TRANSCATHETER AORTIC VALVE IMPLANTATION WITHOUT ON-SITE CARDIAC SURGERY

REAL WORLD OUTCOMES FROM THE FIRST ITALIAN SINGLE-CENTRE EXPERIENCE

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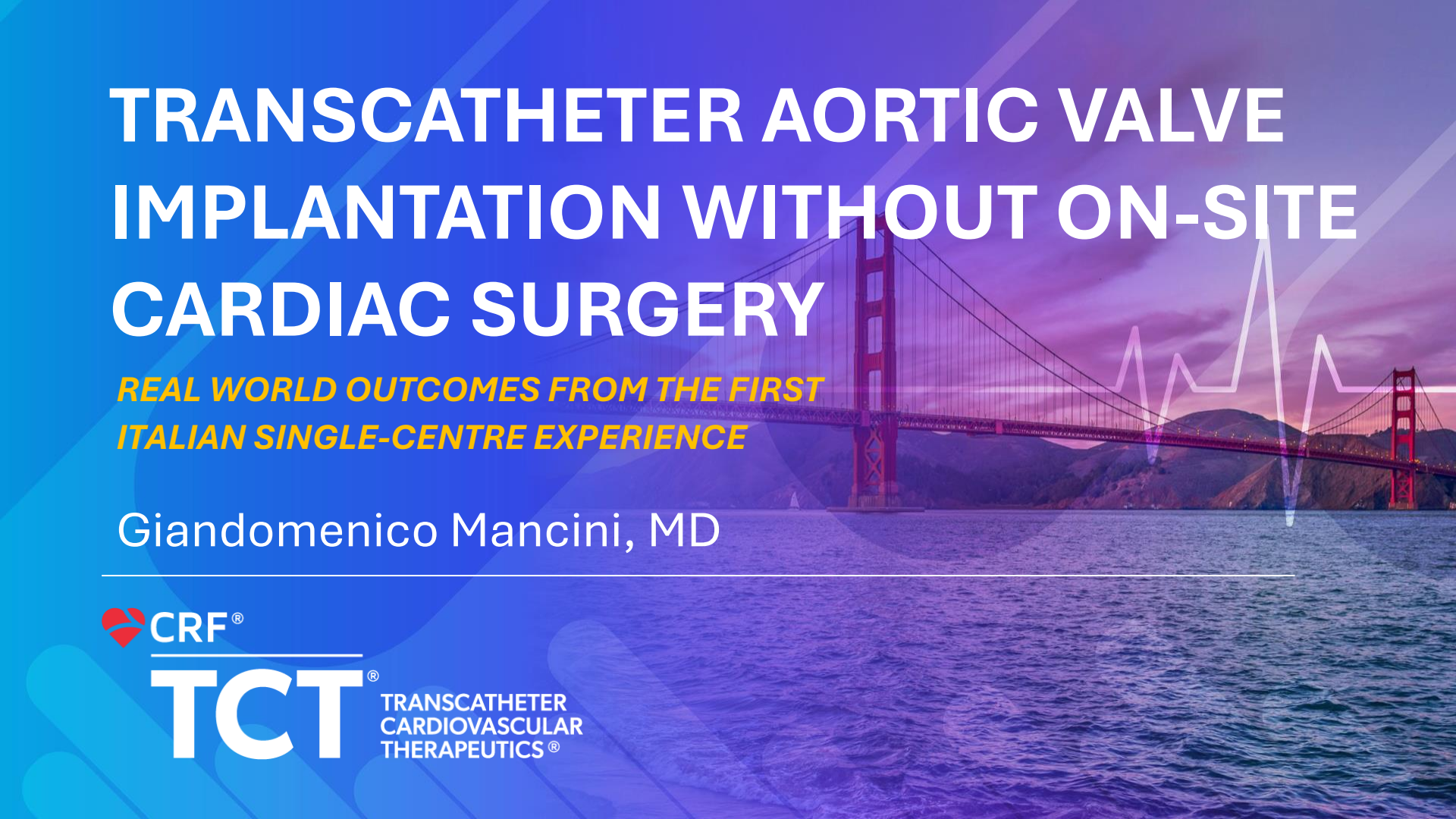

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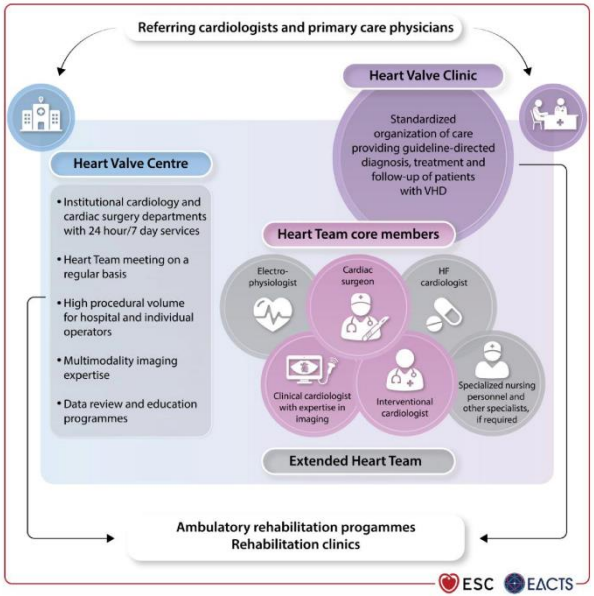
Disclosure of Relevant Financial Relationships

I, Giandomenico Mancini DO NOT have any financial relationships to disclose.

Background

Recommendations	Class	Level
Mode of intervention		
It is recommended that AV interventions are performed in Heart Valve Centres that report their local expertise and outcome data, have on-site interventional cardiology and cardiac surgical programmes, and a structured collaborative Heart Team.	I	C



TAVI is recommended in patients ≥70 years of age with tricuspid AV stenosis, if the anatomy is suitable.	I	A
SAVR is recommended in patients <70 years of age, if the surgical risk is low.	I	B
SAVR or TAVI are recommended for all remaining candidates for an aortic BHV according to Heart Team assessment	I	B
Non-transfemoral TAVI should be considered in patients who are unsuitable for surgery and transfemoral access.	IIa	B

2025 ESC/EACTS Guidelines for the management of valvular heart disease' (European Heart Journal; doi: 10.1093/eurheartj/ehaf194)

TAVI in hospitals without on-site cardiac surgery

2014

- **Eggebrecht et al. (Germany)**
- 1254 vs 178 non iOSCS patients→ no significant differences in rates of major post-procedural complications, in-hospital and 30-day mortality

2015

- **Gafoor et al. (Germany)**
- 97 TAVI in a single center with a visiting surgical team → 100% procedural success. No conversions to surgery.

2016

- **AQUA Registry (Germany)**
- 16,587 vs 1,332 non iOSCS patients→ no significant differences in complications, mortality and ECS rate. No differences in in-hospital deaths after ECS.

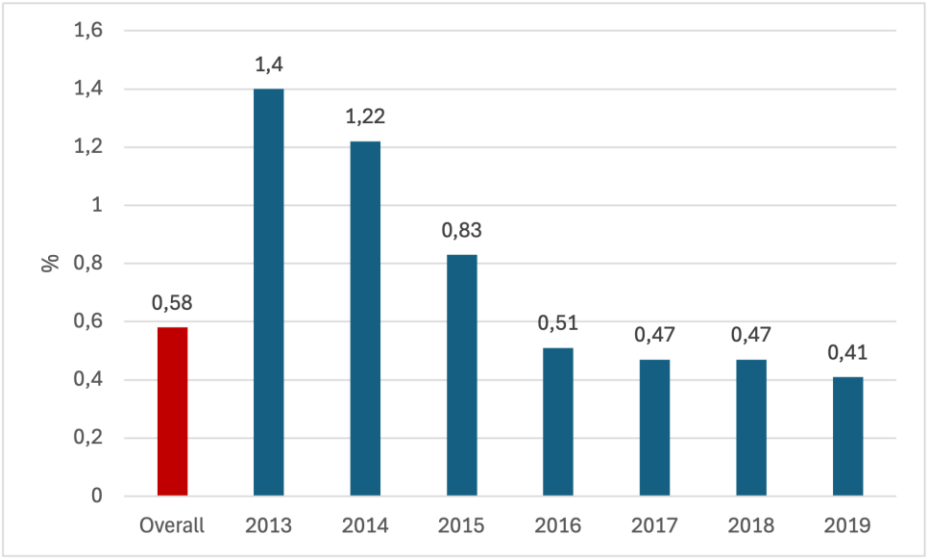
2018

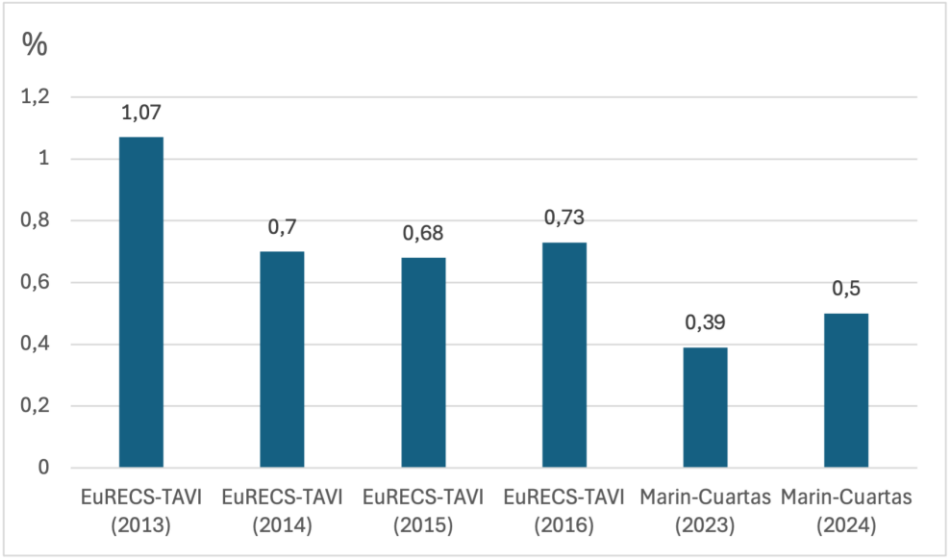
- **Egger et al. (Austria)**
- 1532 vs 290 non iOSCS patients→ in-hospital, one month, one year and 3 years all-cause mortality rates were not significantly different between the groups

2019

- **Roa garrido et al. (Spain)**
- 384 TAVI from 10 centers with reference CS at <90 km and Vascular Surgery on site→ 96,6% technical success. 1 ECS. 2.1% in-hospital CV mortality. 12.2% 1-year mortality.

Emergency Cardiac Surgery during TAVI



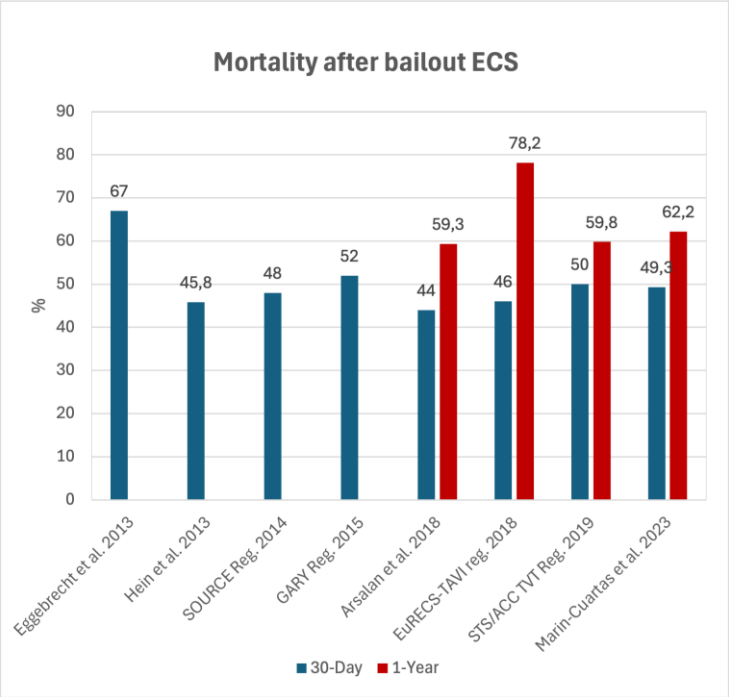


Carroll, JD et al. J Am Coll Cardiol. 2020 Nov 24;76(21):2492-2516.

Eggebrecht, H et al. Eur Heart J. 2018 Feb 21;39(8):676-684.

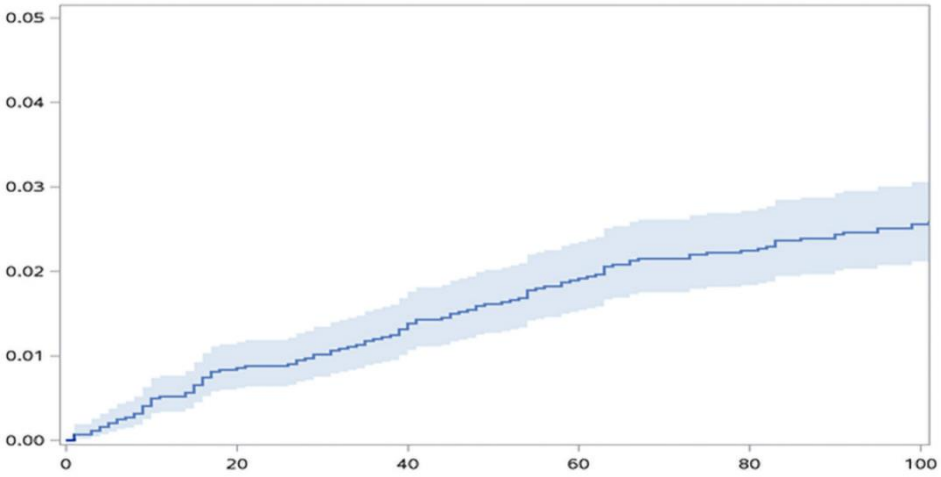
Marin-Cuartas, M et al. Journal of the American Heart Association 2024-07-16 13(14): e033964.

Mortality after Emergency Cardiac Surgery

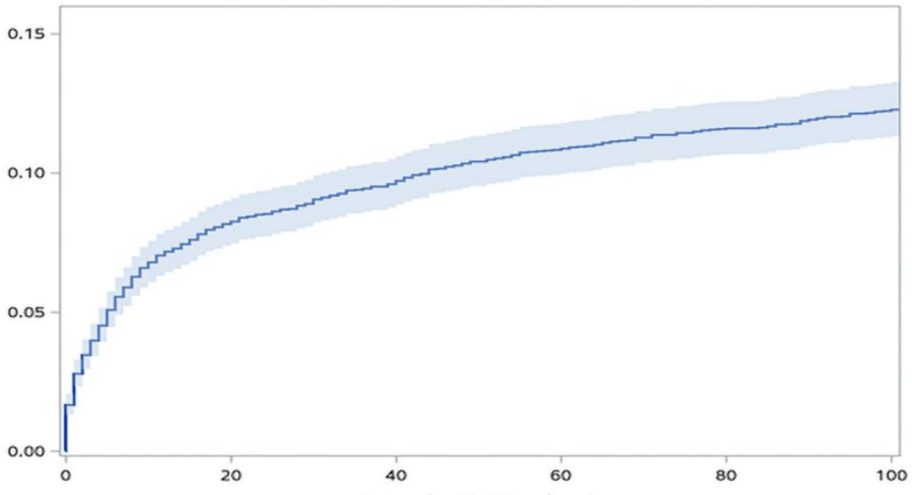


- **The rate of TAVI complications requiring ECS is extremely low (<0,5%) and decreasing.**
- **Prognosis of patients undergoing ECS during TAVI is poor, irrespective of on-site CS.**
- **Many of the major complications likely to benefit from ECS can be managed percutaneously (e.g. pericardial tamponade or coronary obstruction).**
- **Vascular complications remain the major problem of the procedure today**

Mortality while waiting for TAVI



Mortality on wait list in the first 100 days



Heart failure hospitalization on wait list in the first 100 days

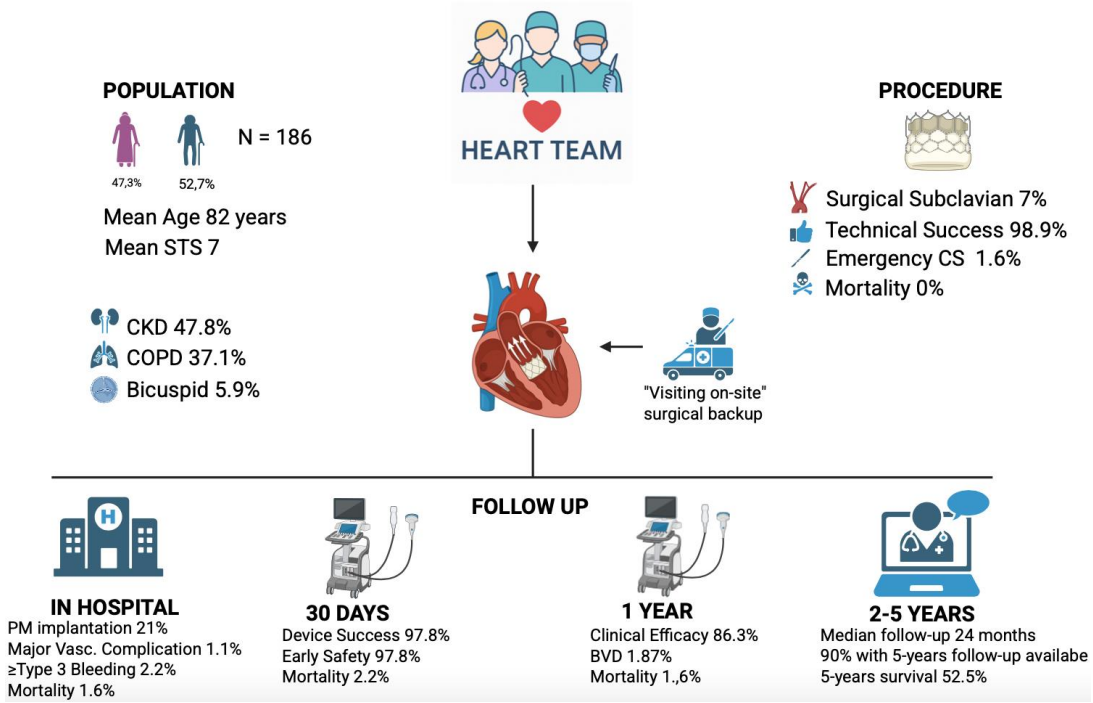
Mortality and morbidity increase while waiting for TAVI!

Malaisrie, C. et al. Ann Thorac Surg. 2014;98:1564–71

Elbaz-Greener, G. et al. Circulation. 2018;138:483–493.

TRANSCATHETER AORTIC VALVE IMPLANTATION IN A HOSPITAL WITHOUT ON-SITE CARDIAC SURGERY

THE FIRST ITALIAN SINGLE-CENTRE EXPERIENCE



Patients demographics and procedural data

PATIENTS DEMOGRAPHICS	
Age (years)	82±6
Female	88 (47.3%)
Previous Cardiac Surgery	25 (13.4%)
COPD	69 (37.1%)
CKD	89 (47.8%)
STS score (%)	7.0±6.0
EuroSCORE II	4.0±4.4
LVEF	52±8
LVEF ≤50%	40 (21.5%)
LVEF ≤30%	9 (4.8%)
Bicuspid	11 (5.9%)

PROCEDURAL DATA	
Elective procedure	184 (98.9%)
Access: surgical subclavian	13 (7.0%)
Valve-in-valve	2 (1.1%)
Valve manufacturer	
Medtronic Corevalve	118 (63.4%)
Abbott Portico/Navitor	39 (21.0%)
Meril Myval	25 (13.4%)
Biosensors Allegra	4 (2.2%)
Technical Success	184 (98.9%)
Intraprocedural death	0 (0.0%)
Conversion to open surgery	2 (1.1%)

Periprocedural complications and in-hospital course

IN HOSPITAL COURSE (N=186)	
Major cardiac structural complications	4 (2.2%)
Cardiac tamponade	3 (1.6%)
LV perforation	1 (0.5%)
Annular rupture	0 (0.0%)
Coronary obstruction	0 (0.0%)
Implantation of multiple TAV	1 (0.5%)
Valve malposition	
Migration	2 (1.1%)
Embolization	0 (0.0%)
Ectopic valve deployment	0 (0.0%)
Acute cardiac decompensation	1 (0.5%)
Aortic regurgitation	
Moderate	13 (7.0%)
Severe	0 (0.0%)
Major access-related non vascular complication	0 (0.0%)

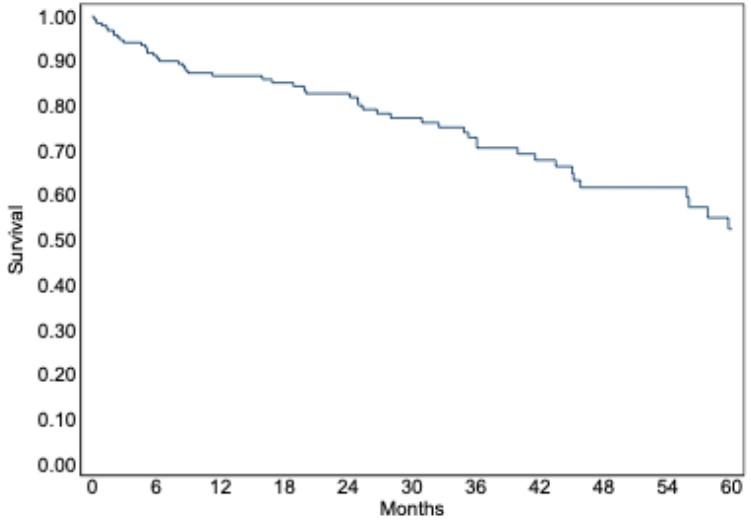
IN HOSPITAL COURSE (N=186)	
Vascular complications	
Major	2 (1.1%)
Minor	33 (17.7%)
≥ type 3 bleeding	4 (2.2%)
Neurologic events	
TIA	3 (1.6%)
Stroke	0 (0.0%)
AKI	
Stage 1	24 (12.9%)
Stage ≥2	0 (0.0%)
New PM/ICD implantation	39 (21.0%)
New onset AF/AFL	9 (4.8%)
In-hospital mortality	3 (1.6%)
Average in-hospital stay (days)	15.1

Follow-up and survival rate

30-DAY OUTCOMES (N=186)	
Mortality	4 (2.2%)
Device Success	182 (97.8%)
Early Safety	182 (97.8%)
Bioprosthetic Valve Dysfunction	0 (0.0%)
New PM/ICD implantation	41 (22.0%)
New stroke	0 (0.0%)

1-YEAR OUTCOMES (N=160)	
Mortality	25 (15.6%)
Clinical Efficacy	138 (86.3%)
Bioprosthetic Valve Dysfunction	3 (1.9%)
New stroke	2 (1.3%)

OVERALL SURVIVAL RATE	
30-days	97.9%
6-months	91.1%
1-year	86.6%
2-years	82.7%
3-years	72.9%
4-years	61.6%
5-years	52.5%



- **Median follow-up for survival: 24 months.**
- **5-years follow-up in 90% of patients.**

Limitations

- Single-centre experience
- Retrospective, non-randomized study
- Small sample size
- Predominant use of self-expandable valves

Conclusions

- Our experience suggests that TAVI can be *safely and effectively* performed in non-surgical centres with a *"visiting on-site cardiac surgery"* model.

- Strict conditions are required: experienced operators, a vascular surgery support and a well-structured multidisciplinary *Heart Team approach.*

- Expanding TAVI beyond surgical centres could significantly increase the number of procedures worldwide, thus *facilitating equitable access*, *shortening waiting lists* and therefore *reducing mortality and morbidity while waiting for TAVI.*