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Safety and Operational Efficiency of Restructuring and Redeploying a Transcatheter Aortic Valve Replacement Service During the COVID-19 Pandemic: The Oxford Experience

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ABSTRACT

Background: The risk of nosocomial COVID-19 infection for vulnerable aortic stenosis patients and intensive care resource utilization has led to cardiac surgery deferral. Untreated severe symptomatic aortic stenosis has a dismal prognosis. TAVR offers an attractive alternative to surgery as it is not reliant on intensive care resources. We set out to explore the safety and operational efficiency of restructuring a TAVR service and redeploying it to a new non-surgical site during the COVID-19 pandemic.

Methods: The institutional prospective service database was retrospectively interrogated for the first 50 consecutive elective TAVR cases prior to and after our institution's operational adaptations for the COVID-19 pandemic. Our endpoints were VARC-2 defined procedural complications, 30-day mortality or re-admission and service efficiency metrics.

Results: The profile of patients undergoing TAVR during the pandemic was similar to patients undergoing TAVR prior to the pandemic with the exception of a lower mean age (79 vs 82 years, $p < 0.01$) and median EuroScore II (3.1% vs 4.6%, $p = 0.01$). The service restructuring and redeployment contributed to the pandemic-mandated operational efficiency with a reduction in the distribution of pre-admission hospital visits (3 vs 3 visits, $p < 0.001$) and the time taken from TAVR clinic to procedure (26 vs 77 days, $p < 0.0001$) when compared to the pre-COVID-19 service. No statistically significant difference was noted in peri-procedural complications and 30-day outcomes, while post-operative length of stay was significantly reduced (2 vs 3 days, $p < 0.0001$) when compared to pre-COVID-19 practice.

Conclusions: TAVR service restructuring and redeployment to align with pandemic-mandated healthcare resource rationalization is safe and feasible.

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1. Background

The COVID-19 pandemic resulted in reorganization of healthcare systems and thousands of deaths worldwide [1]. On-going careful rationalization of healthcare services is required to streamline healthcare delivery and address urgent and emergent medical conditions that continue to progress.

Abbreviations: AS, Aortic stenosis; COVID-19, Coronavirus disease 2019; IQR, Interquartile range; MDT, Multidisciplinary team; NHS, National Health Service; sAVR, Surgical aortic valve replacement; TAVR, Transcatheter aortic valve replacement; VARC-2, Valve Academic Research Consortium - 2.

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Aortic stenosis (AS) is common and affects patients at an increased likelihood of adverse outcomes following COVID-19 infection [2,3]. Untreated severe symptomatic aortic stenosis has a dismal prognosis which is only altered by intervention, either by surgical aortic valve replacement (sAVR) or transcatheter aortic valve replacement (TAVR). Both randomised and registry data demonstrate significant risk of mortality of untreated symptomatic AS, which increases with certain adverse clinical features (i.e. heart failure presentation, syncope, left ventricular dysfunction, high valve gradient, advanced myocardial scarring) [4]. In response to this, the National Health Service (NHS) in England, produced guidance for the management of cardiac patients during this pandemic which resulted in cardiac surgery being limited to emergency cases and the deferral of non-urgent cardiovascular diagnostics and interventions [5]. TAVR offers an attractive alternative to cardiac surgery when treating AS in the COVID-19 pandemic as it is

not reliant on the need for postoperative ventilation and intensive care nursing.

Here, we describe the effect of the rapid introduction of a streamlined care pathway for patients with severe symptomatic AS undergoing TAVR during the COVID-19 pandemic at a site which had not previously performed transcatheter structural heart interventions.

2. Methods

2.1. Change in service

In response to NHS guidance and clinical demand for inpatient capacity at our tertiary center (John Radcliffe Hospital, Oxford UK), on the 27th March 2020 our TAVR service was asked to relocate to an adjacent local private hospital (The Nuffield Health Manor Hospital, Oxford UK) which had never performed transcatheter valvular heart intervention. This site is adjacent to the John Radcliffe but during the pandemic there was no intensive care or cardiac or vascular surgery on-site. This site did not accept acute admissions and all patients and staff were screened for temperatures and COVID-related symptoms prior to entry. The first TAVR was performed at this new site 4 days later on 31st March 2020. In addition to the relocation of the service, there was a change in pre- and post-procedural work-up and care which is illustrated in Fig. 1. In brief, following referral either direct for TAVR or from the urgent sAVR waiting list, the patient was triaged on the basis of high-risk features (Table 1), and if appropriate, invited for a single-

Table 1
High risk features prompting urgent intervention for aortic stenosis.

| Clinical features |
|--|
| NYHA IV symptoms or recent admission with heart failure |
| Rapid deterioration in symptoms (3 months) |
| Exertional syncope |
| Awaiting urgent (i.e. cancer) treatment that cannot proceed before severe aortic stenosis treatment |
| Echocardiography parameters |
| Very high peak (≥ 125 mmHg)/mean (≥ 60 mmHg) gradients |
| Severe left ventricular impairment (LVEF $\leq 30\%$) |
| Deteriorating left ventricular function ($\geq 10\%$ reduction in LVEF% from last documented study) |

LVEF: left ventricular ejection fraction; NYHA: New York Heart Association Classification.

stop elective outpatient visit during which consultation, transthoracic echocardiography and a gated TAVR-CT protocol were undertaken. In the latter ruled out significant proximal coronary disease an invasive angiogram was not performed. These data were presented remotely to the Heart Team via teleconferencing. If the patients were deemed technically suitable for transfemoral TAVR and clinically urgent, an elective admission to undertake TAVR was scheduled at the earliest timeslot available. All patients were asked to strictly “shield”, as per government guidelines, for two-weeks prior to admission and if any COVID-19 related symptoms emerged during this time, or exposure to an individual suspected to have COVID-19, the planned admission was deferred. COVID-19 pre-operative screening was sparsely done due to the limited testing capacity at the time. Patients were admitted on the day of the procedure and transfemoral TAVR undertaken by our established structural heart catheterization laboratory team consisting of interventional cardiologists, one imaging cardiologist, an anaesthetist, two nurses, a cardiac physiologist and a radiographer. The team had migrated in unison from the tertiary center, where historically more than 1000 TAVRs have been performed. All patients received local anaesthesia with anaesthesia-led sedation. Patients were nursed on a standard ward with telemetry monitoring for rhythm disturbances. Early safe discharge was aimed for 24 h following the procedure in the absence of access site complications or conduction issues. Follow-up was performed at 30 days via telephone consultation.

2.2. Patient population

Patients were included if they underwent elective TAVR for the treatment of aortic stenosis. Patients were excluded if they were referred to the TAVR service greater than one year prior to the date of the planned procedure. The pre-COVID-19 period group consisted of 50 consecutive patients prior to relocation and reorganization of services (up to and including 27th March 2020). The COVID-19 period group consisted of 50 consecutive patients immediately following relocation and reorganization of services (after 27th March 2020). Data were retrospectively obtained from the institutional prospective service databases under audit authorization No 5172 from the Oxford University Hospitals NHS Foundation Trust.

2.3. TAVR procedure

All TAVR procedures used either the transfemoral at the new site or transfemoral or transaxillary access route at the surgical center. Transcatheter heart valve choice was at the operator's discretion between those available at the center: Lotus Edge (Boston Scientific), Neo Acurate (Boston Scientific) and the SAPIEN 3 system (Edwards Lifescience). Balloon aortic valvuloplasty before and after TAVR was performed at the operator's discretion when using the Lotus Edge and SAPIEN 3 system, it was mandated prior to insertion of the Neo Acurate valve. Patients received aspirin and clopidogrel after TAVR and were advised to continue taking these medications for at least 1 month after the

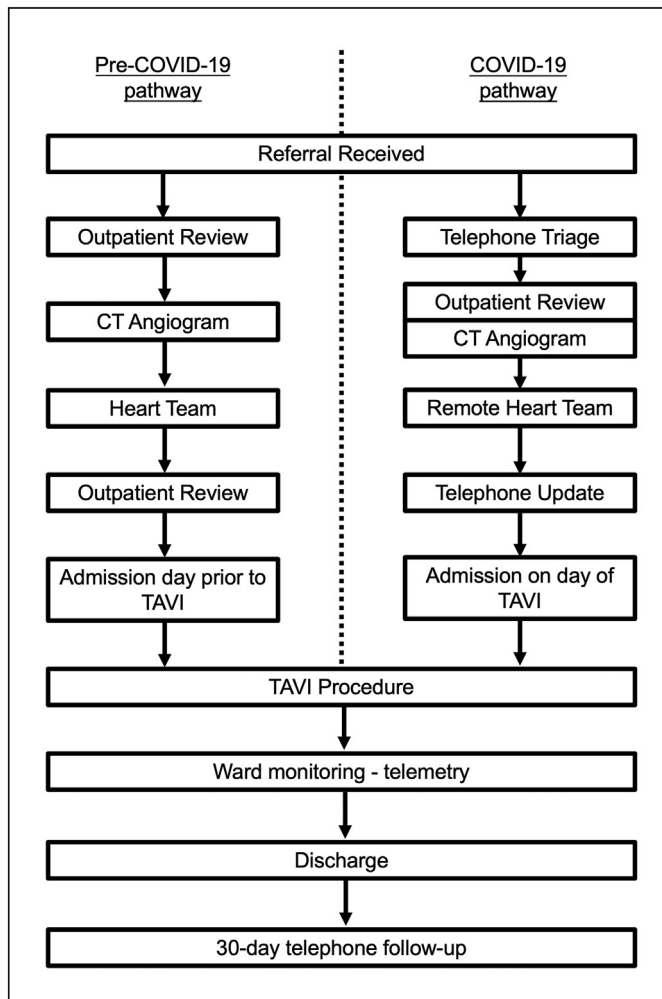


Fig. 1. Patient pathway following referral for consideration of TAVR during the pre-COVID-19 period and following the COVID-19 adjustments.

procedure, in the absence of contraindication or concurrent anticoagulation.

2.4. Outcomes

The aim of this work was to describe the efficiency and safety of a streamlined TAVR patient pathway during the COVID-19 pandemic. We report logistic outcomes to measure efficiency, including time from referral to TAVR multidisciplinary team meeting (MDT), time from MDT to TAVR, TAVR-related number of hospital visits and length of stay. We report in-hospital and 30-day clinical outcomes to demonstrate safety according to VARC-2 standardised definitions, including death from any cause, neurological events, myocardial infarction, rehospitalization, major vascular complication, significant bleeding, new onset atrial fibrillation and pacemaker insertion [6].

This work has not been powered to demonstrate differences in clinical outcomes. Continuous variables, which are presented as means with standard deviations or medians with interquartile ranges, were compared with the use of the Student's *t*-test or the Wilcoxon rank-sum test. Categorical and ordinal variables, which are presented as proportions, were compared with the use of Fisher's exact test or the Wilcoxon rank-sum test. All statistical analyses were performed with the use of SPSS 26.0 (IBM Inc. New York USA).

3. Results

3.1. Patients

Between 9th January 2020 and 26th March 2020, 50 patients underwent elective TAVR at the John Radcliffe Hospital, Oxford during the pre-COVID-19 period. Between 31st March 2020 and 3rd June 2020, 50 patients underwent elective TAVR at the Manor Hospital, Oxford during the COVID-19 period. Characteristics of the patients at baseline are described in Table 2. During the COVID-19 period there was a reduction in the mean age of patients undergoing TAVR (82 vs 79 years, $p < 0.01$) and a numerically small difference in median EuroScore II (4.6 vs 3.1%, $p = 0.01$). Despite this, patients were generally well matched for comorbidities, with the exception of more patients undergoing previous PCI in the pre-COVID-19 period (31 vs 9%, $p < 0.01$).

3.2. Pathway efficiency

Adoption of the COVID-19 period TAVR pathway resulted in changes in both the distribution of number of pre-admission hospital visits (3 IQR 3,4 vs 3 IQR 2,3, $p < 0.001$) and the time taken from TAVR clinic to procedure (77 vs 26 days, $p < 0.0001$) as demonstrated in Table 3. Furthermore, there was a significant reduction in the length of inpatient stay (3 vs 2 days, $p < 0.0001$).

3.3. Procedural outcomes

The procedural outcomes are demonstrated in Table 4. Despite transferring a TAVR service in a new setting, there was no significant difference in the distribution of procedure length during the COVID-19 pandemic (60 vs 60 min, $p = 0.18$). There was a significant increase in the proportion of Sapien 3 valves inserted (34 vs 68%, $p = 0.001$). Post procedural haemodynamic values in both groups are consistent with those seen in previously published data. There was no severe post-procedural aortic regurgitation in either group.

3.4. In-hospital and 30-day clinical outcomes (safety analysis)

In-hospital and 30 days outcome data are shown in Table 5. There was no statistically relevant difference between the two treatment periods in the incidence of death or disabling stroke, but there were numerically more minor strokes during the COVID-19 period. No

Table 2
Characteristics of the patients at baseline.

| Characteristic | Pre-COVID-19 era (n = 50) | COVID-19 era (n = 50) |
|--------------------------------------|------------------------------|--------------------------|
| Clinical | | |
| Age - years | 82 ± 6 | 79 ± 7 |
| Male sex - % | 74 | 56 |
| Height - m | 1.7 ± 0.1 | 1.6 ± 0.1 |
| Weight - kg | 78 ± 16 | 85 ± 15 |
| Body mass index - no. (IQR) | 27 (25, 29) | 29 (28, 34) |
| Euroscore II - % (IQR) | 4.6 (3.0, 9.0) | 3.1 (1.8, 5.4) |
| NYHA Class - average | 3 (3,3) | 3 (3,3) |
| Coronary artery disease - % | 41 | 31 |
| Previous myocardial infarction - % | 15 | 9 |
| Previous PCI - % | 31 | 9 |
| Cerebral vascular disease - % | 20 | 11 |
| Peripheral vascular disease - % | 64 | 44 |
| Extracardiac arteriopathy - % | 64 | 44 |
| Calcification of ascending aorta - % | 8 | 0 |
| Atrial fibrillation - % | 22 | 30 |
| Permanent pacemaker - % | 14 | 8 |
| Diabetes mellitus - % | 25 | 24 |
| Current smoker - % | 6 | 2 |
| COPD - % | 15 | 11 |
| Oxygen-dependent - % | 2 | 2 |
| Poor mobility - % | 70 | 54 |
| Liver disease - % | 4 | 4 |
| Laboratory | | |
| Haemoglobin - g/dL | 126 ± 18 | 132 ± 20 |
| Platelets | 217 ± 69 | 206 ± 65 |
| Creatinine | 89 (79, 111) | 88 (70, 109) |
| Serum albumin <3.5 g/dl - % | 26 | 7 |
| Echocardiography | | |
| Aortic valve area (cm ²) | 0.6 (0.5, 0.8) | 0.7 (0.6, 0.8) |
| Mean gradient (mmHg) | 43 ± 12 | 48 ± 13 |
| Peak gradient (mmHg) | 70 (65, 86) | 77 (65, 103) |
| LV EF <50% - % | 30 | 14 |
| Mitral regurgitation >moderate - % | 28 | 20 |

COPD: chronic obstructive pulmonary disease; IQR: interquartile range; LVEF: left ventricular ejection fraction; PCI: percutaneous coronary intervention.

vascular complications required vascular surgery and they were managed successfully with established percutaneous techniques [7]. One death in the COVID-19 period group post discharge was unrelated to the TAVR procedure and not due to cardiovascular pathology. There was a non-significant reduction in the number of pacemakers inserted following a TAVR procedure in the COVID-19 period group compared to the pre-COVID-19 group.

4. Discussion

There are three main findings of our work. Firstly, an experienced TAVR team can be safely redeployed in less than a week to a new hospital site to rapidly deliver a safe and effective TAVR service. Secondly, a streamlined TAVR patient pathway can reduce the number of hospital visits and length of inpatient stay during the COVID-19 pandemic. Thirdly, TAVR can be undertaken safely during the COVID-19 pandemic with 30-day event rates similar to those published in clinical trials and international registries.

4.1. Balancing the risks of severe AS and COVID-19

Patients with severe AS are usually elderly with significant comorbidity, who are those most susceptible to adverse outcomes following COVID-19 infection. There has been significant concern about the risk of admitting this population electively to hospital during the ongoing pandemic, given the risk of nosocomial COVID-19 infection in these vulnerable patients [8]. Counter to this, is the risk of the morbidity and mortality that is frequently seen when symptomatic severe aortic stenosis is left untreated [3]. Our triaging practice closely aligned with

Table 3
Efficiency metrics of the TAVR pathway.

| | Pre-COVID-19 era (n = 50) | COVID-19 era (n = 50) | p-Value |
|-------------------------------------|---------------------------|-----------------------|---------|
| Number of hospital visits | | | |
| - Median (Interquartile range) | 3 (3, 4) | 3 (2, 3) | <0.001 |
| Time from referral to TAVR clinic | | | |
| - Median days (Interquartile range) | 35 (11, 59) | 32 (22, 57) | 0.45 |
| Time from TAVR clinic to TAVR | | | |
| - Median days (Interquartile range) | 77 (44, 91) | 26 (13, 65) | <0.0001 |
| Length of admission | | | |
| - Median days (Interquartile range) | 3 (3, 4) | 2 (1, 2) | <0.0001 |

the subsequently published ACC/SCAI position statement [9]. However, our practice was less restrictive than the Canadian Association of Interventional Cardiology proposed practice framework – though the implementation of their recommendations allowed for regional interpretive flexibility [10]. These data demonstrate that despite the infection risk and healthcare resource challenges during the current pandemic, TAVR can be safely and effectively delivered to selected patients on an elective basis during the COVID-19 pandemic with results similar to the contemporary literature [11–14].

4.2. Service restructuring considerations

In the context of a pandemic, there is a significant challenge to delivery of cardiovascular healthcare to vulnerable patients during a time when resources are being diverted to prevent critical services being overwhelmed. We used innovative telehealth clinics to assess symptom burden prior to offering in-person review to only those in whom the clinical history and baseline investigations suggested increased risk of adverse outcomes in the short-term. We also performed 30-day telephone follow-up for patients who had TAVR. Our use of telemedicine facilities for pre- and post-operative care processes aligns with the published practice of services [15,16].

It has long been established that the physical separation of patients with transmissible infectious disease patients from other vulnerable patients results in reduced risk of nosocomial infection [17]. With the current reorganization of healthcare delivery, there are many attractive features of relocating elective activity to a “cold” elective site away from an acute hospital setting where most cardiac catheterization laboratories and cardiac operating theatres currently reside. The initiation of structural heart services at non-surgical sites is often a gradual process

Table 4
Procedural Outcomes of TAVR.

| | Pre-COVID-19 era (n = 50) | COVID-19 era (n = 50) |
|--|---------------------------|-----------------------|
| Percutaneous access - % | | |
| Femoral | 98 | 100 |
| Axillary | 2 | 0 |
| Valve type (%) | | |
| Lotus Edge | 40 | 12 |
| Neo Acurate | 26 | 20 |
| Sapien 3 | 34 | 68 |
| Anaesthetic % | | |
| General anaesthetic | 4 | 2 |
| Sedation | 96 | 98 |
| Procedure time – min | 60 (60, 80) | 60 (60, 80) |
| BAV before valve deployment - % | 39 | 24 |
| Post deployment aortic valve peak gradient – mmHg | 11 (8, 15) | 12 (10, 16) |
| Post deployment aortic valve mean gradient – mmHg | 5 (5, 8) | 6 (5, 8) |
| Post deployment aortic valve area – (cm ²) | 2.0 (1.8, 2.0) | 2.0 (1.8, 2.0) |
| Aortic regurgitation following procedure - % | | |
| Mild | 18 | 16 |
| Moderate | 4 | 0 |
| Severe | 0 | 0 |

BAV: balloon aortic valvuloplasty.

but we have demonstrated that when an experienced wider structural heart team of physicians and allied health care professionals are moved to a new site, they are able to deliver safe procedural outcomes within days. Given that acute setting cardiac beds are frequently being designated to meet the influx of patients with COVID-19, we have demonstrated the feasibility of delivering an effective structural heart service at a new site with an experienced team. This should increase the logistical options to deliver urgent elective services to patients with valvular heart disease that maybe underserved during this current pandemic.

4.3. TAVR during the COVID-19 pandemic

Length of stay associated with TAVR procedures has gradually shortened over time, and early discharge has been shown to be safe in select patients [18]. To facilitate early discharge [9,10,16], we admitted patients on the day of the procedure and predominantly chose an

Table 5
In-hospital and 30-day clinical outcomes of patients following TAVR.

| | Pre-COVID-19 era (n = 50) | COVID-19 era (n = 50) | p-Value |
|--|---------------------------|-----------------------|---------|
| In-hospital outcomes | | | |
| Death from any cause or disabling stroke - % | 0/50 (0) | 1/50 (2) | 1.00 |
| Death - % | 0/50 (0) | 0/50 (0) | N/A |
| Any neurological event - % | 0/50 (0) | 3/50 (6) | 0.24 |
| Transient ischaemic attack - % | 0/50 (0) | 0/50 (0) | N/A |
| Any stroke - % | 0/50 (0) | 3/50 (6) | 0.24 |
| Disabling stroke - % | 0/50 (0) | 1/50 (2) | 1.00 |
| Nondisabling stroke - % | 0/50 (0) | 2/50 (4) | 0.50 |
| Coronary obstruction - % | 1/50 (2) | 1/50 (2) | 1.00 |
| Myocardial infarction - % | 0/50 (0) | 1/50 (2) | 0.49 |
| Major vascular complication - % | 1/50 (2) | 3/50 (6) | 0.62 |
| Life-threatening or disabling bleeding - % | 1/50 (2) | 0/50 (0) | 1.00 |
| Acute kidney injury - % | 0/50 (0) | 1/50 (2) | 0.49 |
| New atrial fibrillation - % | 0/50 (0) | 2/50 (4) | 0.50 |
| New permanent pacemaker - % | 10/43 | 5/48 (10) | 0.09 |
| 30-Day outcomes | | | |
| Death from any cause or disabling stroke - % | 0/50 (0) | 2/50 (4) | 0.50 |
| Death from any cause - % | 0/50 (0) | 1/50 (2) | 1.00 |
| Death from cardiac causes - % | 0/50 (0) | 0/50 (0) | N/A |
| Death not from cardiac causes - % | 0/50 (0) | 1/50 (2) | 1.00 |
| Rehospitalization - % | 2/50 (4) | 4/50 (8) | 0.68 |
| Any neurological event - % | 1/50 (2) | 4/50 (8) | 0.36 |
| Transient ischaemic attack - % | 1/50 (2) | 1/50 (2) | 1.00 |
| Any stroke - % | 0/50 (0) | 3/50 (6) | 0.24 |
| Disabling stroke - % | 0/50 (0) | 1/50 (2) | 1.00 |
| Nondisabling stroke - % | 0/50 (0) | 2/50 (4) | 0.50 |
| Myocardial infarction - % | 0/50 (0) | 1/50 (2) | 0.49 |
| Major vascular complication - % | 1/50 (2) | 3/50 (6) | 0.62 |
| Life-threatening or disabling bleeding - % | 1/50 (2) | 0/50 (0) | 1.00 |
| New permanent pacemaker - % | 10/43 | 5/48 (10) | 0.09 |

anatomically suitable valve prosthesis associated with the lowest risk of requiring subsequent permanent cardiac pacing. During the COVID-19 pandemic patients were younger and had lower calcification burden compared to our pre-pandemic practice. Their suitability for the Sapien 3 prosthesis; a prosthesis with a lower risk for permanent pacemaker implantation [19], accounts for the change in the ratio of prostheses used. The associated numerical reduction in permanent pacemaker implantation and length of stay may be attributable to these practice changes. We demonstrated that harnessing the different patient profile to individualise prosthesis selection and minimise predictable post-operative complications in the COVID-19 era resulted in significantly reduced length of stay without increased adverse events or recurrent hospitalizations. A minimalist TAVR approach [20] maintained the low rate of predictable complications in our cohort and naturally forms a cornerstone of worldwide recommendations for TAVR practice during COVID-19 [9,10,16]. Finally, even though anaesthesia-led sedation was our routine practice in Oxford, nurse led anaesthesia is also an alternative shown to reduce resource utilization.

4.4. Relevance to the post-pandemic era

Our work has numerous patient- and healthcare system-oriented ramifications for the post-pandemic TAVR service. Minimalist TAVR in carefully selected patients can be safely performed by experienced teams in non-surgical sites. Secondly, the streamlining of the pre- and post-procedural processes of care through resource rationalization and adoption of telemedicine should continue beyond the pandemic. The incorporation of these changes can sustainably reduce the healthcare resource utilization footprint of a TAVR service.

Given the encouraging clinical trial results [13], the pandemic has presented the Heart team an opportunity to pursue TAVR in low surgical risk severe AS patients on a larger scale than in the immediate past. However, beyond the lack of long-term durability data for low surgical risk patients, cost remains a significant barrier to the widespread adoption of TAVR by publicly-funded services outside the pandemic setting [21]. The incorporation of the service changes described above has the potential to further improve the cost-effectiveness of a TAVR service.

The COVID-19 pandemic has acted as a catalyst for change in healthcare systems worldwide. The resulting adaptations ought to be perceived as opportunities for sustained change and not as temporary disruptions to an often empirically derived TAVR service framework. In this regard, once we have overcome the COVID-19 pandemic a wider consultation process on the future of healthcare delivery models should be considered.

5. Limitations

Our work focuses on describing a model of rapid restructuring and deployment of an established TAVR service in the context of a pandemic and is not powered to identify difference in outcomes. Therefore, our results should be interpreted as pilot data requiring larger datasets to establish outcome non-inferiority. However, the frequency of complications and improvements in time derived efficiency metrics are within plausible ranges.

6. Conclusion

In the context of the COVID-19 pandemic, TAVR can be undertaken safely in selected patients on an elective basis with a similar safety profile to routine pre-COVID-19 practice. Moreover, we show that a TAVR service can be rapidly restructured and streamlined to align with pandemic-mandated operational efficiency through reduction in hospital visits and post-operative length of stay. Finally, rapid redeployment of a TAVR team to a new site is feasible and contributes to a safe and effective service delivery during a pandemic. The features of safety, adaptability and flexibility are of paramount importance for the continuation

of the TAVR service in a pandemic setting. The changes to enable the continuation of TAVR during the pandemic can inform our post pandemic practice.

CRedit authorship contribution statement

Jubin Joseph: Methodology, Investigation, Data curation, Formal analysis, Visualization, Writing - original draft, Writing - review & editing. **Rafail A. Kotronias:** Methodology, Investigation, Data curation, Formal analysis, Visualization, Writing - original draft, Writing - review & editing. **Theodore Estrin-Serlui:** Investigation, Data curation, Writing - review & editing. **Thomas J. Cahill:** Writing - review & editing. **Rajesh K. Kharbanda:** Writing - review & editing. **James D. Newton:** Writing - review & editing. **Catherine Grebenik:** Writing - review & editing. **Sam Dawkins:** Writing - review & editing. **Adrian P. Banning:** Conceptualization, Methodology, Writing - review & editing, Supervision.

Declaration of competing interest

Adrian P. Banning reports grants from Boston Scientific, personal fees from Boston Scientific, personal fees from Abbott, personal fees from Medtronic, personal fees from Phillips, outside the submitted work; Rajesh K. Kharbanda reports personal fees from Boston Scientific, during the conduct of the work; Adrian P. Banning & Rajesh K. Kharbanda are partially funded by the NHS NIHR Biomedical Research Center, Oxford; Rafail A Kotronias's post is funded by the National Institute for Health Research. The rest of the authors have no conflict of interest to declare.

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