Outcomes after inhospital, subacute, and elective TAVI in COMPARE-TAVI 1

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Running head: COMPARE-TAVI 1: procedure priority and outcomes

Word count: 4200

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Abstract

Aims

We aimed to compare procedural, echocardiographic, and clinical outcomes within the first year after transcatheter aortic valve implantation (TAVI) among inhospital and subacute patients to elective patients in the COMPARE-TAVI 1 cohort.

Methods and Results

Among 1030 patients treated with TAVI, 927 (90%) had an elective procedure, 63 (6.1%) had a subacute procedure, and 40 (3.9%) had an inhospital procedure. Procedural characteristics and outcomes were comparable. Among elective, subacute and inhospital patients, mortality at 30 days was 15 (1.6%), 0 (0%), and 0 (0%) and at 1 year 54 (5.8%), 4 (6.3%), 2 (5.0%). Stroke at 30 days was 28 (3.0%), 0 (0%) and 3 (7.5%) and at 1 year 42 (4.5%), 5 (7.9%) and 3 (7.5%). New pacemaker at 30 days was 119 (14%), 12 (21%) and 6 (17%) and at 1 year 130 (16%), 14 (25%) and 7 (19%). Elective, subacute and inhospital patients with LVEF ≤ 40%, improved their LVEF from 33% (28 – 37), 33% (27 – 37), and 28 % (22 – 33) before TAVI to 46% (35-60), 43% (33 – 52) and 42% (33 – 55) at 30-days, and 54% (45 – 62), 53% (43 – 61) and 49% (39 – 63) at 1-year. Differences between the groups were not statistically significant.

Conclusions

After transfemoral TAVI with balloon-expandable valves in COMPARE-TAVI 1, procedural, echocardiographic, and clinical outcomes were comparable among elective, subacute and inhospital patients within the first year.

Keywords: TAVI, THV, ballon-expandable valves, procedure priority

Abbreviations and acronyms

TAVI: transcatheter aortic valve implantation

TAV: transcatheter aortic valve

TAV: transcatheter heart valve

LVEF: left ventricular ejection fraction

Introduction

Transcatheter aortic valve implantation (TAVI) is well-documented for the treatment of aortic stenosis in elective patients.[1–8]

In clinical practice, TAVI is also performed in patients with urgent or emergent treatment needs. The outcomes of such patients are documented in registries that indicate worse outcomes at one year despite procedural outcomes being comparable to those of elective patients.[9–14] While preprocedural technical evaluation of subacute and inhospital patients, almost always, can be performed in the same manner as for elective patients, the assessment of comorbidities and frailty can be difficult in the face of severe aortic stenosis with cardiac decompensation and general deconditioning. Increased comorbidity may explain, at least in part, the observed worse outcomes at one year among patients with urgent and emergent treatment needs in these registries.[9–14] Limitations in these registry studies may be the reliance on retrospective data and lack of systematic clinical and echocardiographic evaluation after one year.[9–14] In the COMPARE-TAVI 1 trial, inhospital, subacute and elective patients were included, and clinical and echocardiographic outcomes were evaluated after one year according to a defined protocol. This provides an opportunity to evaluate these questions in prospectively collected data.

In this study, we use the COMPARE-TAVI 1 trial patient cohort to compare the outcomes after TAVI in patients with inhospital or subacute procedures with those in patients with elective procedures.[15,16]

Methods

Study design

This observational study divided patients undergoing TAVI into three groups based on procedure priority as registered in the COMPARE-TAVI 1 database, i.e., patients with elective, subacute, and inhospital procedures. Patients were categorised as inhospital when the heart team during an admission, most often acute, recommended that TAVI was performed before discharge. Patients were categorised as subacute when the heart team recommended TAVI within two to three weeks. Remaining patients were categorised as elective. Outcomes among patients with subacute or inhospital procedures were compared to outcomes among patients with elective procedures.

We used a cohort of patients defined by the COMPARE-TAVI 1 trial that included 1031 patients scheduled for treatment with transfemoral TAVI.[16] One patient died before TAVI and was not included in this study.

Setting and participants

The COMPARE-TAVI protocol and one-year primary outcomes of the COMPARE-TAVI 1 trial have been published.[15,16] In brief, patients referred from the heart team for transfemoral TAVI were eligible for COMPARE-TAVI 1 if they were eligible for treatment with the two study valves. There were no exclusion criteria, so patients were eligible across all procedure priorities. Patients were randomised to treatment with one of two balloon-expandable transcatheter heart valves (THVs), i.e., Sapien 3 (29 mm) / Sapien 3 Ultra (20,23,26 mm) THVs (Edwards Lifesciences, Irvine, California, USA) or Myval / Myval Octacor THVs (Meril Life Sciences Pvt. Ltd., Vapi, Gujarat, India).

Patients were included between June 2020 and November 2023.[16] Of all patients treated with transfemoral TAVI at the participating centres during periods with active inclusion, 77% were included in the trial. Participating centres were Aarhus University Hospital, Odense University Hospital, and Aalborg University Hospital (all in Denmark).

Variables

We report baseline patient and procedure characteristics and outcomes after 30 days and one year. Among the reported outcomes are death, stroke, and new pacemaker after TAVI. We also report procedural outcomes, bleeding events (within 30 days), valve regurgitation, and endocarditis (at one year only) according to VARC-3 criteria.[17] Outcome data were collected through follow-up visits, patient files, and health registries.[15,16] Some endpoints were adjudicated by two independent cardiologist (acute myocardial infarction, endocarditis, bleeding, readmission with congestive heart failure) or a neurologist (stroke). All endpoints were monitored by trained study monitors.[15,16]

Protocols for computed tomography and echocardiography have been published.[15,16]

Ethical statement

The Central Denmark Region Ethics Committee approved the COMPARE-TAVI 1 trial.[15,16] Participants gave oral and written informed consent before participation and the study was performed in accordance with the Declaration of Helsinki principles.

Statistical methods

Numerical data are presented as median (interquartile range) and were compared using the Wilcoxon rank sum test. Categorical variables are presented as count (frequency) and were compared using the Pearson's Chi-squared test when expected cell counts were ≥ 5 and Fisher's exact test when expected cell counts were < 5. Patients with subacute and inhospital procedures were compared with patients with elective procedures (reference). We constructed cumulative risk curves for death, and cumulative incidence curves for stroke and new pacemaker with death as competing risk. Hazard ratios for death were estimated with Cox proportional hazards models and for stroke and pacemaker with Fine-Gray models as unadjusted as well as adjusted for age, LVEF and EUROSCORE-II.

Results

The cohort comprised 1030 patients treated with TAVI of which 927 (90%) had an elective procedure, 63 (6.1%) had a subacute procedure, and 40 (3.9%) had an inhospital procedure.

Patient characteristics are presented in Table 1. Congestive heart failure was more frequent among patients undergoing subacute and inhospital procedures than among patients undergoing elective procedures, and their New York Heart Association functional class was higher and LVEF was lower. Among subacute patients, aortic valve area was lower while gradients were comparable compared to elective patients. Among inhospital patients valve area was comparable but gradients were lower compared to elective patients. Inhospital patients more often had bicuspid valves and bioprostethic valves compared to elective patients. The

EuroSCORE II and STS-PROM was lowest in elective patients, higher in subacute patients, and highest in inhospital patients.

Procedural characteristic and outcomes are presented in Supplementary Tables 1 and 2. Procedural characteristics and outcomes were not statistically different among subacute and inhospital patients, respectively, as compared to elective patients.

Clinical outcomes are presented in Table 2, Table 3, and Figure 1. No subacute or inhospital patients died within the first 30 days after TAVI. At 1 year, mortality was not statistically different in these groups as compared to elective patients. More subacute patients than elective patients had heart failure after 1 year of follow-up. Otherwise, clinical outcomes were not statistically different.

Echocardiographic outcomes are presented in Table 4. In both the subacute and inhospital groups, the LVEF increased from baseline to 30 days after TAVI. In spite, patients in the subacute and inhospital groups still had lower LVEF than patients in the elective group 30 days and 1 year after TAVI. Gradients, aortic valve area and aortic regurgitation were not statistically different among subacute and inhospital patients as compared to elective patients.

A particular concern treating subacute or inhospital patients with heart failure and reduced LVEF is related to the potential for LVEF improvement after TAVI. To address this concern, we made an analysis limited to patients with reduced LVEF defined as a LVEF of ≤ 40 % (98 elective, 30 subacute, and 26 inhospital). In this subgroup of patients, LVEF was 33% (28 – 37), 33% (27 – 37) and 28% (22 – 33) among elective, subacute and inhospital patients, respectively, before TAVI. At 30 days, LVEF was 46% (35 – 60), 43% (33 – 52), and 42% (33 – 55),

and at 1 year, LVEF was 54% (45 – 62), 53% (43 – 61), and 49% (39 – 63). These changes in LVEF were not statistically different between groups.

Discussion

In the COMPARE-TAVI 1 cohort, patients undergoing subacute and inhospital TAVI had procedural, echocardiographic and clinical outcomes that were comparable to those of elective patients despite presenting more often with heart failure. Importantly, elective, subacute and inhospital patients with reduced LVEF improved their LVEF after TAVI.

Procedure priority definitions

In the STS/ACC TVT Registry procedure priority definitions are based on the timing of intervention as well as clinical status of the patient before the procedure.[9] Urgent procedures are required during same hospitalization, emergent procedures allow no delay, and salvage procedures are also mentioned. These categories are also used in other registry studies.[10,11] The treating physicians categorise the procedures, and the categories urgent and emergent are often reported together as urgent/emergent or similar.[9–11] This combined category (urgent/emergent), in definitions, corresponds to what we refer to as inhospital patients. The subacute patients in this study have an urgency level lower than this category but higher than elective patients. Based on the practise of the centres reporting to the registries used in the registry studies, this group of patients can be in either category. In this study, inhospital patients constituted 3.9% of the cohort. In registry studies, this number varies between 2.3% and 24%.[9–

[14] Such variation can reflect variations in case mix and classification differences and can make comparison of outcomes in different studies difficult.

Outcomes and comorbidity

The outcomes among patients treated with TAVI are highly dependent on patient selection. In patient selection, heart team based evaluation of comorbidities plays a central role.[18] For elective patients, centres have guideline based, established, and tested evaluation pathways. However, these pathways are often unsuitable for subacute patients, and particularly inhospital patients due to the urgency of their condition. As a result, tests may be omitted. Other times tests are performed but their reliability in comorbidity assessment, e.g., pulmonary function tests, may be less due to the impact of aortic valve disease.

In larger registries and cohorts from single or few centers, urgent/emergent patients are often reported to have higher comorbidity levels than elective patients.[9–14] This does not translate into higher procedural risk. [9–13] In some studies it translates into increased shorter term mortality and 1 year mortality,[10–14] and in others, the 30-day mortality is comparable but the 1-year mortality is higher.[9] This increased mortality is often attributed to the higher comorbidity levels of urgent/emergent patients under the assumption that valve performance is similar. In this study, procedural and echocardiographic outcomes among subacute and inhospital patients were comparable to those of elective patients, which agrees with these registry studies and their interpretation. In this study, however, the comorbidity levels were, overall, not different from those of elective patients, and the outcomes were comparable also

after 1 year. This may also agree with the findings in the registry studies and their interpretation.

Patients in critical condition

Even in critically ill patients, the procedural risk does not seem to be increased and favorable outcomes have been reported among patients in cardiogenic shock, although the outcomes were not as favorable as outcomes in patients without cardiogenic shock.[19,20] In COMPARE-TAVI 1, patients in critical condition, including patients admitted to intensive care with cardiogenic shock, were also included. Our data, in contrast to these earlier studies, suggest that even inhospital patients with LVEF ≤ 40% may have great potential for improvement in LVEF and a good 1-year clinical outcome to parallel the overall outomes in the cohort.[16,21] Inhospital critical condition, as such, should therefore not exclude patients from TAVI.

Strengths and limitations

The results obtained in this study are highly dependent on the heart team process for selection of patients to TAVI and differences between the current study and the referenced registry and cohort studies may well relate to this factor. This and other factors can contribute to differences in outcomes of subacute and inhospital patients between centres.[22]

In COMPARE-TAVI 1, the patients were treated with one of two balloon-expandable valves and COMPARE-TAVI 1 only included patients planned for femoral access TAVI. The results may not extend to treatment with other valves and alternative access. In one

registry, the use of balloon-expandable valves was associated with lower risk than the use of self-expandable valves in urgent/emergent patients, although this finding may be biased by selection.[9] Also, the results are obtained at 3 Danish centres with relatively high volumes per centre and operator.

The data from COMPARE-TAVI 1, are detailed, prospectively collected and validated in core labs and end-point committees. These data should, thus, be of at least the same quality as those used in registry and retrospective cohort studies. While 77% of all patients treated with TAVI at the participating centres were enrolled in COMPARE-TAVI 1, we cannot account for procedure priority in the same way for patients not included in COMPARE-TAVI 1 and therefore whether elective patients were more or less likely to be included in the study than subacute or inhospital patients. Also, we cannot account for patients not selected for TAVI or give detailed information on conditions of inhospital patients (such as how many were in intensive care or on inotropes) which introduces uncertainty in relation to generalisability.

This study is observational, so clinical, procedural and unregistered characteristics that may affect outcomes were not perfectly balanced between study groups. The sample size was limited to the patients included in COMPARE-TAVI 1 and the numbers of patients with subacute and inhospital procedures were relatively low, which increases risk of chance findings and, at the same time, indicating equivalence in case of lack of statistical power to show difference. However, the numbers in this report were not very different from numbers in similar reports. Also, with three groups and comparison of multiple characteristics and outcomes differences could appear by chance. We performed a sensitivity analysis in which the subacute and inhospital patients were combined in one group, which was compared to the group of

elective patients. The results of this sensitivity analysis were very similar to the reported results. Overall, our results should be interpreted with caution and indications of differences between groups are therefore compared to findings of other studies here and should preferably be investigated in other cohorts where these findings can be questioned or supported.

Conclusions

In COMPARE-TAVI 1, patients undergoing subacute and inhospital TAVI had procedural, echocardiographic and clinical outcomes up to one year that were comparable to those of patients undergoing elective TAVI despite higher baseline risk and reduced LVEF. These findings support subacute and inhospital TAVI in selected patients but may only apply to transfemoral TAVI with balloon-expandable valves at experienced centres with structured heart team pathways.

Contributions

TT, CJT designed the study and performed the analyses and drafted the paper. All authors contributed to data collection, interpretation of results and critical revision of the paper. All authors accepted the final version before submission.

Data availability statement

Study-related documents can be made available on request. Individual data can be made available for collaborative pooled analyses provided relevant contracts and data sharing agreements are made. Only anonymized data can be shared.

Funding

Institutional research grants from Meril Life Sciences, the Danish Heart Foundation, Vingmed Denmark, and the Central Denmark Region for the conduct of the COMPARE-TAVI 1 trial.

Conflict of interest statement

TT: lecture fees from Terumo and Chiesi. BLN: Unrestricted research grants from the Novo Nordisk Fonden. EHC: institutional research grants from Abbott, proctor fees from Edwards Lifesciences, Meril Life Sciences, Boston Scientific and Abbott, lecture fees from Edwards Life Sciences, Meril Lifesciences, Boston Scientific and Abbott. BLN: institutional research grants from the Novo Nordic CJT: proctor and lecture fees and research grants from Edwards, Terumo, Medtronic and Meril.

All other authors: none.

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Figure legends

Figure 1. Risk of death, stroke and pacemaker among patients with elective, subacute and inhospital procedures within the first year after transcatheter aortic valve implantation (TAVI) in COMPARE-TAVI 1. Death (A), stroke (B) and new pacemaker (C). For stroke and pacemaker, patients were censored if death occurred prior to the event.

Table 1. Patient characteristics

	Elective	Subacute		Inhospital	
	N = 927	N = 63	p	N = 40	p
Clinical					
Age, years	82 (78 – 85)	81 (77 – 85)	0.81	80 (77 – 84)	0.37
Sex			0.71		0.71
Female	375 (40)	24 (38)		15 (38)	
Male	552 (60)	39 (62)		25 (63)	
Diabetes mellitus	196 (21)	16 (25)	0.43	11 (28)	0.34
Hyperlipidemia*	608 (66)	47 (75)	0.15	28 (70)	0.57
Hypertension*	706 (76)	43 (68)	0.15	28 (70)	0.37
Congestive heart failure	141 (15)	34 (54)	<0.001	34 (85)	<0.001
Pacemaker	97 (10)	7 (11)	0.87	4 (10)	>0.99
Previous PCI	166 (18)	17 (27)	0.072	12 (30)	0.053
Previous CABG	65 (7.0)	6 (9.5)	0.45	6 (15)	0.066
Previous AMI	87 (9.4)	15 (24)	<0.001	7 (18)	0.10
Previous Stroke			0.79		0.76
No	787 (85)	52 (83)		34 (85)	
Yes, no sequelae	108 (12)	9 (14)		4 (10)	
Yes, with sequelae	32 (3.5)	2 (3.2)		2 (5.0)	
Peripheral artery disease	60 (6.5)	4 (6.5)	>0.99	3 (7.5)	0.74
NYHA class			<0.001		<0.001
I	85 (9.2)	3 (4.8)		1 (2.5)	
II	504 (54)	17 (27)		9 (23)	
III	335 (36)	39 (62)		21 (53)	
IV	1 (0.1)	4 (6.3)		9 (23)	
EuroSCORE II	2.4 (1.5 – 3.7)	5.5 (3.4 – 8.9)	<0.001	8.0 (5.6 – 10.6)	<0.001
STS-PROM	2.3 (1.5 – 3.5)	3.0 (2.0 – 5.7)	<0.001	3.4 (2.1 – 5.2)	<0.001
Echocardiography					
LVEF, %	58 (49 – 65)	41 (33 – 56)	<0.001	34 (25 – 48)	<0.001
Aortic valve peak gradient, mmHg	73 (60 – 88)	69 (53 – 92)	0.35	63 (45 – 74)	<0.001
Aortic valve mean gradient, mmHg	47 (38 – 57)	43 (32 – 55)	0.18	39 (29 – 51)	<0.001
Aortic valve area, cm^2	0.70 (0.60 – 0.80)	0.60 (0.50 – 0.80)	0.014	0.70 (0.60 – 0.80)	0.66
Computed tomography**					
Valve morphology			0.15		0.005
Tricuspid	812 (88)	52 (83)		28 (70)	
Bicuspid	84 (9.1)	6 (9.5)		8 (20)	
Bioprosthetic	31 (3.3)	5 (7.9)		4 (10)	
Annulus area, mm^2	476 (415 – 540)	493 (421 – 545)	0.34	506 (411 – 580)	
Annulus perimeter, mm	79 (74 – 84)	80 (74 – 85)	0.62	80 (74 – 88)	
Annulus short axis, mm	22.0 (20.4 – 24.0)	22.6 (20.9 – 24.0)	0.19	22.6 (20.7 – 24.8)	
Annulus long axis, mm	27.7 (26.0 – 29.4)	27.4 (25.9 – 29.0)	0.95	28.1 (25.9 – 30.4)	
Valve calcification			0.016		0.48
None	6 (0.7)	3 (4.9)		1 (2.5)	
Mild (small isolated spots)	127 (14)	5 (8.2)		5 (13)	
Moderate (>1 large spot)	407 (44)	23 (38)		17 (43)	
Severe (all leaflets heavily calcified)	378 (41)	30 (49)		17 (43)	
Annulus calcification			0.81		0.002
None	440 (48)	30 (49)		25 (64)	
Small spots	277 (30)	16 (26)		6 (15)	
One/more large spots	132 (14)	9 (15)		1 (2.6)	
Confluent LVOT spots	67 (7.3)	6 (9.8)		7 (18)	

Table 1. Patient characteristics

	Elective	Subacute		Inhospital	
	N = 927	N = 63	p	N = 40	p

Numerical data are presented as median (interquartile range). Categorical variables are presented as count (frequency). *Treated medically. **Annulus dimensions do not include patients with bioprosthetic valves.

PCI: percutaneous coronary intervention, CABG: coronary artery bypass grafting, AMI: acute myocardial infarction, NYHA: New York Heart Association, LVEF: left ventricular ejection fraction

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Table 2. Clinical outcomes

	Elective	Subacute		Inhospital	
	N = 927	N = 63	p	N = 40	p
30-day outcomes					
Death	15 (1.6)	0 (0)	0.62	0 (0)	>0.99
Stroke	28 (3.0)	0 (0)	0.25	3 (7.5)	0.13
New pacemaker*	119 (14)	12 (21)	0.15	6 (17)	0.70
VARC 3 bleeding			0.20		0.93
Type < 2	762 (82)	57 (90)		35 (88)	
Type 2	106 (11)	6 (9.5)		4 (10)	
Type 3	50 (5.4)	0 (0)		1 (2.5)	
Type 4	9 (1.0)	0 (0)		0 (0)	
1-year outcomes					
Death	54 (5.8)	4 (6.3)	0.78	2 (5.0)	>0.99
Stroke	42 (4.5)	5 (7.9)	0.22	3 (7.5)	0.43
New pacemaker*	130 (16)	14 (25)	0.067	7 (19)	0.54
Heart failure	12 (1.3)	6 (9.5)	<0.001	0 (0)	>0.99
Acute myocardial infarction	8 (0.9)	0 (0)	>0.99	0 (0)	>0.99
Percutaneous coronary intervention	19 (2.0)	1 (1.6)	>0.99	0 (0)	>0.99
Reoperation	8 (0.9)	0 (0)	>0.99	0 (0)	>0.99
Endocarditis	13 (1.4)	2 (3.2)	0.25	1 (2.5)	0.45

* Among patients without pacemaker before TAVI. All data are presented as count (frequency).

TAVI: transcatheter aortic valve implantation, VARC: Valve Academic Research Consortium

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Table 3. Hazard ratios for death, stroke and new pacemaker

		Unadjusted			Adjusted		
		HR	**95% CI**	**p-value**	**HR**	**95% CI**	**p-value**
Death							
	Elective	—	—		—	—	
	Subacute	1.09	0.39 to 3.01	0.87	0.95	0.33 to 2.73	0.92
	Inhospital	0.86	0.21 to 3.55	0.84	0.66	0.14 to 3.07	0.60
Stroke							
	Elective	—	—		—	—	
	Subacute	1.74	0.70 to 4.32	0.23	1.83	0.71 to 4.69	0.21
	Inhospital	1.71	0.52 to 5.63	0.38	1.89	0.59 to 6.05	0.28
New pacemaker							
	Elective	—	—		—	—	
	Subacute	1.69	0.98 to 2.92	0.061	1.54	0.85 to 2.78	0.15
	Inhospital	1.23	0.59 to 2.58	0.57	1.00	0.45 to 2.22	0.99

Abbreviations: CI = Confidence Interval, HR = Hazard Ratio.
Adjusted HR: adjusted for age, left ventricular ejection fraction.
HR estimated with Cox proportional models (death) and Fine-Gray Models (Stroke and New pacemaker).

Table 4. Echocardiographic outcomes

	Elective	Subacute		Inhospital	
	N = 927	N = 63	p	N = 40	p
30-day outcomes					
LVEF, %	62 (54 – 69)	54 (39 – 66)	<0.001	49 (37 – 59)	<0.001
Aortic valve peak gradient, mmHg	17 (13 – 23)	17 (14 – 21)	0.74	15 (13 – 19)	0.033
Aortic valve mean gradient, mmHg	10 (8 – 12)	10 (8 – 12)	0.70	8 (7 – 11)	0.053
Aortic valve area, cm^2	1.80 (1.50 – 2.20)	1.70 (1.40 – 2.30)	0.14	1.80 (1.40 – 2.10)	0.51
Aortic regurgitation			0.58		0.43
None, trace or mild	905 (99)	62 (98)		39 (98)	
Moderate or severe	12 (1.3)	1 (1.6)		1 (2.5)	
1-year outcomes					
LVEF, %	63 (55 – 69)	59 (47 – 66)	0.002	56 (41 – 65)	<0.001
Aortic valve peak gradient, mmHg	17 (13 – 23)	19 (14 – 22)	0.61	15 (11 – 21)	0.12
Aortic valve mean gradient, mmHg	10.0 (7.0 – 13.0)	10.0 (8.0 – 13.0)	0.90	9.0 (6.0 – 12.0)	0.10
Aortic valve area, cm^2	1.90 (1.50 – 2.30)	1.80 (1.40 – 2.20)	0.17	1.90 (1.60 – 2.30)	0.61
Aortic regurgitation			>0.99		>0.99
None, trace or mild	893 (97)	62 (98)		39 (98)	
Moderate or severe	24 (2.6)	1 (1.6)		1 (2.5)	

Numerical data are presented as median (interquartile range). Categorical variables are presented as count (frequency).
LVEF: left ventricular ejection fraction

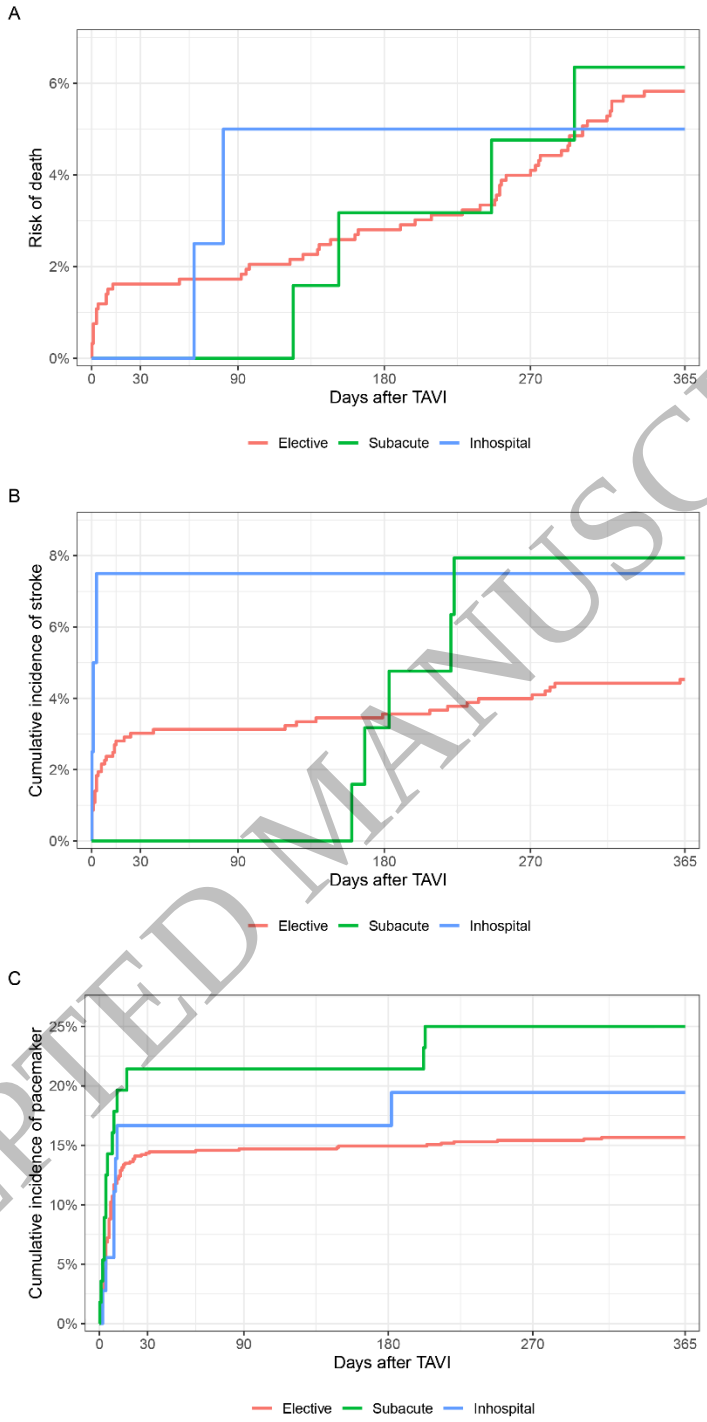
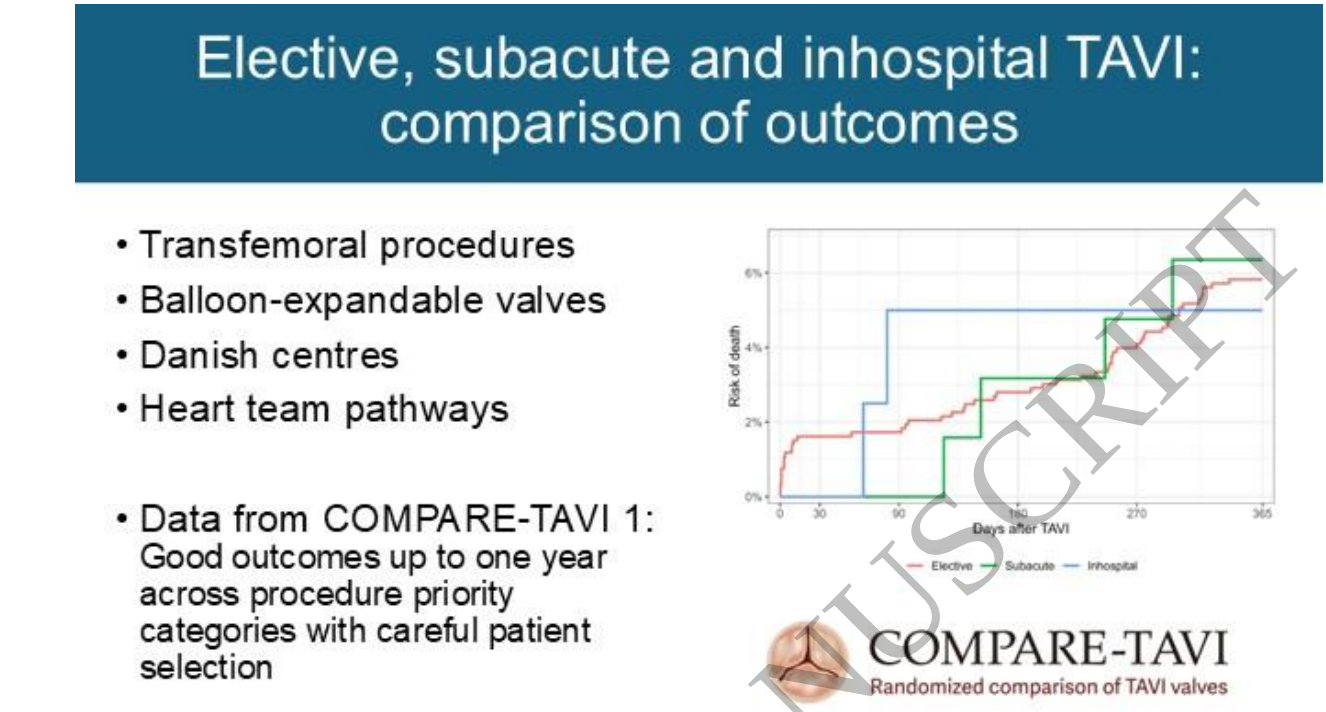


Figure 1

114x229 mm (x DPI)



Graphical Abstract