Apical vs subclavian transcatheter aortic valve implantation: an 8-year United Kingdom analysis

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Abstract

Objectives: Subclavian (SC) and transapical (TA) approach are the main alternatives to the default femoral delivery for transcatheter aortic valve implantation (TAVI). Aim of this study was to compare, complications and morbidity/mortality associated with SC and TA in a long-term time frame. **Methods:** From January 2007 to July 2015, 1,506 patients underwent TAVI surgery in 36 United Kingdom TAVI centres. Primary outcomes were complications according to VARC-2 criteria. The secondary outcome was long-term survival. **Results:** The enrolled patients were distributed as follows: 1,216 in the trans-apical (TA) group and 290 in the subclavian (SC) group. There were no differences in the rates of acute myocardial infarction, emergency valve-in-valve, paravalvular leak, balloon post dilatation, cardiac tamponade, stroke, renal replacement therapy, vascular injuries, and 30-days mortality among the groups. Conversely, the rate of permanent pacemaker implantation (p = 0.02), the procedural time duration (p = 0.04), and the 12-month mortality (p = 0.03) was higher in SC than in TA, while in-hospital length of stay was reduced in SC than in TA (p = 0.01). Up to 8-years, the long-term mortality was not different among groups (p = 0.77), and no difference in long-term survival between self vs balloon expandable device was found (p = 0.26). **Conclusions:** According to our results, TA provided the best 12-months survival compared to SC, while the long-term survival up to 2, 900 days is not significantly different between groups, so SC and TA may both represent a safe non-femoral access if femoral is precluded.

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Visual abstract

The study compares outcomes of SC and TA TAVI, which are the main alternatives to femoral approach.

TA has better 12-months survival than SC, but both are associated with similar survival up to 2,900 days.

SC and TA are established, feasible, and safe alternative strategies to the femoral access for TAVI.

Abstract

Objectives: Subclavian (SC) and transapical (TA) approach are the main alternatives to the default femoral delivery for transcatheter aortic valve implantation (TAVI). Aim of this study was to compare, complications and morbidity/mortality associated with SC and TA in a long-term time frame.

Methods: From January 2007 to July 2015, 1,506 patients underwent TAVI surgery in 36 United Kingdom TAVI centres. Primary outcomes were complications according to VARC-2 criteria. The secondary outcome was long-term survival.

Results: The enrolled patients were distributed as follows: 1,216 in the trans-apical (TA) group and 290 in the subclavian (SC) group. There were no differences in the rates of acute myocardial infarction, emergency valve-in-valve, paravalvular leak, balloon post dilatation, cardiac tamponade, stroke, renal replacement therapy, vascular injuries, and 30-days mortality among the groups. Conversely, the rate of permanent pacemaker implantation ($p = 0.02$), the procedural time duration ($p = 0.04$), and the 12-month mortality ($p = 0.03$) was higher in SC than in TA, while in-hospital length of stay was reduced in SC than in TA ($p = 0.01$). Up to 8-years, the long-term mortality was not different among groups ($p = 0.77$), and no difference in long-term survival between self vs balloon expandable device was found ($p = 0.26$).

Conclusions: According to our results, TA provided the best 12-months survival compared to SC, while the long-term survival up to 2, 900 days is not significantly different between groups, so SC and TA may both represent a safe non-femoral access if femoral is precluded.

Key words : Aortic valve replacement; Transcatheter aortic valve implantation; Minimally invasive surgery; Subclavian; Transapical.

Abbreviation and acronyms

AVR, aortic valve replacement

BMI, body mass index

CCS, Canadian Cardiovascular Society

CI, confidence interval

COPD, chronic obstructive pulmonary disease

CSHA, Canadian Study of Health and Ageing

DA, direct aortic

LMS, left main stem

LVEF, left ventricular ejection fraction

MI, myocardial infarction

MVR, mitral valve regurgitation

NCCAD, National Central Cardiac Audit Database

NHS, National Health Service

NICOR, National Institute for Cardiovascular Outcomes Research

NYHA, New York Heart Association

PCI, percutaneous cardiac intervention

PPI, permanent pacemaker implantation

PS, propensity score

SC, subclavian

TA, transapical

TAVI, transcatheter aortic valve implantation

TF, transfemoral

TIA, transient ischemic attack

VARC-2, Valve Academic Research Consortium-2

Introduction

The transfemoral (TF) approach is the established default vascular access for transcatheter aortic valve implantation (TAVI)[1,2]. However, small vessel calibre and/or peripheral vascular disease (calcification, previous stenting deployment, tortuosity, pathological stenosis) may preclude femoral TAVI in a significant number of patients[3]. Despite the miniaturization of transcatheter aortic valve delivery systems, it is estimated that 10% to 15% of patients will still have unsuitable ileo-femoral arteries for TAVI[4]. Alternative approaches are transapical (TA), direct aortic (DA), subclavian/axillary (SC), carotid, and transcaval approach[5]. In the timeline, the TA access was the first one alternative which was developed, but it had high rate of bleeding and mortality compared to TF[6], so in 2008 was described the first SC implantation route for transcatheter aortic valve, which was aiming to address the TA downsides[7]. Currently, the TA TAVI is performed less frequently in the United Kingdom (UK)[8]. Consequently, the SC/axillary is becoming the predominant alternative access approach[9]. Because trials data recommend TAVI for high-, intermediate-, and even low-risk operable patients[10] and because there is a lack of data prospectively comparing outcomes after SC vs TA TAVI, it is useful to analyse the UK TAVI registry to determine whether there was a difference in procedural- related complications according to Valve Academic Research Consortium-2 (VARC-2) criteria, and in short-, medium-, and long-term survival between these main two alternative vascular approaches, which are fundamental in case of femoral contraindication for TAVI delivery. In this regard, the aim of this study was to compare complications and morbidity/mortality associated with TA and SC, which are the main choice for TAVI when TF is precluded in a real-world long-time national data setting.

Material and Methods

The UK TAVI registry collected data from 100% of the patients who underwent TAVI in any of the 36 TAVI centres in the United Kingdom. Patients undergoing TAVI in England and Wales are linked to the Office of National Statistics by the National Health Service (NHS) Central Register via a unique NHS number. This provides the system for tracking all-cause mortality. Each UK TAVI centre uses the same database, National Institute for Cardiovascular Outcomes Research (NICOR) recommended, and these data are routinely transferred to the National Central Cardiac Audit Database (NCCAD). The NICOR complies the section 251 of the NHS Act 2006, so ethical approval was not mandatory for this retrospective analysis. However, each patient provided a written informed consent both for surgery and research purpose at the time of its TAVI as per standard institutional protocol. Validated life status data were available for patients up to July 2015 so, from January 2007 (UK TAVI registry start) to January 2015, among the 8,320 patients who received a TAVI procedure, we selected the 1,506 patients who underwent SC or TA TAVI. We analysed patients' demographics, indications for TAVI, procedural characteristics, and adverse outcomes up to the hospital discharge. In our study, the primary outcomes were procedural and in-hospital complications according to VARC-2 criteria (i.e., stroke, major/minor vascular complications, major/minor bleeding, tamponade, permanent pacemaker implantation, acute kidney impairment within 7 days, renal replacement therapy, emergency valve in valve needs, paravalvular leak, balloon re-dilatation), and in-hospital, 30-day, and 1-year mortality. Meanwhile, in our analysis the secondary outcome which was explored was the long-term survival up to 2,900 days. Long-term follow-up was completed in 96% of patients. The average follow-up was 836 days. Statistical analyses were performed using SPSS 25.0 (IBM Corporation, Armonk, NY) and R (The R Project for Statistical Computing). The chi-square and Kruskal-Wallis tests were used as appropriate. For survival analysis, Kaplan-Meier curves were computed, and a log-rank p value was calculated. For the time-to-death analysis, a Cox regression model analysis was applied and a propensity score (PS) matching analysis was employed to address biases, which are related to an observational study. Adjustment for confounding variables was performed by weighting regression model with PS. A Cox proportional hazard model was applied for the primary outcome measure, corrected for Euro SCORE, valve type (self vs balloon expandable), presence and severity of coronary artery disease (one, vs two, vs three coronary arteries), access route (SC vs. TA), heart rhythm (atrial fibrillation vs. sinus rhythm), and year of implantation (2015 vs. 2007). A 2-sided p value <0.05 was considered significant.

Results

In the absence of randomised controlled trial data, prospectively collected observational data offer reliable alternative for such a comparison. In this regard, we reported a large series of SC and TA cases over a long period and each limitation of no-randomized observational study was robustly addressed by a propensity score analysis. From the UK TAVI registry, 1,506 patients were suitable for our analysis. The TA arm grouped 1,216 patients, while the SC collected 290 patients. Demographic characteristics of the 1,506 patients are summarized in Table I. To reduce biases which are related to confounding variables and to the observational study per se, we performed a propensity score matching weighted analysis for LogEuroSCORE II, valve type (balloon-expandable/self-expandable), presence and severity of coronary artery disease (one, vs two, vs three coronary arteries), access route (SC vs. TA), heart rhythm (atrial fibrillation vs. sinus rhythm), and year of implantation (2015 vs. 2007). Stroke, major/minor vascular complications, major/minor bleeding, tamponade, permanent pacemaker implantation, acute kidney impairment within 7 days, renal replacement therapy, emergency valve in valve needs, paravalvular leak, balloon re-dilatation, and in operating room, 30-days, and 12-month mortality were all treated as dichotomous post-operative outcomes and their analysis is summarized in Table II. In the Cox proportional hazard model, 1,263 patients were fit to be entered and the results are presented in Table III. The median age of patients was 80 (IQR 75–85) years and 30% were female. SC access patients were marginally older than TA ones. Significantly more men were approached via SC route ($p = 0.04$), while the Logistic EuroSCORE was almost similar among groups ($p = 0.06$). The body mass index (BMI) distribution was comparable. SC access was almost exclusively used for the self-expandable device (93.9%), whereas most TA cases were for a balloon-expandable device (89.8%). Acute Kidney Injury stage III within 7 days after procedure and the renal replacement therapy rate were almost similar between groups. Conversely, the rate of permanent pacemaker implantation (PPI) in the SC (28%) was significantly greater than that in the TA (11.0%) group ($p = 0.02$), but this data did not affect the overall survival at our analysis. Vascular complications and major peripheral vascular injuries that required vascular surgery repair were observed with comparable frequency within groups, 1.0% in SC and 0.6% in TA. While in SC they were purely related to the access, in TA they occurred as complication of femoral percutaneous access for concomitant coronary intervention (4 cases) or accidental injury of the femoral artery, which occurred during the placement of the venous temporary intracavitary pacemaker catheter (8 cases). The rates of in-hospital acute myocardial infarction (within 72 hours after the procedure), in-hospital TIA, and stroke were not significantly different among groups ($p = 1.0$, $p = 0.25$, and $p = 0.09$, respectively). The rates of moderate and severe paravalvular leakage, balloon re-dilatation after valve deployment, emergency valve in valve procedure, bleeding, cardiac tamponade, emergency cardiac surgery, and in-operating room death were not significantly different among groups. Conversely, we found that in the SC the procedural time (193.24 $\pm$77.3529 minutes) was significantly longer ($p= 0.04$) than that in TA (123.10 $\pm$55.12 minutes), meanwhile the average length of hospital stay was significantly reduced ($p = 0.01$) in SC group (9.8 $\pm$7.5

days) compared to TA (13.3 ±7.5 days). Moreover, the 30-days mortality was not significantly different in SC compared to TA, while the 12-months mortality was significantly higher in SC than in TA ($p = 0.01$). Estimates of long-term survival are represented by Kaplan-Meier curves. Long-term survival in the SC and TA groups at 8-year follow up was not significantly different ($p = 0.77$), as it is represented in Figure 1. Finally, based on our analysis, there was no significant difference in long-term survival between patients who received balloon-expandable devices compared to those who received self-expandable devices ($p = 0.26$), as it is shown in Figure 2.

Discussion

In more recent years, in UK there has been an increase in the use of the SC and axillary route, including percutaneous approaches performed under local anaesthetic, and a corresponding decline in TA access. SC and TA still remain the preferred alternative to the default femoral delivery, and they are fundamental in case of iliofemoral hostility, which may contraindicate its navigation. Despite the progressive reduction in the calibre of TAVI delivery systems, which are nowadays available on the market, in a significant proportion of patients, which range from 10 to 15%, small vessels, calcification, previous stenting deployment, tortuosity, and pathological stenosis may preclude a percutaneous femoral approach. Because patients who received a surgical alternative access commonly have a worse risk-profile, it could be useful to analyse which worse outcomes are related to the patient rather than to the procedure. There is a lack of data prospectively comparing outcomes and long-term survival after SC vs TA TAVI. In this regard, the UK TAVI national registry offer the opportunity to explore whether there was a difference in outcomes and survival between TA and SC and this is the reason because we decided to focus our analysis on this wide pool of data. Our study found that the SC approach was associated with increased short-term (12 months), but not long-term (up to 96 months) mortality. Compared to TA, the SC approach has the advantages of obviating separation of the pleura, and thus may reduce postoperative pain and respiratory complications that are commonly related to each thoracotomy. On the other hands, SC it can be restricted by anatomical features such as tortuosity or small vessel calibre. In case of pre-existing left internal mammary artery bypass graft SC may also expose patient to the risk of acute myocardial ischemia during navigation. Furthermore, the relative lack of a muscular component to the subclavian wall makes this artery more incline to iatrogenic dissection. This study collected, compared, and analysed surgical TAVI implantation in a large sample of patients in a national real-world setting. Considering that there is a paucity of data directly comparing outcomes for SC and TA TAVI approaches, in the absence of randomised controlled trial data, prospectively collected observational data offer the best alternative for such kind of comparison. We reported a large series of SC and TA cases over a long period and each limitation of no-randomized observational study was robustly corrected by an accurate and rigorous propensity score analysis. We aimed to describe and analyse the whole pool of data regarding the early and intermediate experience of an entire country (UK), and to clarify the outcomes associated with the main two different surgical choices, which are alternative to the femoral delivery. We found no difference in long-term mortality between SC and TA, and their respective Kaplan-Meier survival curves were almost overlapped. According to our analysis, SC had faster recovery process than TA, in fact the median in hospital length of stay was 2.8 days less than those with the TA approach. Conversely, the main downside of SC was the high rate of PPI, but this outcome is likely to be related to the use of Core Valve (Medtronic) for the SC approach. However, in our dataset, PPI after TAVI did not affect the overall long-term survival. As with any operative technique, the choice to select a specific approach is determined by different combinations of patients' comorbidity, vascular anatomy/pathology, transcatheter heart valve type, availability of new performing devices on the market, and skill mixing along with the expertise and experience of the entire Heart Team, who remains the key factor to lead to the best choice tailored for each patient.

Conclusion

According to our data, the TA and SC approaches were associated with almost similar long-term survival. Based on these findings, the key message of this study is that SC and TA are established, feasible and comparatively safe alternative strategies to the default retrograde femoral access for TAVI. However, in more recent years, there has been an increase in the use of the subclavian and axillary route, including percutaneous approaches performed under local anaesthetic, and a corresponding decline in TA access. As with any operative technique, the choice to select a specific approach is determined by different combinations of patients' comorbidity, vascular characteristics, transcatheter aortic valve prosthesis, availability of new performing devices on the market, and skill, mastery, expertise, and experience of the entire Heart Team, who remains the key factor to lead to the best choice tailored for each single patient.

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Conflict of interest

The authors declare that there are no conflicts of interest pertaining to this manuscript.

Author contribution statement

Francesca D'Auria, M.D., Ph.D. (Conceptualization; Formal analysis; Investigation; Methodology; Project administration; Supervision; Validation; Visualization; Writing – original draft; Writing – review & editing). Danilo Flavio Santo, M.D. (Methodology; Validation; Writing – review & editing). Aung Myat, M.D. (Data curation; Writing – review & editing; data providing). Roberto Lorusso, M.D., Ph.D. (Methodology; Supervision; Validation; Writing – review & editing). Justine Mafalda Ravaux, M.D. (Methodology; Validation; Writing – review & editing). Uday Trivedi, M.D. (Methodology; Writing – original draft). David Hildick-Smith, M.D. (Data curation; Project administration; Supervision; Validation; Writing – review & editing).

Figure Legends

Figure 1. Unadjusted Kaplan-Meier curves comparing long-term survival up to 2,900 days in the SC and TA groups.

Figure 2. Kaplan-Meier curves comparing balloon-expandable to self-expandable devices up to 2,900 days.

Tables

Table 1. Baseline demographic characteristics in the groups.

Variable	Subclavian (n=290)	Transapical (n=1216)	P value
Age (y)	80.5 (± 6.81)	80.2 (± 7.92)	0.54
Male	202 (70 %)	709 (58 %)	0.03[a]
Female	88 (30 %)	507 (42 %)	0.04 [a]
NYHA III-IV	226 (78 %)	1216 (100 %)	0.058
CCS 3-4	41 (14 %)	163 (13 %)	0.62
Logistic Euro-SCORE	22 (±1.6)	20 (±2.3)	0.06
Frailty score (CSHA) 6 -7	19 (7 %)	85 (7%)	0.98
Katz index (1-2)	2 (0.7 %)	12 (1 %)	0.89
Poor mobility	29 (10 %)	127 (10 %)	0.98
Critical preoperative status	4 (1 %)	13 (1 %)	0.99
Height (m)	1.66 (± 0.10)	1.63 (± 0.10)	0.79
Weight (kg)	74.35 (±17.45)	74.31 (±15.42)	0.75
Creatinine (mmol/l)	115 (± 60.80)	120 (±23.01)	0.42

Variable	Subclavian (n=290)	Transapical (n=1216)	P value
Pre op dialysis	1 (0.34 %)	4 (0.32 %)	0.41
Diabetes	79 (27 %)	328 (27 %)	0.92
Insulin	13 (16 %)	195 (16 %)	0.92
Oral drugs	45 (57 %)	681 (56 %)	0.89
Diet treatment	21 (27 %)	340 (28 %)	0.90
Non-diabetic	211 (73 %)	888 (73 %)	0.94
Current smoker	24 (8 %)	97 (8 %)	0.97
Ex-smoker	177 (61 %)	705 (58 %)	0.89
Never smoker	89 (31 %)	413 (34 %)	0.88
COPD/Pulmonary disease	89 (31 %)	378 (31 %)	0.98
Severe liver disease	2 (0.7 %)	12 (1 %)	0.87
Atrial fibrillation	74 (26 %)	255 (21 %)	0.78
Neurological disease	65 (22 %)	231 (19 %)	0.85
Extracardiac arteriopathy	152 (52 %)	632 (52 %)	0.98
Ascending aorta calcification	65 (22 %)	280 (23 %)	0.84
Previous cardiac surgery	86 (30%)	556 (46%)	0.15
Previous MI	75 (26 %)	328 (27 %)	0.81
Previous PCI	75 (26 %)	194 (16 %)	0.76
Coronary artery disease	141 (49 %)	559 (46 %)	0.68
LMS disease > 50 %	19 (6 %)	61 (5 %)	0.55
LVEF > 50 %	155 (54 %)	705 (58 %)	0.61
LVEF 30-49 %	107 (37 %)	389 (32 %)	0.54
LVEF < 30%	26 (9 %)	122 (10 %)	0.46
Aortic peak gradient (mmHg)	78.03 (± 28.99)	76.03 (± 29.19)	0.43
Aortic mean gradient (mmHg)	48.06 (± 15.37)	47.06 (± 19.37)	0.64
Aortic valve area (cm^2)	1.07 (± 4.72)	1.02 (± 4.74)	0.45
Aortic annulus (mm)	23.76 (± 2.82)	23.71 (± 2.12)	0.34
MVR (moderate-severe)	20 (7 %)	97 (8 %)	0.09

NYHA, New York Heart Association; CCS, Canadian Cardiovascular Society; CSHA, Canadian Study of Health and Ageing; COPD, chronic obstructive pulmonary disease; MI, myocardial infarction; PCI, percutaneous cardiac intervention; LMS, left main stem; LVEF, left ventricular ejection fraction; MVR, mitral valve regurgitation. ^{a} $p < 0.05$

Table 2. Transcatheter aortic valve implantation outcomes according to VARC-2 criteria (raw data) and Odds Ratio derived from logistic regression model after adjustment with Propensity Score (PS)-weighted population (1,263 patients fitted for matching).

Variable	Subclavian (n = 290)	Transapical (n= 1216)	PS-Adjusted Odds Ratio
Permanent Pacemaker Implantation	82 (28%)	139 (11%)	0.14
Acute Kidney Injury stage III (within 7 days)	3 (1.0%)	19 (4.2%)	0.04
Renal Replacement Therapy	7 (2.4%)	68 (5.6%)	2.02

Variable	Subclavian (n = 290)	Transapical (n= 1216)	PS-Adjusted Odds Ratio
Vascular Complication	6 (2%)	12 (1%)	0.08
Vascular Surgery Repair	3 (1.0%)	7 (0.6%)	0.60
TIA	6 (2.1%)	12 (1.0%)	1.86
Stroke	12 (4.1%)	101 (8.3%)	0.14
Acute MI (<72 hours)	0 (0.0%)	4 (0.32%)	2.24
Moderate/Severe paravalvular regurgitation	15 (5.1%)	14 (3.1%)	0.10
Balloon redilatation	26 (8.9%)	38 (8.5%)	0.05
Emergency V-in-V	6 (2.1%)	8 (1.8%)	0.05
Tamponade	6 (2.1%)	12 (2.7%)	1.86
Life threatening Bleeding	1 (0.3%)	7 (1.6%)	2.04
Major Bleeding	4 (1.4%)	13 (2.9%)	1.03
Minor Bleeding	10 (3.4%)	19 (4.2%)	0.82
In OR death	2 (0.7%)	10 (0.8%)	1.06
In hospital death	3 (1.0%)	31 (6.9%)	0.04
30-day mortality	7 (2.4%)	13 (2.9%)	1.21
12-month mortality	58 (20.0%)	74 (16.6%)	0.04
In Hospital length of stay (days)	9.8 (±7.5)	13.3 (±7.5)	0.49
Procedural time (minutes)	193.24 (±77.3529)	123.10 (±55.12)	0.59

TIA, transient ischemic attack; MI, myocardial infarction; CI, confidence interval; PS, propensity score.

[a] p <0.05

Table 3. Cox proportional Hazard Model for overall survival.

Variable	Hazard ratio	95% CI	P value
Logistic Euro SCORE	1.04	1.02-1.06	< 0.05
Valve type (balloon-expandable vs self-expandable	1.00	0.85-1.22	1.0
Year of implant (2015 vs 2007)	0.39	0.26-0.62	< 0.05
Heart rhythm (atrial fibrillation vs sinus rhythm)	1.32	1.12-1.54	0.048
1 coronary artery disease vs no coronary artery disease	1.15	1.0-1.38	0.13
2 coronary arteries disease vs no coronary artery disease	1.14	0.91-1.43	0.29
3 coronary arteries disease vs no coronary artery disease	1.04	0.84-1.28	0.82
Subclavian vs Apical	1.22	0.88-1.70	0.079

CI, confidence interval

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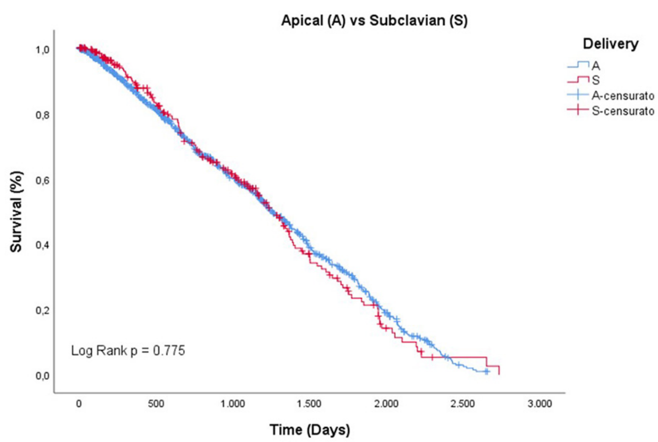

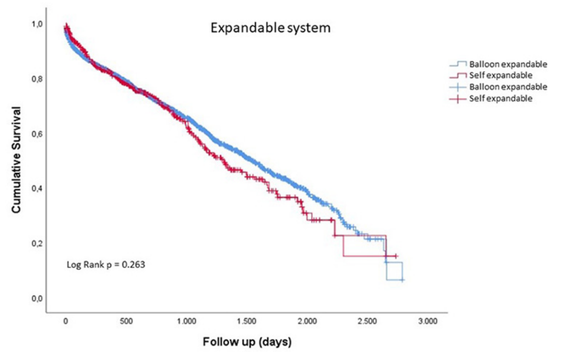
Expandable system
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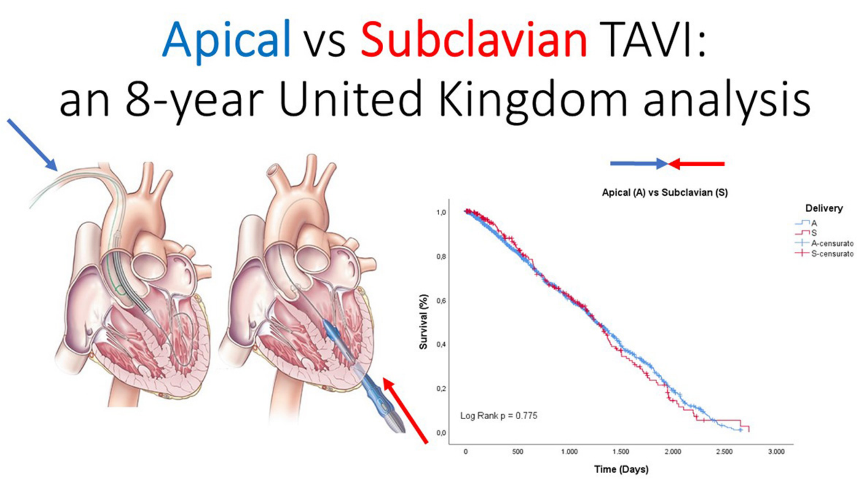
Balloon expandable
Self expandable
Cumulative Survival
Log Rank p = 0.263
Follow up (days)


Apical vs Subclavian TAVI:
an 8-year United Kingdom analysis
Apical (A) vs Subclavian (S)
Delivery
A
S
A-censurato
S-censurato
Survival (%)
Log Rank p = 0.775
Time (Days)