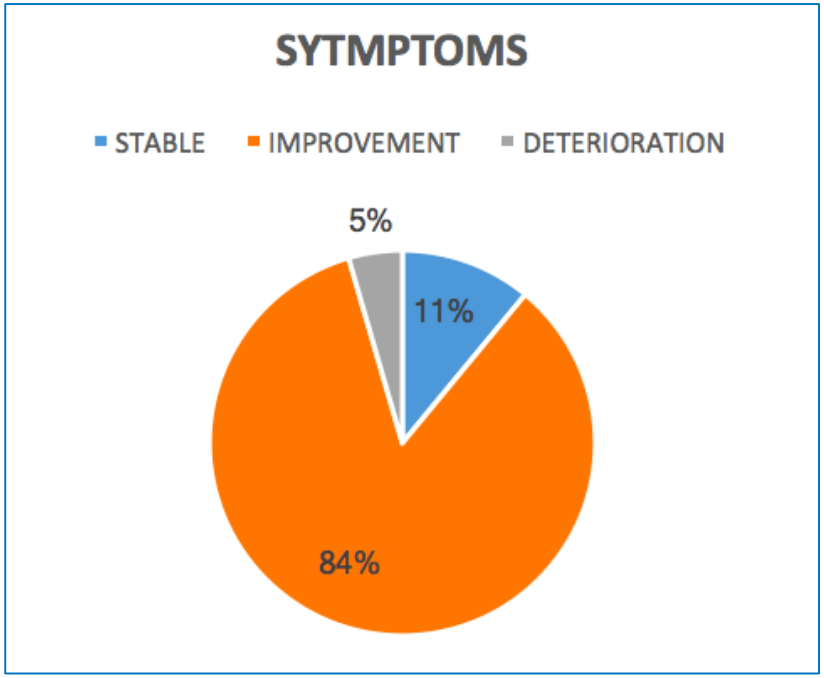
Pre-discharge echocardiographic Results	
LVEF (%), mean±SD	58.1±8.3
Transaortic mean gradient (mmHg), mean±SD	**8.2±3.6**
Transaortic max gradient (mmHg), mean±SD	14.8±6.4
Aortic valve area (cm^2), mean±SD	1.81±0.48
Prosthesis-patient mismatch (36 pts):	
• Insignificant (>0.85 cm^2/m^2), n(%)	28(77.7)
• Moderate (<0.85 and >0.65 cm^2/m^2), n(%)	8(22.3)
• Severe (<0.65 cm^2/m^2), n(%)	0(0)
Residual paravalvular leak:	
• **None, n(%)**	**38(40)**
• **Mild, n(%)**	**54(56.9)**
• **Moderate, n(%)**	**3(3.1)**
• **Severe, n(%)**	**0(0)**

What are the essential results?

90-days Follow-up available in 52 pts

1 Non-cardiac Death (sepsis)	0 MI and Stroke	4 Cardiac Hospit.	2 Minor Bleedings	0 PPM implant



NO DEVICE FAILURE

30-days echocardiographic data (34 pts)	
LVEF (%), mean±SD	57.4±6.9
Transaortic mean gradient (mmHg), mean±SD	**7.7±4.5**
Aortic valve area (cm^2), mean±SD	1.65±0.34
Residual paravalvular leak:	
• None, n(%)	16(47)
• Mild, n(%)	18(53)
• Moderate, n(%)	0(0)
• Severe, n(%)	0(0)

Why is this important?

- We have reported one of the first available real-word cohort of patients treated with Acurate neo 2 THV for severe native aortic valve stenosis

- Our findings have documented the efficacy and safety of this new iteration

- The low incidence of more-than-mild paravalvular leak is encouraging

The essentials to remember

- Why? First-generation Acurate *neo* was associate with a not negligible rate of more-than-mild PVL
- What? To test the performance of novel Acurate *neo*2 in patients suffering from severe native aortic stenosis
- How? Assessing procedural device success and in-hospital outcomes after TAVR
- What are the results? Procedural success was achieved in 98%, with a low rate of more-than-mild paravalvular leaks (3.1%) and major complications
- Why this is important? Our cohort is one of the first available, demonstrating the novel device performance

Collaborators:

Fondazione Poliambulanza Istituto Ospedalierp: Gaetano Pero; Luca Bettari

IRCCS Policlinico San Donato: Francesco Bedogni; Elena Acerbi

Humanitas Rozzano Hospital: Damiano Regazzoli; Bernhard Reimers

Istituto Clinico Sant'Ambrogio: Mariano Pellicano; Maurizio Tespili

San Raffaele Hospital: Marco Ancona

Ospedale Niguarda: Francesco Soriano; Antonio Gabriele Franchina

Ospedale Civile di Legnano: Arnaldo Poli

Humanitas Gavazzeni: Roberto Nerla

GVM Maria Cecilia Hospital: Francesco Gallo