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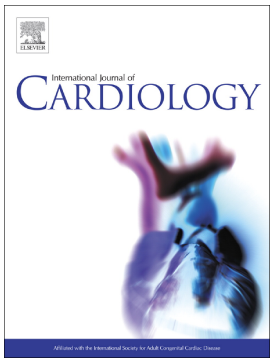
Myat, Aung; Papachristofi, Olympia; Trivedi, Uday; Bapat, Vinayak; Young, Christopher; De Belder, Adam; Cockburn, James; Baumbach, Andreas; Banning, Adrian P.; Blackman, Daniel J.; Maccarthy, Philip; Mullen, Michael; Muir, Douglas F.; Nolan, James; Zaman, Azfar; De Belder, Mark; Cox, Ian; Kovac, Jan; Brecker, Stephen; Turner, Mark

DOI:
10.1016/j.ijcard.2020.03.059

Document Version
Peer reviewed version

Citation for published version (Harvard):
Myat, A, Papachristofi, O, Trivedi, U, Bapat, V, Young, C, De Belder, A, Cockburn, J, Baumbach, A, Banning, AP, Blackman, DJ, Maccarthy, P, Mullen, M, Muir, DF, Nolan, J, Zaman, A, De Belder, M, Cox, I, Kovac, J, Brecker, S, Turner, M, Khogali, S, Malik, I, Redwood, S, Prendergast, B, Ludman, P, Sharples, L & Hildick-smith, D 2020, 'Transcatheter aortic valve implantation via surgical subclavian versus direct aortic access: a United Kingdom analysis', *International Journal of Cardiology*, vol. 308, pp. 67-72.
https://doi.org/10.1016/j.ijcard.2020.03.059

Transcatheter aortic valve implantation via surgical subclavian versus direct aortic access: A United Kingdom analysis



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PII: S0167-5273(19)36135-2

DOI: https://doi.org/10.1016/j.ijcard.2020.03.059

Reference: IJCA 28461

To appear in: *International Journal of Cardiology*

Received date: 15 December 2019

Revised date: 6 February 2020

Accepted date: 20 March 2020

Please cite this article as: A. Myat, O. Papachristofi, U. Trivedi, et al., Transcatheter aortic valve implantation via surgical subclavian versus direct aortic access: A United Kingdom analysis, *International Journal of Cardiology* (2018), https://doi.org/10.1016/j.ijcard.2020.03.059

TRANSCATHETER AORTIC VALVE IMPLANTATION VIA SURGICAL SUBCLAVIAN VERSUS DIRECT AORTIC ACCESS: A UNITED KINGDOM ANALYSIS

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All authors take responsibility for all aspects of the reliability and freedom from bias of the data presented and their discussed interpretation.

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Word Count

2773 (Main text only)

Acknowledgement of Grant Support

The work was supported by the National Health Service (NHS) National Institute of Health Research (NIHR) through an Academic Clinical Lectureship currently undertaken by Dr Aung Myat at Brighton and Sussex Medical School, Brighton, United Kingdom. Professor Adrian P. Banning is partially funded by the NHS NIHR Oxford Biomedical Research Centre, Oxford, United Kingdom.

Disclosures

Aung Myat, Olympia Papachristofi, Uday Trivedi, Adam de Belder, James Cockburn, Andreas Baumbach, Michael Mullen, Mark de Belder, Ian Cox, Iqbal S. Malik, Peter Ludman and Linda Sharples report no conflicts to declare pertaining to this manuscript.

Adrian P. Banning reports institutional funding from Boston Scientific for a Fellowship. Daniel J. Blackman is a Consultant and Proctor for Medtronic and Boston Scientific. Philip MacCarthy declares consulting/proctorship contracts with Edwards Lifesciences and research support from Boston Scientific. Douglas Muir is a Proctor for Edwards Lifesciences and Abbott Vascular. Jan Kovac is a Proctor and Consultant for Edwards Lifesciences, Medtronic, Boston Scientific and Abbott. Stephen Brecker is a Clinical Advisor/Consultant for Medtronic, Boston Scientific and Abbott. Mark Turner is a proctor for Medtronic pulmonary valves currently, and has been a proctor for Edwards Lifesciences pulmonary valves in the past, but no longer holds a contract with them. He is also a Consultant and Advisory Board Member for St Jude (now Abbott), and has previously received educational meeting support from Edwards Lifesciences, Medtronic and Abbott. Saib Khogali is a Proctor for Boston Scientific and Medtronic. Simon Redwood declares Proctor and Lecture fees from Edwards Lifesciences. Bernard Prendergast declares

unrestricted research grants and lecture fees from Edwards Lifesciences. David Hildick-Smith has advisory and proctoring contracts with Boston Scientific, Edwards and Medtronic.

Abstract

Background: Surgical subclavian (SC) and direct aortic (DA) access are established alternatives to the default transfemoral route for transcatheter aortic valve implantation (TAVI). We sought to find differences in survival and procedure-related outcomes after SC- versus DA-TAVI.

Methods: We performed an observational cohort analysis of cases prospectively uploaded to the UK TAVI registry. To ensure the most contemporaneous comparison, the analysis focused on SC and DA procedures performed from 2013 to 2015.

Results: Between January 2013 and July 2015, 82 (37%) SC and 142 (63%) DA cases were performed that had validated 1-year life status. Multivariable regression analysis showed procedure duration was longer for SC cases (SC 193.5 ± 65.8 vs. DA 138.4 ± 57.7 minutes; p<0.01) but length of hospital stay was shorter (SC 8.6 ± 9.5 vs. DA 11.9 ± 10.8 days; p=0.03). Acute kidney injury was observed less frequently after SC cases (odds ratio [OR] 0.35, 95% confidence interval [CI 0.12-0.96]; p=0.042) but vascular access site-related complications were more common (OR 9.75 [3.07-30.93]; p<0.01). Procedure-related bleeding (OR 0.54 [0.24-1.25]; p=0.15) and in-hospital stroke rate (SC 3.7% vs. DA 2.1%; p=0.67) were similar. There were no significant differences in in-hospital (SC 2.4% vs. DA 4.9%; p=0.49), 30-day (SC 2.4% vs. DA 4.2%; p=0.71) or 1-year (SC 14.5% vs. DA 21.9%; p=0.344) mortality.

Conclusions: Surgical subclavian and direct aortic approaches can offer favourable outcomes in appropriate patients. Neither access modality conferred a survival advantage but there were significant differences in procedural metrics that might influence which approach is selected.

Keywords

Aortic stenosis; transcatheter aortic valve implantation; subclavian; axillary; direct aortic

1. Introduction

The retrograde transfemoral (TF) route is the established default vascular access for transcatheter aortic valve implantation (TAVI) (1,2). In some patients, however, the transfemoral approach is not possible because of significant atherosclerotic disease and/or unsuitable iliofemoral anatomy, such as tortuosity or small calibre. Alternatives include the transapical (TA), direct aortic (DA), subclavian or axillary (SC), carotid and transcaval access sites. With the miniaturisation of TAVI delivery systems and the relative invasiveness of surgical thoracotomy in often multi-morbid patients, TA access is now performed less frequently in the United Kingdom (UK). Consequently the SC and DA routes have become the predominant alternative surgical approaches, both performed under general anaesthetic. Either approach mandate a surgical cutdown - the former to the subclavian artery and the latter via an upper partial sternotomy or small right anterior thoracotomy. Both were originally developed for the Medtronic CoreValve (Medtronic, Dublin, Ireland) due to its longer profile, which made a TA approach problematic. The DA access can also be used for the Edwards Lifesciences Sapien (Irvine, CA, USA) valve.

There is a lack of data directly comparing outcomes after SC versus DA access TAVI. Hence we analysed the UK TAVI national registry to determine whether there was a difference in short- and medium-term survival and other important procedure-related outcomes between these two alternative vascular access approaches.

2. Methods

The UK TAVI registry has recorded baseline demographics, procedural characteristics, complications and clinical outcomes for every patient treated with TAVI since January 2007. It is mandatory to complete the dataset for every individual undergoing attempted TAVI in

the UK. The data are collated and the process quality controlled by the National Institute of Cardiovascular Outcomes Research (NICOR) (1,3,4).

The current study is an observational cohort analysis of all procedures prospectively uploaded to the NICOR servers from January 2007 to December 2015. A Heart Team in each centre determined patient eligibility for TAVI, selected prosthesis type and corresponding access route according to size and degree of tortuosity, calcification, and atheroma of the aorto-iliofemoral arterial tree. All patients provided written informed consent at the time of their TAVI procedure as per standard institutional protocols. We identified all those who had TAVI performed via the SC versus DA access route and compared them according to patient and procedural characteristics, clinical outcomes and survival. Missing data were excluded from the analyses.

DA access has only been used from 2013 onwards, whereas SC access was available from 2007. To ensure a more contemporaneous and statistically more robust comparison of SC versus DA access outcomes, we focussed our analyses on procedures performed from January 2013 to July 2015. We used multivariable regression to adjust for remaining confounding.

The primary analysis looked at 30-day and 1-year all-cause mortality after SC versus DA access TAVI up to July 2015. The secondary analysis was designed to investigate important process measures and postoperative complications including: procedure duration, postoperative length-of-stay (LoS), vascular access site and related complications, in-hospital permanent pacemaker implantation (PPI), pericardial tamponade, valve embolization, further valve intervention before discharge, stroke, bleeding, aortic valve regurgitation, acute kidney injury (AKI) and requirement for new renal replacement therapy.

2.1 Data cleaning

Registry results are presented to the British Cardiovascular Intervention Society (BCIS) annually, ensuring continual validation and verification of data integrity. All data, inclusive of peri- and postprocedural complications up to hospital discharge are reported by each participating TAVI centre in accordance with the definitions outlined by the national dataset. Range checks to expose extreme values and assessments of internal consistency are applied when individual records are uploaded to the central NICOR server. Centres uploading records with missing, extreme, or inconsistent values are contacted and asked to ratify records if necessary.

2.2 Mortality tracking

Patients undergoing TAVI in England and Wales (comprising the vast majority of procedures in the registry), are linked to the Office of National Statistics by the National Health Service (NHS) Central Register via a unique NHS number. This provides a robust system for tracking all-cause mortality. Validated life status data were available for patients up to July 2015. This was used for survival analyses at 30 days and 1 year for the current investigation. NICOR has support under section 251 of the NHS Act 2006. According to NHS research governance arrangements, formal ethics approval was not required for this study (1,3). This study was conducted in accordance with the Declaration of Helsinki and good clinical practice.

2.3 Statistical analysis

Continuous variables are summarised as mean and standard deviation, or as median and interquartile ranges (IQR) where appropriate. Unadjusted differences were assessed with the two-sample *t*-test, or two-sample Wilcoxon rank-sum test. Categorical variables are presented as absolute numbers and percentages, and comparison between groups was undertaken by the

χ^2, or Fisher exact tests (the latter for variables with five events or less per group); ordinal categorical variables were compared using the linear-by-linear association test, taking into account their ordered nature. A Kaplan-Meier survival curve was produced to illustrate the percentage survival of all patients undergoing SC versus DA TAVI from 2013 to 2015 with log-rank test p-values additionally obtained. Survival was examined as a time-to-event outcome, using the Cox proportional hazards model. The proportional hazards assumption was assessed using scaled Schoenfeld residuals.

Linear regression models were employed for continuous outcomes (considering logarithmic transformations to address non-normality issues where necessary), and binary outcomes analysed using logistic regression. In order to adjust for selection bias, candidate covariates considered for risk-adjustment were age at operation, sex, body mass index (BMI), Canadian Study of Health and Aging (CSHA) clinical frailty score, diabetes, history of pulmonary disease, previous myocardial infarction (MI), previous percutaneous coronary intervention (PCI), previous cardiac surgery, elective procedure (or not), extensive calcification of ascending aorta, aortic balloon valvuloplasty, and year of operation; these were selected based on group consensus and the existing literature.

Multivariable regression analysis was undertaken to examine the association of access route with the co-primary outcomes, adjusted for patient characteristics. Multivariable models were further used for all other continuous outcomes, and binary outcomes with a sufficient number of events to allow for modelling. Note that procedure-related bleeding and AKI were modelled as binary variables if these occurred, but not their gravity. Relevant predictors for each outcome of interest were identified by first performing univariable regression analyses; those variables found significant (i.e. with 2-sided p-value <0.05) were subsequently assessed simultaneously in multivariable models. Additional sensitivity analysis to assess the impact of selection bias was undertaken. Propensity score matching was performed but the results

obtained were similar to those in the adjusted regression analysis so were therefore omitted. A 2-sided p-value <0.05 was considered significant for all statistical tests. Data handling and analysis were performed with R (v3.3.2).

3. Results

From January 2007 to December 2015 a total of 9903 TAVI procedures were recorded in the UK TAVI registry. Of the 2473 procedures reported in 2015, the TF approach was the default vascular access strategy (n=2073, 83.8%). TA access was the next most common (n=163, 6.6%) followed by DA (n=56, 2.3%) and SC (n=43, 1.7%) routes.

In the primary analysis, there were 4033 TAVI procedures undertaken from January 2013 up to July 2015. Of these 296 (7.3%) were performed via the DA and SC access routes (192 [64.9%] and 104 [35.1%] respectively) (see Online Supplement Figure 1). After exclusion of cases with missing information on mortality (short or long-term, 27 cases) or other outcomes of interest (e.g. procedure duration, 14 cases), and key covariates examined (e.g. age, 31 cases), the final analysis cohort included 224 cases, 142 (63.4%) by DA and 82 (36.6%) by the SC route. Follow-up ranged from 35 to 920 days (median follow-up amongst survivors 545 days).

3.1 Patient and operative characteristics by vascular access route

The median age of patients was 81 (IQR 75-85) years and 54.9% were male. DA access patients were marginally older. Significantly more men were approached via the SC route (Table 1). The BMI distribution was comparable. SC access was almost exclusively used for the CoreValve (93.9%, 77 of 82) prosthesis, whereas the majority of DA cases were for a Sapien valve (64.1%, 91 of 142).

3.2 Unadjusted outcomes by vascular access route

Unadjusted 30-day mortality (post-TAVI) for the full cohort was 3.6%. In-hospital, 30-day and 1-year post-TAVI survival did not significantly differ between groups, although more DA deaths occurred overall (Table 2). Long-term survival did not differ significantly between those individuals exposed to SC versus DA access (Figure 1).

Median procedure time was approximately one hour longer for SC cases, although SC cases were associated with earlier hospital discharge. A higher proportion of SC patients required a permanent pacemaker post TAVI though this was not statistically significant. The SC route was associated with significantly more vascular access complications and aortic regurgitation compared to the DA approach. Conversion to full sternotomy, bailout valve in valve intervention, further valve intervention and renal replacement therapy prior to discharge were rarely required for either access route.

3.3 Adjusted outcomes by vascular access route

The only significant predictor for long-term mortality after an adjusted Cox regression analysis was patient frailty as assessed by the CSHA frailty score (hazard ratio [HR] 1.68, 95% confidence interval [CI 1.35, 2.09]; $p<0.01$). The SC route was associated with a comparatively lower all cause mortality risk (HR 0.71 [0.39, 1.29]; $p=0.258$) although this did not reach statistical significance.

Multivariable logistic regression showed that the two access routes differed in certain key outcomes (Table 3). The SC cases were associated with a 38% longer mean procedure time yet resulted in a 29% shorter mean length of hospital stay compared to DA cases. It is worthwhile noting that the overall time in theatre reduced by 10% per calendar year. The SC approach significantly reduced the odds of AKI (odds ratio [OR] 0.35, [0.12, 0.96]; $p=0.042$). However, the SC route was also associated with a doubling in the odds of aortic regurgitation

(OR 2.08 [1.11, 3.91]; p=0.023) and a nearly tenfold increase in vascular access site-related complications (OR 9.75 [3.07, 30.93]; p<0.01).

4. Discussion

The TF approach remains the default vascular access strategy for TAVI. It is minimally invasive and allows performance of TAVI under conscious sedation. However, roughly 10% of patients require an alternative access route (1,5).

The TA route is associated with more postoperative bleeding and a higher mortality than the TF approach (6,7). This led to the development of subclavian/axillary access, first described in 2008 (8). A surgical cut down is usually required, although a fully percutaneous method has been more recently described (9) along with a move to perform appropriate cases under local anaesthetic.

The SC approach has been shown to have equivalent procedural success and medium term results when compared with TF access using a propensity-matched analysis of the Italian CoreValve Registry (10). Equivalence in survival was also demonstrated against TA access in a small multicentre study comprising 202 procedures, despite the TA access causing significantly more bleeding and a trend towards greater in-hospital mortality (11). Use of the SC approach, however, can be restricted by anatomical features such as tortuosity or small vessel calibre. Those with a pre-existing left internal mammary artery bypass graft may also be exposed to the risk of ischemia during instrumentation (12). Moreover the relative lack of a muscular component to the wall of the subclavian artery makes it more susceptible to dissection.

The DA approach was first reported in 2010. It offers direct delivery within close proximity to the aortic annulus, a high level of control and enhanced accuracy when positioning the prosthesis. A surgical incision via an upper partial sternotomy or small right

anterior thoracotomy means invasiveness is relatively high. Risk is further exacerbated by the need for general anaesthesia and mechanical ventilation (13,14). A suprasternal DA approach, performed under general anaesthesia but avoiding sternotomy and thoracotomy, has also been reported (15).

DA access is a safe and feasible alternative to a TF strategy, when the latter cannot be used (16–19). DA access appears to have at least equivalent or better rates of long- and short-term mortality, stroke and bleeding when previously compared to the TA route (20–23). Much of the observational data used to support these comparisons, however, are limited to predominantly high surgical risk individuals. Further validation in intermediate and lower risk cohorts are required in response to the inevitable broadening of the eligibility criteria for TAVI.

There is a paucity of data directly comparing the SC and DA routes for TAVI. In the absence of randomised controlled trial data, prospectively collected observational data offer the best alternative for such a comparison. In a prior analysis of the UK TAVI registry from January 2007 to December 2012, SC access demonstrated a similar 1-year survival rate to TF. The TA and DA approaches were, however, found to have significantly higher mortality both at 1 and 2 years. The investigators concluding that a SC strategy may represent the safest non-femoral access route for TAVI (24).

The present study directly compared the SC and DA approaches and showed no survival advantage in favour of either strategy with respect to in-hospital, 30-day and 1-year all cause mortality, although deaths after the DA approach were numerically higher. The SC route was associated with significantly more vascular access site complications and aortic regurgitation. The latter may be explained by the fact almost all SC procedures were performed using the Medtronic CoreValve prosthesis (25,26). The numerically higher rate of permanent pacemaker implantation after SC procedures are also likely to be associated with

CoreValve use (27). Moreover, in a recent propensity-matched analysis of the FRANCE-TAVI nationwide registry from January 2013 to December 2015, where patients treated with balloon-expandable prostheses (n=3910) were matched 1:1 with individuals treated with self-expandable heart valves (n=3910), use of the latter device was found to cause significantly more post-procedural paravalvular regurgitation ($p<0.0001$) and the need for permanent pacemaker implantation ($p<0.0001$) (28). The true extent of our findings, therefore, require further validation in a larger cohort as the respective confidence intervals were relatively wide (Table 3).

Some UK centres no longer use DA access as the recovery from a thoracotomy was found to be slow and patients were susceptible to chest infections, post-operative renal dysfunction and had a longer hospital stay. Further reports from the UK TAVI registry encompassing all procedural reports from 2016 and 2017 appear to echo this trend. The reports show an increasing trend towards use of SC over DA access (2016: SC 94 vs. DA 65 procedures; 2017: SC 107 vs. DA 53 procedures) (29,30). Future studies will incorporate this data to further delineate whether there is a survival advantage of SC over DA access.

4.1 Limitations

The current work suffers from all the limitations inherent to observational analyses of clinical registry data, thus the results should be interpreted with caution. The data were prospectively collected by each TAVI centre but there was no event adjudication committee for this study. This exposes our analysis to potentially significant under-reporting of complications, though mortality tracking avoided this issue with regard to life status.

The number of SC and DA cases available for the analysis were relatively small. This is a product of both the truncated period in which there was validated life status available and that the predominant vascular access strategy remains the TF route in the UK. Regrettably we

were unable to utilise data from 2016 and 2017 in our primary analysis due to a lack of validated life status during this time period. The relatively small size of our study cohort may have resulted in limited power to detect significant associations between route and outcomes, and to identify potentially important covariates.

There was a notable amount of missing data primarily related to in-hospital outcomes. Multiple imputation, however, was not pursued given the proportions involved was almost equitable between access routes (21% SC vs. 25% DA). Furthermore the clinical nature of the cohort examined allowed for thorough risk-adjustment in model building in order to account for differences in patient profiles treated via either strategy. Nevertheless, residual confounding cannot be excluded.

5. Conclusions

Surgical subclavian (or transaxillary) and direct aortic vascular access routes are established, feasible and comparatively safe alternative strategies to the default retrograde transfemoral access for TAVI. We found no significant difference in short- or medium-term survival between the two. However, in more recent years, there has been an increase in the use of the transaxillary route (including percutaneous approaches performed under local anaesthetic) and a corresponding decline in DA access. As with any operative technique, however, the decision to select a specific approach will be determined by varying combinations of patient comorbidity, vascular anatomy, transcatheter heart valve preference and the skill mix and expertise of the Heart Team.

Acknowledgements

None to declare.

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Figure Legends

Figure 1

Kaplan-Meier plot for survival after direct aortic versus subclavian access transcatheter aortic valve implantation (TAVI) from the UK TAVI registry, January 2013 to July 2015

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Table 1

Patient and procedural characteristics for the primary analysis dataset (n=224) according to vascular access route for TAVI.

Variables (Expressed as number and percentage of cases unless otherwise specified)	**Subclavian n=82 (36.6%)**	**Direct aortic n=142 (63.4%)**	**p-value**
Patient characteristics			
Mean (SD) age at admission (years)	78.3 (6.8)	80.0 (8.9)	0.139
Median (IQR) age at admission (years)	79.5 (73, 84)	81.5 (76, 85)	0.028
Male	54 (65.9%)	69 (48.6%)	0.018
Mean (SD) BMI (kg/m^2)	27.6 (5.4)	27.2 (6.7)	0.609
Median (IQR) BMI (kg/m^2)	26.7 (24.1, 31.7)	26.8 (22.7, 29.6)	0.407
Diabetes	24 (29.3%)	37 (26.1%)	0.716
Current or ex-smoker	59 (72.0%)	85 (59.9%)	0.178
CSHA frailty score (range 1 to 7)			0.117
Very fit (1)	2 (2.4%)	2 (1.4%)	
Well (2)	6 (7.3%)	13 (9.2%)	
Well (with treated co-morbid disease) (3)	28 (34.2%)	29 (20.4%)	
Apparently vulnerable (4)	19 (23.2%)	33 (23.2%)	
Mildly frail (5)	12 (14.6%)	30 (21.2%)	
Moderately frail (6)	12 (14.6%)	33 (23.2%)	
Severely frail (7)	3 (3.7%)	2 (1.4%)	
History of pulmonary disease			0.223
No pulmonary disease	48 (58.6%)	94 (66.2%)	
COPD/emphysema	27 (32.9%)	43 (30.3%)	
Asthma	6 (7.3%)	3 (2.1%)	
Other significant pulmonary disease	1 (1.2%)	2 (1.4%)	

Variables (Expressed as number and percentage of cases unless otherwise specified)	**Subclavian n=82 (36.6%)**	**Direct aortic n=142 (63.4%)**	**p-value**
Previous cardiac surgery			0.067
None	59 (72.0%)	116 (81.7%)	
Previous CABG	21 (25.6%)	19 (13.4%)	
Other	2 (2.4%)	7 (4.9%)	
Previous TAVI	1 (1.2%)	0 (0%)	
Previous PCI	24 (29.3%)	25 (17.6%)	0.062
Previous MI	11 (13.4%)	34 (23.9%)	0.085
Balloon aortic valvuloplasty prior to TAVI			<0.0001
Completed	64 (78.0%)	72 (50.7%)	
Not performed	18 (22.0%)	70 (49.3%)	
Extracardiac arteriopathy	47 (57.3%)	77 (54.2%)	0.757
Extensive calcification of ascending aorta (grade 3 or 4)	16 (19.5%)	20 (14.1%)	0.381
Critical pre-operative status	3 (3.7%)	5 (3.5%)	1
Elective procedure	77 (93.9%)	122 (85.9%)	0.108
Left ventricular ejection fraction (LVEF)*			0.747
≥50%	41 (50.0%)	84 (59.1%)	
(30-49%]	36 (43.9%)	43 (30.3%)	
<30%	4 (4.9%)	15 (10.6%)	
Procedural characteristics			
Valve manufacturer			0.001
Boston Scientific	0 (0%)	10 (7.0%)	
Edwards Lifesciences	1 (1.2%)	93 (65.5%)	

Variables (Expressed as number and percentage of cases unless otherwise specified)	Subclavian n=82 (36.6%)	Direct aortic n=142 (63.4%)	p-value
Medtronic	80 (97.6%)	39 (27.5%)	
Unknown	1 (1.2%)	0 (0%)	
Valve model			
CoreValve	77 (93.9%)	37 (26.1%)	
CoreValve Evolut R	3 (3.7%)	0 (0%)	
Engager	0 (0%)	1 (0.7%)	
Lotus	0 (0%)	10 (7.1%)	
SAPIEN 3 model 9000TFX	0 (0%)	9 (6.3%)	
SAPIEN 3 model 9600TFX	1 (1.2%)	28 (19.7%)	
SAPIEN XT model 9300TFX	0 (0%)	54 (38.0%)	
Unknown	1 (1.2%)	3 (2.1%)	
Year of Procedure			0.706
2013	40 (48.8%)	77 (54.2%)	
2014	32 (39.0%)	51 (35.9%)	
2015	10 (12.2%)	14 (9.9%)	

*One unknown LVEF subclavian case.

Key: BMI=body mass index; CABG=coronary artery bypass grafting; COPD=chronic obstructive pulmonary disease; CSHA=Canadian Study on Health and Aging; IQR=interquartile range; MI=myocardial infarction; PCI=percutaneous intervention coronary; SD=standard deviation; TAVI=transcatheter aortic valve implantation.

Table 2

Clinical outcomes according to vascular access route from the UK TAVI registry.

Variables (Expressed as number and percentage of cases unless otherwise specified)	**Subclavian access (n=82, 36.6%)**	**Direct aortic access (n=142, 63.4%)**	**p-value**
In-hospital death	2 (2.4%)	7 (4.9%)	0.492
Death 30 days post TAVI	2 (2.4%)	6 (4.2%)	0.714
Death 1 year post TAVI*	8 (14.5%)	21 (21.9%)	0.344
Mean (SD) procedure time (mins)	193.5 (65.8)	138.4 (57.7)	<0.0001
Median (IQR) procedure time (mins)	184 (161, 227.5)	125 (96, 173.8)	<0.0001
Mean (SD) length of stay (days)†	8.6 (9.5)	11.9 (10.8)	0.025
Median (IQR) length of stay (days)†	6 (4,8)	7 (6,14)	0.0002
Vascular access site related complications			0.001
None	65 (79.3%)	137 (96.5%)	
Minor	11 (13.4%)	3 (2.1%)	
Major	6 (7.3%)	2 (1.4%)	
Permanent pacemaker implantation post procedure	20 (24.4%)	21 (14.8%)	0.107
Tamponade	0 (0%)	4 (2.8%)	-
Further valve intervention prior to discharge	0 (0%)	1 (0.7%)	-
Bailout valve-in-valve (non-emergency)	8 (9.8%)	1 (0.7%)	0.0006
Conversion to full sternotomy during procedure			-
No	82 (100%)	140 (98.6%)	
Yes (haemorrhage)	0 (0%)	1 (0.7%)	
Yes (valve surgery)	0 (0%)	1 (0.7%)	
Cerebrovascular accident	3 (3.7%)	3 (2.1%)	0.671
Bleeding			0.181
None	72 (87.8%)	117 (82.4%)	
Minor	7 (8.5%)	15 (10.6%)	

Variables (Expressed as number and percentage of cases unless otherwise specified)	**Subclavian access (n=82, 36.6%)**	**Direct aortic access (n=142, 63.4%)**	**p-value**
Major	3 (3.7%)	7 (4.9%)	
Life threatening or disabling	0 (0%)	3 (2.1%)	
Acute kidney injury			0.066
None	77 (93.9%)	116 (81.7%)	
Stage 1	1 (1.2%)	11 (7.8%)	
Stage 2	1 (1.2%)	9 (6.3%)	
Stage 3	3 (3.7%)	6 (4.2%)	
New renal replacement therapy prior to discharge	1 (1.2%)	8 (5.6%)	0.16

*These figures correspond to a total of 151 patients performed before June 2014 to ensure at least 1-year of follow-up.

†The length of stay analysis is based on the 215 patients alive at discharge.

Key: AKI=acute kidney injury; CVA=cerebrovascular accident; IQR=interquartile range; SD=standard deviation.

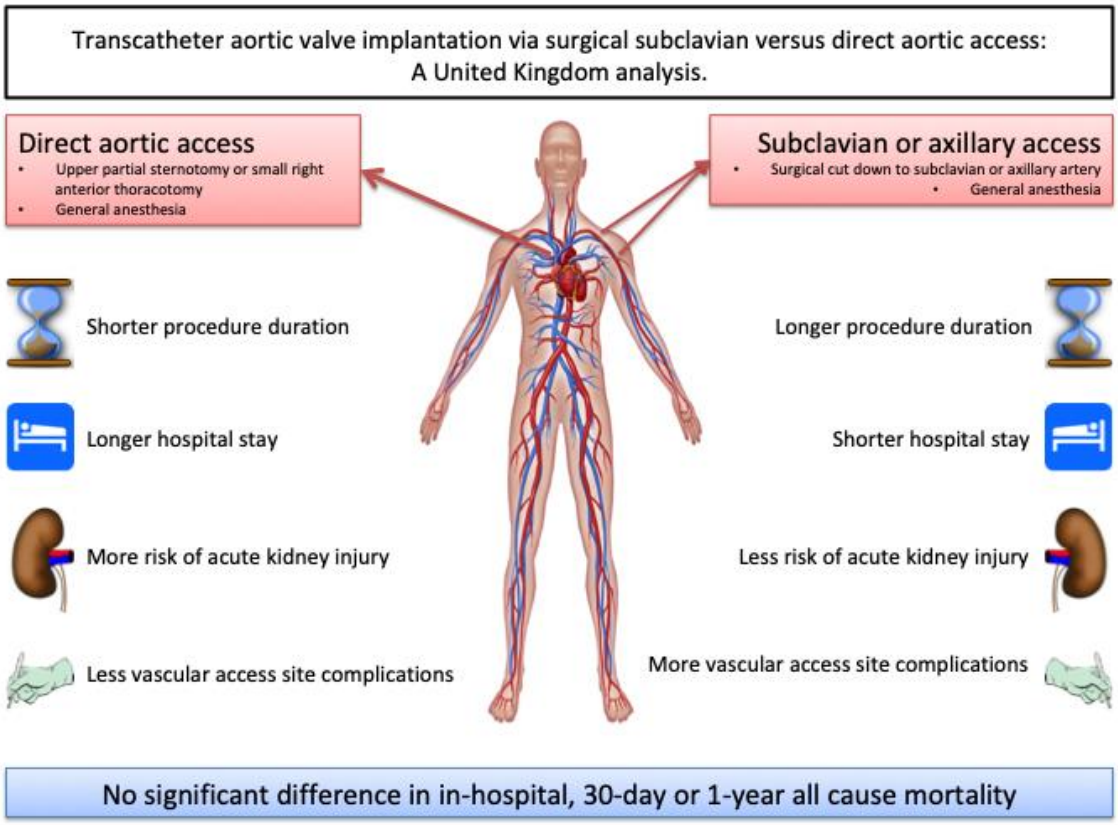
Table 3

Effect of surgical subclavian versus direct aortic access on post TAVI complications and procedural parameters obtained from multivariable logistic regression models.

Outcome	**Odds Ratio**	**95% CI**	**p-value**
Procedure time	1.38*	(1.23, 1.53)	**<0.001**
Permanent pacemaker implantation	1.66	(0.83, 3.34)	0.154
Bleeding	0.54	(0.24, 1.25)	0.149
Acute kidney injury	0.35	(0.12, 0.96)	**0.042**
Aortic regurgitation	2.08	(1.11, 3.91)	**0.023**
Vascular access site complications	9.75	(3.07, 30.93)	**<0.01**
Death 1 year post TAVI	0.59	(0.23, 1.57)	0.306
Outcome	**Mean ratio***	**95% CI**	**p-value**
Procedure duration (minutes)	1.38	(1.23, 1.53)	**<0.001**
Post-operative length of stay in hospital (modelled on the 215 patients alive at discharge)	0.71	(0.58, 0.87)	**0.001**

*This is the geometric mean ratio, as outcomes have been log-transformed to improve normality.

Key: TAVI=transcatheter aortic valve implantation



Graphical abstract

Highlights

- Similar 30-day and 1-year survival after subclavian versus direct-aortic access
- Acute kidney injury occurred less frequently after subclavian access
- Procedure duration was significantly longer using subclavian access
- Subclavian access site-related complications were more frequent
- Similar bleeding and stroke events after subclavian versus direct-aortic access