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Procedural and thirty-day outcomes following transfemoral implantation of the fully repositionable and retrievable Lotus valve without routine pre-dilatation in a consecutive patient cohort: a single centre experience☆

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ABSTRACT

Background / Purpose: The Lotus valve (Boston Scientific, Natick, MA, USA) is a contemporary transcatheter aortic valve implantation (TAVI) device that is fully repositionable and retrievable to aid implantation and optimise procedural results. The ability to implant the device without routine pre-dilatation is another possible advantage reducing associated risks and procedure times. The aim of this study is to report procedural and 30-day outcomes following TAVI in a consecutive patient group presenting with severe symptomatic aortic stenosis with the Lotus valve system without routine pre-dilatation.

Methods / Materials: 146 consecutive patients that underwent TAVI at the John Radcliffe Hospital, Oxford between January 2015 – December 2016 were retrospectively analysed.

Results: The mean age was 81.1 ± 7.4 years and the mean logistic EuroSCORE was 14.6 ± 10. 134 (91.8%) of patients were treated under conscious sedation. 144 (98.6%) of procedures were successful. Two patients (1.4%) died during the follow-up period. None or mild residual aortic regurgitation was achieved in 98.6% of patients. The mean and peak transvalvular gradients were 8.6 ± 3.6mmHg and 16.6 ± 6.6mmHg respectively. Eight patients (5.5%) suffered a stroke. Over time, there was a reduction in major vascular complications (14.3% vs. 2.2%, p = 0.03) and a trend toward shorter procedure times (97.6 ± 44.3 vs. 86.8 ± 31.4 minutes, p = 0.14) and the administration of less contrast (104.4 ± 45.2 vs. 91.7 ± 37.6 millilitres, p = 0.16). The overall new pacemaker implantation rate was 36.3%.

Conclusions: The use of the Lotus valve as a 'workhorse' device without routine pre-dilatation is safe and efficacious and is associated with a very low incidence of residual aortic regurgitation and acceptable transvalvular haemodynamics.

1. Introduction

Transcatheter aortic valve implantation (TAVI) is now the accepted treatment option for patients deemed to be inoperable or of high surgical risk presenting with severe symptomatic aortic stenosis [1–3]. A number of randomised trials have demonstrated efficacy and mortality benefit over medical therapy [4] and conventional surgery in high-risk patients [5]. With increasing institutional and operator experience combined with technological advancements, there has been an interest in the applicability of TAVI in the management of intermediate [6,7] and even low risk [8] patients. Additionally, in a bid to further simplify the procedure, there has been a decreasing trend in the proportion of patients undergoing pre-dilatation prior to valve implantation [9]. This approach is potentially also associated with benefits of shorter procedure times, reduced radiation and contrast use and the avoidance of balloon aortic valvuloplasty (BAV) related complications (e.g. cerebrovascular events, conduction disturbances, severe aortic regurgitation) [10,11].

First generation devices however were limited by vascular complications, paravalvular leak, stroke, renal impairment and the requirement of permanent pacemaker implantation [12]. Newer generation devices have therefore been developed with improvements in both the delivery systems and prostheses to overcome these and is particularly important when considering the treatment of lower-risk, younger patients. The Lotus valve (Boston Scientific, Natick, MA, USA) is a second-generation device that is fully repositionable and retrievable with an adaptive seal to reduce the occurrence of paravalvular leak. The use of this valve has been demonstrated to be safe and efficacious in the setting of

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clinical trials [13,14], single- [15] and multi-centre [16,17] registries. However, these were all limited to specific pre-selected groups that were also predominantly treated with pre-dilatation prior to valve implantation that may not be representative of an 'all-comer' contemporary patient cohort treated with present day techniques.

We here describe our experiences of implantation of the Lotus device as a 'workhorse' device in an unselected consecutive patient cohort without routine pre-dilatation.

2. Materials and Methods

2.1. Study population

All patients that underwent transfemoral TAVI for native severe symptomatic aortic stenosis at the John Radcliffe Hospital, Oxford, United Kingdom between January 2015 (first Lotus valve (Boston Scientific, Natick, MA) implant) and December 2016 were prospectively collected and retrospectively analysed. All first time transfemoral TAVI patients were treated with the Lotus device during this period (with no other device used). Patients that underwent valve-in-valve TAVI, intervention for aortic regurgitation or underwent TAVI via non-transfemoral (TF) access were excluded. All patients underwent pre-procedural transthoracic echocardiography (TTE) to confirm the diagnosis and computed tomography (CT) to aid in procedural planning that was performed with dedicated software for measurements of peripheral vasculature and aortic anatomy (3mensio, 3mensio 7.0 software, Pie Medical Imaging, Maastricht, The Netherlands). All patients were discussed by the multi-disciplinary 'Heart Team' and were considered to be at elevated risk for surgical aortic valve replacement (SAVR). Patient characteristics including predicted surgical risk were noted. All patients gave their written informed consent for the study.

2.2. The Lotus valve

The Boston Scientific Lotus valve consists of a woven nitinol-framed bioprosthesis with bovine pericardial leaflets, which is pre-mounted on a catheter delivery system. The device is positioned using a mechanical deployment device and is designed to enable repositioning and complete retrieval even after the valve is fully expanded and locked in its final position. The design also incorporates an 'Adaptive Seal' at the distal end of the prosthesis to minimise the occurrence of paravalvular leak. The device requires the insertion of a 20-22 French (Fr) transfemoral sheath and is available in 23mm, 25mm and 27mm sizes.

2.3. Procedure

All patients underwent implantation of the Lotus valve via the transfemoral route with percutaneous ultrasound guided puncture sites closed with suture-based closure devices (Proglide, Abbott Laboratories, Abbott Park, IL, USA) when possible or facilitated by vascular surgical cut-down. Prosthesis sizing was at the operator's discretion based upon the MSCT findings. All procedures were preferentially performed under conscious sedation when possible or under general anaesthesia provided by a cardiac anaesthetist. Unfractionated heparin was administered peri-procedurally aiming for an activated clotting time (ACT) of 300 seconds. The transcatheter aortic valve implantation (TAVI) was performed under fluoroscopic and echocardiographic guidance. Briefly, after crossing the stenosed aortic valve, a Safari stiff wire (Boston Scientific, Natick, MA) was positioned in the left ventricle over which the Lotus device was delivered without routine pre-dilatation. Throughout the study period, our implantation technique did not change and we attempted to achieve the highest implantation height possible with the least number of valve repositions possible in a bid to reduce the risk of the requirement for permanent pacemaker implantation. Valve position and function was fully evaluated prior to definitive deployment. Following valve deployment, aortic valve haemodynamics were assessed by echocardiography with peak and mean transvalvular gradients noted in addition to the aortic regurgitation grade in keeping with current guidelines [18]. Following the procedure, patients were administered dual anti-platelet therapy (aspirin 75mg daily and clopidogrel 75mg daily) for a minimum period of three months, or single anti-platelet agent with warfarin (or novel anti-coagulant NOAC)) when indicated.

2.4. Clinical follow-up

Procedural and 30-day outcomes were prospectively collected in a dedicated TAVI database and follow-up was conducted either by clinic visits or telephone consultations. All definitions of the clinical end points used were in concordance with the Valve Academic Research Consortium 2 (VARC-2) definitions [12] that were independently adjudicated by at least 2 interventional cardiologists. Other information collected included the severity of aortic regurgitation following TAVI and the requirement for permanent pacemaker implantation (PPM).

2.5. Statistics

Continuous variables are presented as the mean ± standard deviation (SD). Normality of each continuous variable was tested with the Kolmogorov-Smirnov test. Differences in continuous variables between groups were compared using the Student t-test or Mann Whitney-U test for parametric and nonparametric variables, respectively. Categorical variables are presented as numerical values and percentages and were compared using the Fisher's exact test. All reported p-values were 2-sided, and values of $p<0.05$ were regarded as statistically significant. Analyses were performed with SPSS version 21.0 (SPSS Inc., Chicago, IL) and GraphPad Prism version 5.0 (GraphPad, San Diego, CA, USA).

3. Results

3.1. Patient population

146 consecutive patients were treated within the study period and were included in the final analysis. Baseline demographics of the study population are summarised in Table 1. The mean age was 81.1 ± 7.4 years and 47.3% of patients were male. Seventeen patients

Table 1
Patient characteristics (n = 146).

Clinical Variable	
Age, years	81.1 ± 7.4
Sex (male)	69 (47.3%)
Diabetes mellitus	47 (32.2%)
Hypertension	92 (63%)
Hypercholesterolaemia	84 (57.5%)
Smoking	53 (36.3%)
Chronic obstructive pulmonary disease	21 (14.4%)
Baseline renal failure	11 (7.5%)
Pulmonary hypertension	17 (11.6%)
Myocardial infarction	20 (13.7%)
Previous CVA / TIA	26 (17.8%)
Previous PCI	29 (19.9%)
Previous CABG	23 (15.8%)
Peripheral vascular disease	15 (10.3%)
Atrial fibrillation	33 (22.6%)
LV function ≤ 35%	20 (13.7%)
Previous permanent pacemaker	22 (14.2%)
AV peak gradient	76.5 ± 21.8 mmHg
AV mean gradient	46.0 ± 14.7 mmHg
AVA	0.67 ± 0.17cm^2
Logistic EuroSCORE	14.6 ± 10
STS score (mortality)	3.5 ± 2.2

AV: aortic valve; AVA: aortic valve area; CABG: coronary artery bypass grafting; CVA: cerebrovascular accident; LV: left ventricular; PCI: percutaneous coronary intervention; STS: Society of Thoracic Surgeons; TIA: transient ischaemic attack.

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