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Transcatheter aortic valve implantation outcomes by patient age and sex in COMPARE-TAVI 1: a cohort study

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ABSTRACT

Objectives To explore the outcomes among patients treated with TAVI (transcatheter aortic valve implantation) in the COMPARE-TAVI 1 trial by age groups and sex.

Design Cohort study.

Setting Three Danish university hospitals.

Participants Patients treated with TAVI in the COMPARE-TAVI 1 trial (N=1030), 60 (5.8%), 337 (32.7%), 592 (57.5%) and 41 (4.0%) were in the four age groups, < 70, 70–79, 80–89 and 90+ years while 414 (40.2%) and 616 (59.8%) were of female and male sex.

Interventions Transfemoral TAVI with balloon-expandable valves (Sapien or Myval) performed between June 2020 and November 2023.

Outcome measures Post hoc analyses of trial secondary outcomes that include end-point committee-adjudicated outcomes.

Results In the four age groups, 1-year mortality rates were 8.3%, 5.6%, 5.6% and 7.3% while it was 5.8% in both sexes. Across the four age groups, 1-year stroke rates were 6.7%, 1.8%, 3.2% and 4.9%, and 5.1% among females and 4.7% among males. In the four age groups, 1-year new pacemaker rates were 7.5%, 15%, 19% and 13% while it was 15% among females and 18% among males. Females had smaller annuli than males and their gradients were higher and the effective orifice area lower after TAVI but their frequency of prosthesis-patient mismatch was similar at 1 year.

Conclusion While comorbidity levels varied between groups, clinical outcomes were similar across age groups and between sexes.

Trial registration number NCT04443023.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Detailed outcome data, including end-point committee-adjudicated outcomes, from a published randomised clinical trial increases internal validity.
⇒ Complete follow-up and all-comers design increases external validity.
⇒ Observational cohort study design, although the only option for studying the effects of age and sex, limits firm conclusions on effects of age and sex.
⇒ Patient numbers and follow-up time of, so far only 1 year, limit conclusions.
⇒ Comparisons are made between multiple groups across multiple variables in exploratory analyses and differences may, thus, reflect both real differences and chance findings, so they should be interpreted with caution.

INTRODUCTION

In the COMPARE-TAVI 1 trial, patients referred for transfemoral transcatheter aortic valve implantation (TAVI) were randomised to TAVI using one of two balloon-expandable valves.[1] The 1-year primary outcome of the trial has been published.[2] During periods of active enrolment, 77% of all patients treated with transfemoral TAVI at the participating centres were included in the trial making COMPARE-TAVI 1 an all-comers trial. High inclusion rates, as seen in this trial, increase the generalisability of the results.

It is important and recommended to explore disparities in clinical outcome in certain subgroups of patients.[3] In this study, we report the outcomes of patients treated with TAVI in the COMPARE-TAVI 1 trial by age and sex.

METHODS

Study design

This is an observational study performed within the patient cohort defined by the COMPARE-TAVI 1 trial which included 1031 patients scheduled for treatment with transfemoral TAVI. One of these patients died before TAVI, and the study cohort presented here includes the 1030 patients that were treated with TAVI.[2]

The patients in this cohort were divided into four groups based on age, that is, patients younger than 70 years (<70), aged 70 to 79 years (70–79), aged 80 to 89 years (80–89) and aged 90 years and older (90+). The cohort was

Table 1 Patient characteristics by age group

Characteristic	<70 N=60	70–79 N=337	80–89 N=592	90+ N=41	P value
Clinical					
Age, years	66 (62–69)	77 (75–79)	84 (82–86)	92 (90–92)	<0.001
Sex					0.004
Female	23 (38)	123 (36)	241 (41)	27 (66)	
Male	37 (62)	214 (64)	351 (59)	14 (34)	
Diabetes mellitus	22 (37)	93 (28)	104 (18)	4 (9.8)	<0.001
Hyperlipidaemia*	43 (72)	250 (74)	375 (63)	15 (37)	<0.001
Hypertension*	44 (73)	261 (77)	444 (75)	28 (68)	0.56
Congestive heart failure	19 (32)	61 (18)	121 (20)	8 (20)	0.12
Pacemaker	7 (12)	27 (8.0)	73 (12)	1 (2.4)	0.058
Previous PCI	11 (18)	69 (20)	109 (18)	6 (15)	0.77
Previous CABG	4 (6.7)	26 (7.7)	44 (7.4)	3 (7.3)	>0.99
Previous AMI	7 (12)	37 (11)	60 (10)	5 (12)	0.88
Previous stroke					0.035
No	53 (88)	278 (82)	505 (85)	37 (90)	
Yes, no sequelae	2 (3.3)	43 (13)	72 (12)	4 (9.8)	
Yes, with sequelae	5 (8.3)	16 (4.7)	15 (2.5)	0 (0)	
Peripheral artery disease	2 (3.4)	24 (7.2)	39 (6.6)	2 (4.9)	0.84
NYHA class					0.19
I	4 (6.7)	28 (8.3)	53 (9.0)	4 (9.8)	
II	28 (47)	186 (55)	302 (51)	14 (34)	
III	27 (45)	118 (35)	229 (39)	21 (51)	
IV	1 (1.7)	4 (1.2)	7 (1.2)	2 (4.9)	
EuroSCORE II	1.4 (1.0–2.6)	1.9 (1.3–3.2)	2.9 (1.9–4.6)	5.4 (3.7–8.7)	<0.001
STS-PROM	1.4 (1.0–2.4)	1.7 (1.2–2.6)	2.6 (1.9–4.1)	4.0 (3.1–5.4)	<0.001
Echocardiography					
LVEF, %	59 (40–68)	58 (49–66)	57 (47–65)	53 (46–63)	0.39
Aortic valve peak gradient, mm Hg	73 (57–84)	73 (60–86)	72 (59–88)	75 (64–95)	0.48
Aortic valve mean gradient, mm Hg	45 (36–56)	47 (38–56)	46 (37–56)	50 (40–62)	0.41
Aortic valve area, cm^2	0.70 (0.60–0.90)	0.70 (0.60–0.90)	0.70 (0.60–0.80)	0.60 (0.50–0.70)	<0.001
CT†					
Valve morphology					<0.001
Tricuspid	38 (63)	277 (82)	537 (91)	40 (98)	
Bicuspid	19 (32)	43 (13)	35 (5.9)	1 (2.4)	
Bioprosthetic	3 (5.0)	17 (5.0)	20 (3.4)	0 (0)	
Annulus area, mm^2	496 (432–580)	485 (424–547)	476 (413–536)	431 (401–500)	0.007
Annulus perimeter, mm	81 (76–87)	80 (75–85)	79 (74–84)	75 (72–80)	0.008
Annulus short axis, mm	21.9 (21.0–24.7)	22.2 (20.5–24.0)	22.0 (20.3–24.0)	21.0 (20.0–22.5)	0.018
Annulus long axis, mm	28.8 (26.1–29.8)	28.0 (26.0–29.8)	27.4 (25.7–29.2)	26.6 (25.0–28.3)	0.005
Valve calcification					0.96
None	1 (1.7)	3 (0.9)	6 (1.0)	0 (0)	
Mild (small isolated spots)	6 (10)	42 (13)	83 (14)	6 (15)	
Moderate (>1 large spot)	26 (43)	144 (43)	261 (45)	16 (39)	
Severe (all leaflets heavily calcified)	27 (45)	143 (43)	236 (40)	19 (46)	

Continued

Table 1 Continued

Characteristic	<70 N=60	70–79 N=337	80–89 N=592	90+ N=41	P value
Annulus calcification					0.48
None	29 (48)	171 (52)	277 (47)	18 (45)	
Small spots	18 (30)	99 (30)	173 (30)	9 (23)	
One/more large spots	6 (10)	39 (12)	87 (15)	10 (25)	
Confluent LVOT spots	7 (12)	23 (6.9)	47 (8.0)	3 (7.5)	

*Treated medically.
†Annulus dimensions do not include patients with bioprosthetic valves.
AMI, acute myocardial infarction; CABG, coronary artery bypass grafting; LVEF, left ventricular ejection fraction; LVOT, left ventricular outflow tract; NYHA, New York Heart Association; PCI, percutaneous coronary intervention.

also divided based on sex into male and female patients. Outcomes among patients were compared across these four age groups and two sexes.

Setting and participants

The COMPARE-TAVI protocol and the 1-year primary outcome of the COMPARE-TAVI 1 trial are published.[1 2] Patients eligible for COMPARE-TAVI 1 were referred for transfemoral TAVI by the heart team. There were no exclusion criteria, so the trial included all-comers, that is, patients of all ages and both sexes had equal access to participation after referral from the heart team.

Patients were randomised to TAVI using one of two balloon-expandable valves, that is, Sapien 3 (29 mm)/Sapien 3 Ultra (202 326 mm) THVs (Edwards Lifesciences, Irvine, California, USA) or Myval/Myval Octacor THVs (Meril Life Sciences, Vapi, Gujarat, India).

Patients were included from June 2020 to November 2023. Patent-related legal proceedings caused pauses in inclusion during this time. Within active inclusion periods, 77% of all patients treated with transfemoral TAVI at the participating centres were included in the trial. The participating centres were Aarhus University Hospital, Odense University Hospital and Aalborg University Hospital (all in Denmark).

Variables

We report patient and procedure characteristics and outcomes after 30 days and 1 year. Outcomes include death, stroke and new pacemaker after TAVI, bleeding events (within 30 days), valve regurgitation and endocarditis (at 1 year only) according to Valve Academic Research Consortium (VARC-3) criteria.[4] These outcomes were secondary outcomes in the trial. The primary trial outcome was a composite outcome that is not reported here.

Outcomes were collected through follow-up visits, electronic patient files and health registries.[1 2] Selected endpoints were adjudicated by two independent cardiologists (acute myocardial infarction, endocarditis, bleeding, readmission with congestive heart failure) or neurologists (stroke). All endpoints were monitored by trained monitors.[1 2]

CT and echocardiography were performed as specified in the study protocol. For patients with bioprosthetic valves, annulus dimensions are not included in the presented data.

Patient and Public Involvement

Patients or the public were not involved in the design, or conduct, or reporting, or dissemination plans of our research.

Statistical methods

Continuous data are presented as median (IQR) and were compared using the Wilcoxon or Kruskal-Wallis rank sum tests. Categorical variables are presented as counts (frequencies) and were compared using Pearson's χ^2 test when expected cell counts were ≥5 and Fisher's exact test with simulated p values when expected cell counts were <5. Cumulative incidence curves for death, stroke and new pacemaker after TAVI were constructed. HRs for death were estimated with Cox proportional hazards models and subdistribution HRs for stroke and pacemaker with Fine-Gray models with death as a competing risk. In the age group analyses, HRs were adjusted for sex, diabetes, hyperlipidaemia, previous stroke and EUROSCORE-II, and the age group 70–79 was used as reference. In the sex group analyses, HRs were adjusted for age group, diabetes, hyperlipidaemia and EUROSCORE-II, and male sex was used as the reference. The selection of these clinical variables for the adjusted analyses was based on the observed group differences presented in tables 1 and 2.

RESULTS

Participants and procedures

The age and sex distributions are presented in figure 1. The distribution of patients was 5.8% (<70), 32.7% (70–79), 57.5% (80–89) and 4.0% (90+) in the four age groups. The distribution of patients between the two sexes was 40.2% female and 59.8% male. The age distributions among female and male patients were not identical although similar. The median age differed by 1 year which was statistically significant. Among patients 90 years and older, 66% were female.

Table 2 Patient characteristics by sex

Characteristic	Female N=414	Male N=616	P value
Clinical			
Age, years	82 (78–86)	81 (77–84)	0.007
Age group			0.004
<70	23 (5.6)	37 (6.0)	
70–79	123 (30)	214 (35)	
80–89	241 (58)	351 (57)	
90+	27 (6.5)	14 (2.3)	
Diabetes mellitus	70 (17)	153 (25)	0.002
Hyperlipidaemia*	243 (59)	440 (71)	<0.001
Hypertension*	307 (74)	470 (76)	0.41
Congestive heart failure	66 (16)	143 (23)	0.004
Pacemaker	29 (7.0)	79 (13)	0.003
Previous PCI	50 (12)	145 (24)	<0.001
Previous CABG	12 (2.9)	65 (11)	<0.001
Previous AMI	20 (4.8)	89 (14)	<0.001
Previous stroke			0.078
No	358 (86)	515 (84)	
Yes, no sequelae	48 (12)	73 (12)	
Yes, with sequelae	8 (1.9)	28 (4.5)	
Peripheral artery disease	22 (5.4)	45 (7.3)	0.22
NYHA class			0.12
I	38 (9.2)	51 (8.3)	
II	194 (47)	336 (55)	
III	175 (42)	220 (36)	
IV	6 (1.5)	8 (1.3)	
EuroSCORE II	2.9 (1.9–4.7)	2.3 (1.4–4.0)	<0.001
STS-PROM	2.7 (1.9–4.5)	2.0 (1.4–3.0)	<0.001
Echocardiography			
LVEF, %	59 (50–68)	55 (45–63)	<0.001
Aortic valve peak gradient, mm Hg	74 (61–89)	71 (58–85)	0.016
Aortic valve mean gradient, mm Hg	47 (38–58)	46 (37–55)	0.021
Aortic valve area, cm^2	0.70 (0.50–0.80)	0.70 (0.60–0.90)	<0.001
CT			
Valve morphology			0.020
Tricuspid	372 (90)	520 (84)	
Bicuspid	33 (8.0)	65 (11)	
Bioprosthetic	9 (2.2)	31 (5.0)	
Annulus area, mm^2	412 (381–457)	518 (475–574)	<0.001
Annulus perimeter, mm	74 (71–77)	83 (79–87)	<0.001
Annulus short axis, mm	20.6 (19.5–22.0)	23.0 (22.0–24.6)	<0.001
Annulus long axis, mm	25.9 (24.2–27.0)	29.0 (27.2–30.1)	<0.001
Valve calcification			<0.001
None	1 (0.2)	9 (1.5)	
Mild (small isolated spots)	75 (18)	62 (10)	

Continued

Table 2 Continued

Characteristic	Female N=414	Male N=616	P value
Moderate (>1 large spot)	204 (50)	243 (40)	
Severe (all leaflets heavily calcified)	128 (31)	297 (49)	
Annulus calcification			0.039
None	214 (53)	281 (46)	
Small spots	101 (25)	198 (33)	
One/more large spots	55 (14)	87 (14)	
Confluent LVOT spots	37 (9.1)	43 (7.1)	

*Treated medically.
†Annulus dimensions do not include patients with bioprosthetic valves.
AMI, acute myocardial infarction; CABG, coronary artery bypass grafting; LVEF, left ventricular ejection fraction; LVOT, left ventricular outflow tract; NYHA, New York Heart Association; PCI, percutaneous coronary intervention.

Patient and procedure characteristics for patients in the four age groups are presented in table 1 and online supplemental table 1A. Patients younger than 70 years (<70) more often had diabetes mellitus, congestive heart failure and stroke with sequelae. Patients older than 90 years (90+) had lower rates of hyperlipidaemia and pacemaker before TAVI. EuroSCORE II and STS-PROM that include age as a risk factor increased with age across the age groups. Echocardiographic and CT characteristics were similar across groups, except that patients younger than 70 years (<70) more often were treated for bicuspid valve disease, and among patients older than 90 years (90+) none were treated for bioprosthetic valve failure. Also, patients older than 90 years (90+) that were more

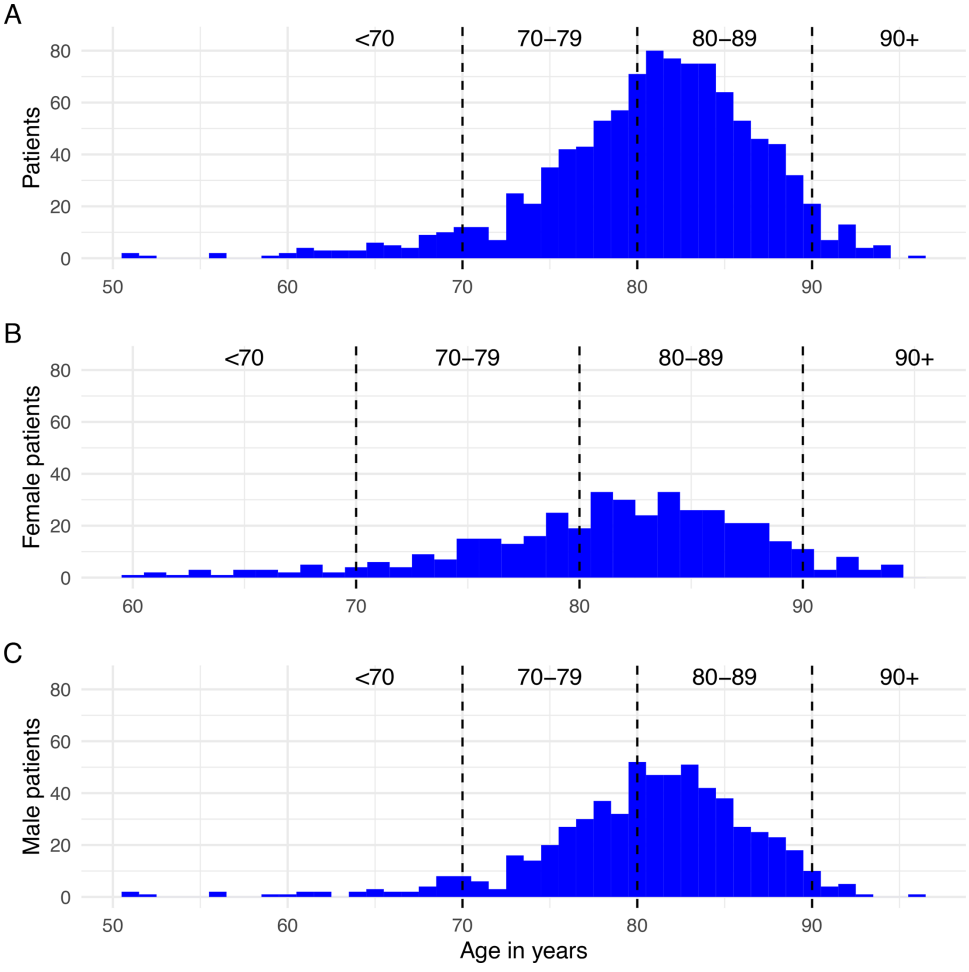

Figure 1 Age distribution. All patients (A), female patients (B) and male patients (C).

Table 3 Clinical outcomes by age group

Characteristic	<70 N=60	70–79 N=337	80–89 N=592	90+ N=41	P value
30-day outcomes					
Death	1 (1.7)	4 (1.2)	9 (1.5)	1 (2.4)	0.67
Stroke	4 (6.7)	6 (1.8)	19 (3.2)	2 (4.9)	0.10
New pacemaker*	3 (5.7)	42 (14)	87 (17)	5 (13)	0.13
VARC 3 bleeding					0.28
Type <2	50 (83)	290 (86)	479 (81)	35 (85)	
Type 2	7 (12)	34 (10)	71 (12)	4 (9.8)	
Type 3	2 (3.3)	10 (3.0)	38 (6.4)	1 (2.4)	
Type 4	1 (1.7)	3 (0.9)	4 (0.7)	1 (2.4)	
1-year outcomes					
Death	5 (8.3)	19 (5.6)	33 (5.6)	3 (7.3)	0.69
Stroke	6 (10)	11 (3.3)	31 (5.2)	2 (4.9)	0.11
New pacemaker*	4 (7.5)	45 (15)	97 (19)	5 (13)	0.10
Heart failure	1 (1.7)	5 (1.5)	12 (2.0)	0 (0)	0.93
Acute myocardial infarction	1 (1.7)	0 (0)	6 (1.0)	1 (2.4)	0.054
Percutaneous coronary intervention	2 (3.3)	6 (1.8)	12 (2.0)	0 (0)	0.71
Reoperation	2 (3.3)	1 (0.3)	5 (0.8)	0 (0)	0.14
Endocarditis	2 (3.3)	3 (0.9)	11 (1.9)	0 (0)	0.32

*Among patients without pacemaker before transcatheter aortic valve implantation.
VARC, Valve Academic Research Consortium.

often female had smaller annuli. Procedural characteristics were similar across the four age groups.

Patient and procedure characteristics by sex are presented in table 2 and online supplemental table 1B. Males more often had diabetes mellitus, hyperlipidaemia, ischaemic heart disease (previous percutaneous coronary intervention, coronary artery bypass grafting and acute myocardial infarction) and heart failure, while hypertension, previous stroke and peripheral artery disease were more evenly distributed between sexes. Females had lower rates of pacemaker prior to TAVI, were slightly older and had higher EuroSCORE II and STS-PROM. Additionally, females had smaller annuli than males. Procedural characteristics were similar between sexes.

Outcomes

Procedural outcomes for patients in the four age groups are presented in online supplemental table 2A. These were similar across the four groups. Procedural outcomes in the two sexes are presented in online supplemental table 2B. The observed rates of annular rupture and tamponade were low but higher in females than in males. All patients with annular rupture also had cardiac tamponade.

The clinical outcomes in the four age groups are presented in table 3 and figure 2. There was no statistically significant difference in the outcomes. The highest observed mortality was among patients younger than 70 years (<70), followed by the mortality among patients older than 90 years (90+), while the lowest observed mortality was among patients in the remaining two groups (70–79 and 80–89). The clinical outcomes in the two sexes are presented in table 4 and figure 2. Females had higher bleeding rates of BARC 2, 3 and 4 bleeding. Unadjusted and adjusted HRs and subdistribution HRs by age group and sex are reported in tables 5 and 6.

Echocardiographic outcomes were similar in the four age groups and are presented in online supplemental table 3A. Echocardiographic outcomes in the two sexes are presented in online supplemental table 3B. In females, gradients were higher and effective orifice area was lower than in males. One month after TAVI, the frequency of prosthesis-patient mismatch was slightly higher among females compared with males, but after 1 year the frequencies were similar.

DISCUSSION

Main findings

The main finding of this study is that across different age groups and sexes, and the comorbidities that vary with them, the heart teams appropriately selected patients for treatment, resulting in good and similar outcomes across the age groups and sexes.

Differences between age groups and sexes

In this observational study, comparisons are made between multiple groups across multiple variables, both

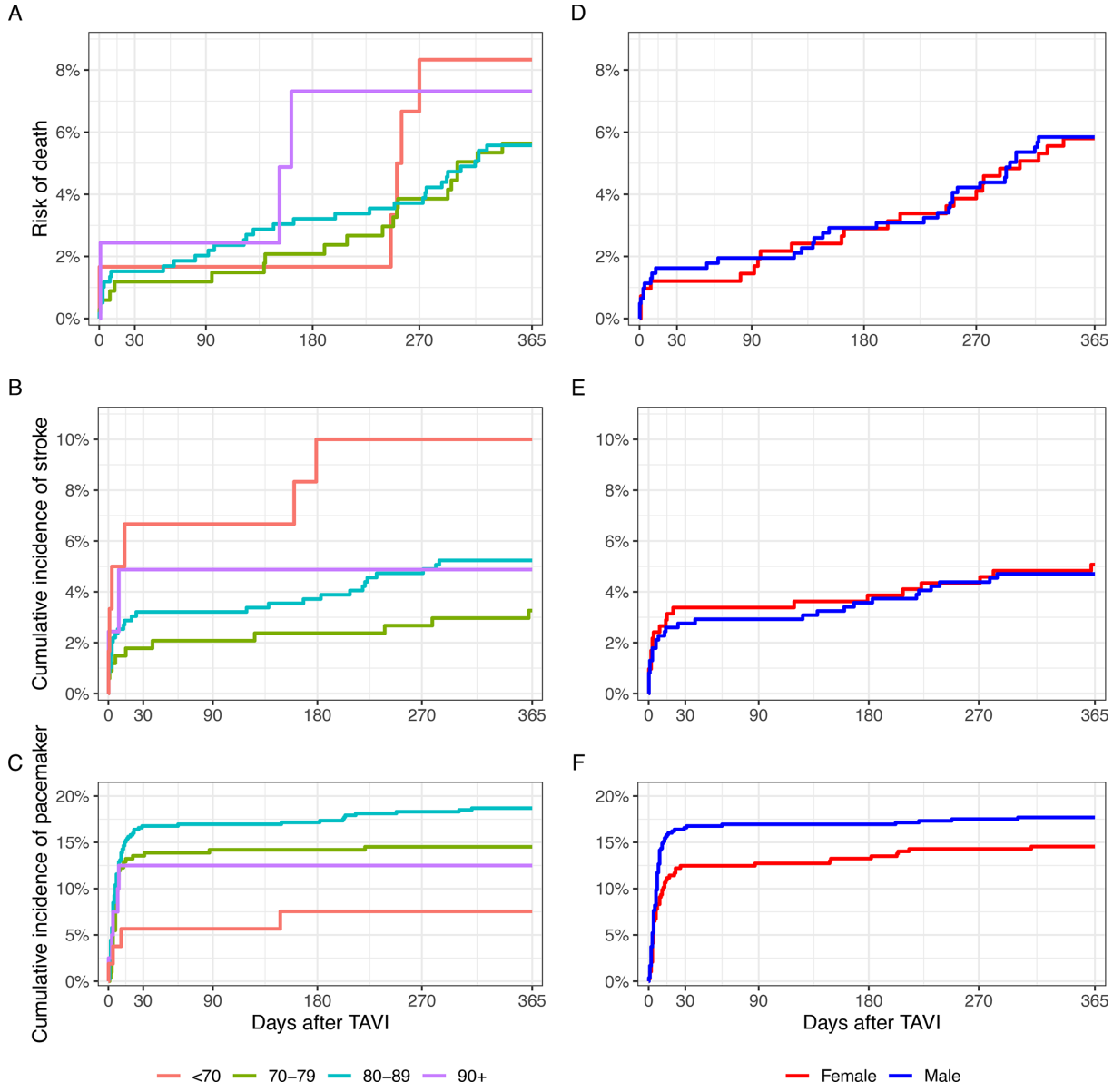

Figure 2 Outcomes among patients across age and sex groups. Across age groups: death (A), stroke (B) and new pacemaker (C). Across sex groups: death (C), stroke (D) and new pacemaker (E). For stroke and new pacemaker, death was treated as competing risk. TAVI, transcatheter aortic valve implantation.

baseline and outcome. In such exploratory analyses, apparent differences may reflect both real differences and chance findings, so they should be interpreted with caution. The low number of events also imposes limitations on the analyses, including options for interaction testing. With this in mind, we discuss the following potential differences across age groups and sexes in relation to findings in other cohorts.

Regarding age, the European Society of Cardiology guidelines applicable in the majority of the patient inclusion period of this study recommended surgical aortic valve replacement (SAVR) for patients aged <75 years with low surgical risk while TAVI was recommended in patients aged ≥75 years, in patients with a high surgical risk and in inoperable patients.[5] In Danish treatment recommendations issued by the Danish Society of Cardiology, this recommendation was modified slightly. Generally, SAVR was recommended for patients younger than 70 years of age, and TAVI was recommended for patients over 80 years of age. For patients aged 70–80, it was recommended that the choice between SAVR and TAVI was based on factors such as age, expected remaining lifespan, comorbidities and frailty. There was a general recommendation of taking patient preference into consideration. Based on this approach to patient selection for TAVI centred around the age cut-offs 70 years and 80 years, we chose to divide patients into the described age groups. This grouping has been used in two previous registry studies.[6 7] Both of these studies indicated that TAVI patients have increasing risk of mortality with increasing age. Also, these registries report outcome data from procedures performed between 2011 and 2018

Table 4 Clinical outcomes by sex

Characteristic	Female N=414	Male N=616	P value
30-day outcomes			
Death	5 (1.2)	10 (1.6)	0.59
Stroke	14 (3.4)	17 (2.8)	0.57
New pacemaker*	48 (12)	89 (17)	0.084
VARC 3 bleeding			0.009
Type <2	324 (78)	530 (86)	
Type 2	60 (14)	56 (9.1)	
Type 3	25 (6.0)	26 (4.2)	
Type 4	5 (1.2)	4 (0.6)	
1-year outcomes			
Death	24 (5.8)	36 (5.8)	0.97
Stroke	21 (5.1)	29 (4.7)	0.79
New pacemaker*	56 (15)	95 (18)	0.20
Heart failure	8 (1.9)	10 (1.6)	0.71
Acute myocardial infarction	2 (0.5)	6 (1.0)	0.49
Percutaneous coronary intervention	7 (1.7)	13 (2.1)	0.63
Reoperation	5 (1.2)	3 (0.5)	0.28
Endocarditis	5 (1.2)	11 (1.8)	0.46

*Among patients without pacemaker before transcatheter aortic valve implantation.
VARC, Valve Academic Research Consortium.

and procedural, 30-day and 1-year mortality rates were higher than in the current study. In this study, mortality was similar across age groups. The highest estimated mortality and stroke rate was among patients younger than 70 years (<70). This did not seem to be related to increased procedural risk. A more likely explanation for this is that comorbidity was more pronounced in this age group, and patients were thus selected for TAVI because of higher expected surgical risk. This is supported by the baseline characteristics. Also, considering the guideline

Table 5 HRs (death) and subdistribution HRs (stroke and new pacemaker) by age group

	Unadjusted			Adjusted		
	HR	95% CI	P value	HR	95% CI	P value
Death						
70–79	–	–		–	–	
80–89	0.99	0.56 to 1.75	0.98	0.90	0.51 to 1.60	0.72
90+	1.33	0.39 to 4.49	0.65	1.10	0.31 to 3.85	0.88
<70	1.50	0.56 to 4.02	0.42	1.51	0.56 to 4.08	0.41
Stroke						
70–79	–	–		–	–	
80–89	1.62	0.82 to 3.22	0.17	1.51	0.77 to 2.94	0.23
90+	1.52	0.33 to 6.93	0.59	1.38	0.29 to 6.52	0.69
<70	3.19	1.18 to 8.62	0.022	3.32	1.14 to 9.66	0.027
New pacemaker						
70–79	–	–		–	–	
80–89	1.32	0.93 to 1.87	0.12	1.33	0.93 to 1.91	0.12
90+	0.87	0.34 to 2.20	0.76	0.86	0.33 to 2.20	0.75
<70	0.50	0.18 to 1.39	0.19	0.49	0.17 to 1.36	0.17

Table 6 HRs (death) and subdistribution HRs (stroke and new pacemaker) by sex

	Unadjusted			Adjusted		
	HR	95% CI	P value	HR	95% CI	P value
Death						
Male	–	–		–	–	
Female	0.99	0.59 to 1.66	0.97	0.88	0.52 to 1.50	0.64
Stroke						
Male	–	–		–	–	
Female	1.08	0.62 to 1.89	0.79	0.98	0.54 to 1.78	0.95
New pacemaker						
Male	–	–		–	–	
Female	0.80	0.58 to 1.11	0.18	0.80	0.57 to 1.12	0.19

recommendations referenced above, the default treatment for patients in this age group was SAVR and, still, the heart team directed these patients to TAVI.

Regarding sex, previous registry and trial cohort data suggest that males undergoing TAVI have more comorbidity than females undergoing TAVI, yet mortality and stroke rates appear similar while females may have a higher risk of major bleeding.[8 9] These observations are in line with our data. Collectively, these data suggest that, in contrast to SAVR where female sex is associated with worse outcomes,[10 11] outcomes among females and males are similar after TAVI. Females had smaller annuli than males, and overall in COMPARE-TAVI 1, there was an association between annulus size and effective orifice area.[2] An echocardiographic substudy of COMPARE-TAVI 1 supports that the difference in annulus size is the main explanation for the lower effective orifice area and higher gradients observed among females compared with males.[12]

In the COMPARE-TAVI 1 trial, rates of new pacemaker were higher among patients treated with Myval.[2] The valve distribution of used valve types did not differ between age and sex groups, and neither did the pacemaker rates.

Strengths and limitations

This study benefits from prospective data of high-quality from a randomised clinical trial, including end-point committee-adjudicated outcomes. While it is a limitation that follow-up is currently only 1 year, the trial will provide follow-up data for a total of 10 years in due time. With the high inclusion rates, the results are largely generalisable to TAVI populations. However, the study provides data on patients selected for TAVI by the heart team but does not provide information regarding this selection process, and the results are obtained with transfemoral TAVI with balloon-expandable valves at centres with established structural heart teams.

Additional limitations are related to the observational nature of this study, as discussed above. The limitations related to the number of patients are particularly important in the <70 years and 90+ years groups that included smaller numbers of patients.

CONCLUSION

In the COMPARE-TAVI 1 cohort, patients were divided into patients younger than 70 years (<70), aged 70 to 79 years (70–79), aged 80 to 89 years (80–89) and aged 90 years and older (90+), and female and male sex. While comorbidity levels varied between groups, clinical outcomes were similar across age groups and between sexes.

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Patient consent for publication Not applicable.

Ethics approval This study involves human participants. The Central Denmark Region Ethics Committee approved COMPARE-TAVI 1 (1-10-72-389-17). All participants gave written informed consent before participating and the study was performed in accordance with the principles stated in the Declaration of Helsinki.

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