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Benchmark Program

Transcatheter Valve Care Pathway

BENCHMARK Registry country analysis clinical summary

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BENCHMARK Registry: The use of TAVI optimisation practices is confirmed to be safe and effective across 5 European countries

Presented at PCR London Valves on 21 November 2023

The Edwards Benchmark Program is an evidence-based global TAVI patient pathway optimisation program, developed for all stages of the clinical pathway. Data from the BENCHMARK Registry presented at EuroPCR 2023 further validated the Edwards Benchmark program, with 30-day results demonstrating a reduction in mean length of hospital stay of 2 days after implementation of BENCHMARK Practices, along with a reduction in intensive care usage (combined ICU/CCU/IMC time) of 14 hours. Patient safety was uncompromised, with no change in all-cause mortality, rehospitalisation or incidence of stroke, and both patient and staff satisfaction were increased following implementation of the BENCHMARK Practices.[1]

A recent analysis presented at the PCR London Valves conference compared outcomes from BENCHMARK Registry centres across 5 European countries. The results demonstrate that implementing BENCHMARK Practices improves efficiency without compromising patient safety across different European countries, despite differences in healthcare systems and patient populations.[2]

Background

- The BENCHMARK Registry (ClinicalTrials.gov Identifier: NCT04579445) is an investigator-initiated, observational, multicentre registry that enrolled 2,405 patients from 28 sites across 7 European countries. The data presented here are from 26 sites across 5 of these countries
- A set of 8 tailored BENCHMARK Practices were developed and implemented through peer-to-peer education and mentoring, with the aim of streamlining the TAVI patient pathway to improve efficiency while maintaining patient safety
- The BENCHMARK Registry has demonstrated that implementing best practices into the standard of care for patients undergoing transfemoral TAVI improved efficiency, including reducing hospital length of stay and costs, without compromising patient safety

Study design

- Consecutive patients undergoing transfemoral TAVI with balloon-expandable valves for severe symptomatic aortic stenosis were enrolled into the BENCHMARK Registry. The following 8 BENCHMARK Practices were implemented at participating centres across 7 European countries:

1. **Education** of patient and family
2. **Education and alignment** of the internal team
3. Determination of anticipated discharge date at admission based on **pre-procedural risk stratification**
4. **Echo- or angiographic check at end of procedure** is performed to confirm proper closing of access site/proper management of complications
5. **Early mobilisation** of the patient
6. **Decision tree** used to determine the need **for new PPM**
7. **Daily visit** to patient by implanter and interaction with rest of the team
8. **Criteria-based discharge**

- Each centre assessed the level of adoption of these practices and patient outcomes before and after implementing the BENCHMARK Practices
- The primary endpoint of the BENCHMARK Registry is to evaluate the effect of implementing BENCHMARK Practices in TAVI centres on the length of hospital stay and intensive care usage. Secondary endpoints include procedural and 30-day safety outcomes
- This analysis compared outcomes from 26 sites across **5** of the 7 countries (Table 1); the Czech Republic and Romania were excluded due to single-centre participation

Table 1. Number of patients and sites included in this analysis, by country

	Patients	Sites
France	890	9
Spain	454	5
Germany	362	6
Italy	300	4
Austria	176	2

Primary endpoints

- Hospital length of stay and intensive care usage

Secondary endpoints

- Procedural and 30-day safety outcomes

Results

Table 2. Patient characteristics

	Age, mean ± SD, years	Female, %	NYHA III or IV, %	EuroSCORE II, mean ± SD, %
France	80.1±7.0	38.7	49.8	4.6±6.5
Spain	80.7±6.4	41.6	57.7	3.8±2.6
Germany	79.6±6.6	36.7	64.4	6.8±7.3
Italy	81.6±4.9	44.0	57.0	6.0±6.5
Austria	80.1±6.4	34.7	60.8	4.0±3.8
p value	**<0.001**	0.070	**<0.001**	**<0.001**

Mean age

Varied significantly across countries, with the lowest mean age in Germany

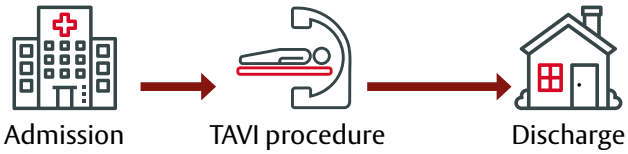
NYHA III or IV and EuroSCORE II

Varied significantly across the countries

Aortic valve-related symptoms

Statistically significant differences across countries, with the highest rates in Austria and lowest in France

Hospital length of stay (*Figure 1*)



- The mean hospital length of stay prior to implementation of BENCHMARK Practices was highest in Germany and lowest in France
- All countries except Austria saw a strong reduction in the mean length of stay

Intensive care usage (*Figure 2*)

- The combined mean time in the ICU/CCU/IMC was highest in France and Spain (prior to the implementation of BENCHMARK Practices), with the highest reductions in both countries after implementation of BENCHMARK Practices

Figure 1. Mean length of hospital stay before and after implementation of BENCHMARK Practices, by country

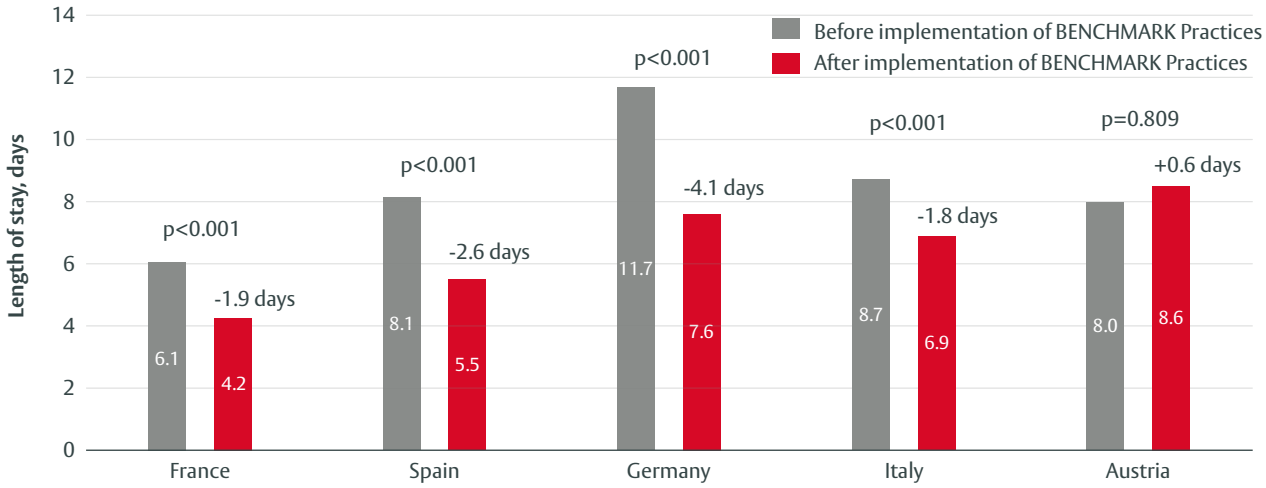
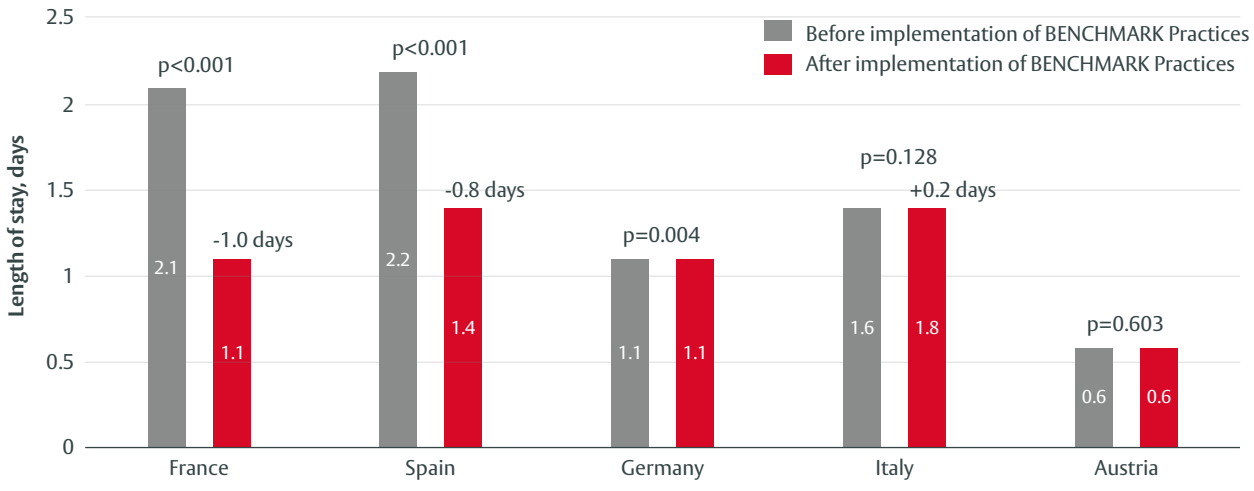


Figure 2. Mean length of stay in ICU/CCU/IMC before and after implementation of BENCHMARK Practices, by country



Use of local anaesthesia with/without conscious sedation (*Table 3*)

After implementation of BENCHMARK Practices, the use of local anaesthesia with or without conscious sedation exceeded 90% in all countries (ranging from 90.3% in Spain to 98.3% in Germany)

- Procedure and intervention times varied significantly across the countries, with the highest times reported in Spain and Italy (p<0.001)

Table 3. Procedural outcomes after implementation of BENCHMARK practices, by country

	France 568 patients, 9 sites	Spain 248 patients, 5 sites	Germany 235 patients, 6 sites	Italy 202 patients, 4 sites	Austria 109 patients, 2 sites	p-value
Local anaesthesia ± conscious sedation, patients (%)	544 (96.8)	224 (90.3)	231 (98.3)	202 (96.7)	104 (95.4)	<0.001
Procedure time, mean ± SD, minutes	46.2±23.2	73.0±31.1	46.4±22.1	87.4±38.1	41.5±23.7	<0.001
Overall intervention time, mean ± SD, minutes	63.9±31.5	106.3±40.6	88.7±30.0	111.6±36.3	80.4±35.7	<0.001

30-day safety outcomes (*Table 4*)

There were no significant differences in the combined safety endpoint, including all-cause mortality, stroke/TIA and valve-related rehospitalisation across the countries

– Rehospitalisation (all-cause) rates were significantly reduced in Austria after implementation of BENCHMARK Practices (5.5% *vs* 20.9%, p=0.002)

Safety endpoints, such as coronary obstruction, major vascular complications, bleeding and AKI were also retained across all countries before and after implementation of BENCHMARK practices

– There was a significant reduction in vascular complications in Germany after implementation of BENCHMARK Practices (0.0% *vs* 5.9%, p<0.001)

Table 4. Safety outcomes at 30 days, by country

n (%)		France	Spain	Germany	Italy	Austria
Number of patients	*Before BENCHMARK*	322	206	127	98	67
	After BENCHMARK	569	248	235	202	109
Combined endpoint*	*Before BENCHMARK*	6 (2.3)	8 (3.9)	4 (3.4)	5 (5.3)	**3 (5.1)**
	After BENCHMARK	13 (2.5)	9 (3.7)	11 (5.3)	2 (2.2)	**0 (0.0)**
All-cause mortality	*Before BENCHMARK*	0 (0.0)	1 (0.5)	0 (0.0)	1 (1.1)	0 (0.0)
	After BENCHMARK	4 (0.8)	1 (0.4)	2 (1.0)	0 (0.0)	0 (0.0)
Stroke / TIA	*Before BENCHMARK*	2 (0.8)	3 (1.5)	2 (1.7)	2 (2.2)	1 (1.7)
	After BENCHMARK	5 (1.0)	6 (2.5)	3 (1.4)	4 (4.2)	0 (0.0)
Life-threatening bleeding	*Before BENCHMARK*	2 (0.8)	5 (2.4)	1 (0.9)	2 (2.2)	1 (1.7)
	After BENCHMARK	2 (0.4)	9 (3.7)	1 (0.5)	3 (3.2)	1 (0.9)
AKI (stage 2/3, incl. dialysis)	*Before BENCHMARK*	0 (0.0)	4 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)
	After BENCHMARK	0 (0.0)	4 (1.7)	0 (0.0)	2 (2.2)	2 (1.9)
Coronary obstruction requiring intervention	*Before BENCHMARK*	1 (0.4)	1 (0.5)	3 (2.6)	0 (0.0)	0 (0.0)
	After BENCHMARK	0 (0.0)	1 (0.4)	3 (1.5)	1 (1.1)	0 (0.0)
Major vascular complication	*Before BENCHMARK*	6 (2.3)	9 (4.4)	**7 (5.9)**	6 (6.7)	4 (6.8)
	After BENCHMARK	9 (1.7)	11 (4.5)	**0 (0.0)**	4 (4.3)	1 (0.9)
Re-hospitalisation (all-cause)	*Before BENCHMARK*	21 (6.5)	13 (6.3)	6 (4.7)	0 (0.0)	**14 (20.9)**
	After BENCHMARK	22 (3.9)	12 (4.8)	25 (10.6)	2 (1.0)	**6 (5.5)**

Data in red signify a statistically significant difference before and after implementation of BENCHMARK practices

Percentages refer to the available follow-up data for each event. *Includes all-cause mortality, stroke/TIA and valve-related rehospitalisation

BENCHMARK registry

Conclusion

- Implementing the BENCHMARK Practices significantly improves efficiency in the TAVI pathway, including reducing length of stay in hospital, without compromising patient safety across Europe, regardless of differences in healthcare systems and patient characteristics
- Country-specific measures to enable further optimisation and refinement of the TAVI pathway are being developed
- Adoption of streamlined hospital pathways for TAVI patients can increase hospital capacity and efficiency in treating patients with severe aortic stenosis

1. **Frank D *et al*. BENCHMARK: Streamlined TAVI pathway with uncompromised safety in 28 European centres. Late-breaking clinical data presented at EuroPCR, 16–19 May 2023, Paris**
2. **Saia F *et al*. BENCHMARK: The use of TAVI optimization practices is safe and effective across different countries. Clinical data presented at PCR London Valves, 19–21 November 2023, London**

Abbreviations

AKI:	acute kidney injury
CCU:	coronary care unit
EuroSCORE:	European System for Cardiac Operative Risk Evaluation
ICU:	intensive care unit
IMC:	intermediate care unit
NYHA:	New York Heart Association
PPM:	permanent pacemaker
SD:	standard deviation
TAVI:	transcatheter aortic valve implantation
TIA:	transient ischaemic attack

To learn more and **to join the Edwards Benchmark program**, write to **Benchmark_EU@edwards.com** or talk to our local representatives

BENCHMARK Registry centres

Austria:

1. St. Pölten University Hospital
2. KH Nord, Klinik Floridsdorf, Vienna

Czech Republic:

3. IKEM Prague

France:

4. Centre Hospitalier Universitaire de Besançon
5. Polyclinique Du Bois, Lille
6. Infirmerie Protestante de Lyon
7. Hopital Saint Joseph, Marseille
8. Centre Hospitalier Universitaire de Montpellier
9. IMM (Institut Mutualiste Montsouris), Paris
10. Pitie Salpetriere Hospital Paris
11. CHU Rennes
12. CHRU Tours

Germany:

13. Herzzentrum Köln, Cologne
14. University Medical Center Göttingen
15. University Hospital Heidelberg
16. Saarland University Medical Center, Homburg
17. CKMS Munich, Artemed Clinics
18. Brüderkrankenhaus Trier

Italy:

19. L'Ospedale S.Giuseppe Moscati di Avellino
20. Careggi Hospital, Florence
21. Centro Cardiologico, Monzino Hospital, Milan
22. Azienda Ospedaliera Ordine Mauriziano di Torino

Romania:

23. Institutul de Urgenta pentru Boli Cardiolvasculaire, Bucharest

Spain:

24. Hospital de la Santa Creu i Sant Pau, Barcelona
25. Hospital Bellvitge, Barcelona
26. Hospital Clinico San Carlos, Madrid
27. Hospital Regional Universitario de Málaga
28. Hospital Universitari Son Espases, Palma De Mallorca

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