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Time to TAVI: streamlining the pathway to treatment

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ABSTRACT

Introduction Severe aortic stenosis is a major cause of morbidity and mortality. The existing treatment pathway for transcatheter aortic valve implantation (TAVI) traditionally relies on tertiary Heart Valve Centre workup. However, this has been associated with delays to treatment, in breach of British Cardiovascular Intervention Society targets. A novel pathway with emphasis on comprehensive patient workup at a local centre, alongside close collaboration with a Heart Valve Centre, may help reduce the time to TAVI.

Methods The centre performing local workup implemented a novel TAVI referral pathway. Data were collected retrospectively for all outpatients referred for consideration of TAVI to a Heart Valve Centre from November 2020 to November 2021. The main outcome of time to TAVI was calculated as the time from Heart Valve Centre referral to TAVI, or alternative intervention, expressed in days. For the centre performing local workup, referral was defined as the date of multidisciplinary team discussion. For this centre, a total pathway time from echocardiographic diagnosis to TAVI was also evaluated. A secondary outcome of the proportion of referrals proceeding to TAVI at the Heart Valve Centre was analysed.

Results Mean±SD time from referral to TAVI was significantly lower at the centre performing local workup, when compared with centres with traditional referral pathways (32.4±64 to 126±257 days, p<0.00001). The total pathway time from echocardiographic diagnosis to TAVI for the centre performing local workup was 89.9±67.6 days, which was also significantly shorter than referral to TAVI time from all other centres (p<0.003). Centres without local workup had a significantly lower percentage of patients accepted for TAVI (49.5% vs 97.8%, p<0.00001).

Discussion A novel TAVI pathway with emphasis on local workup within a non-surgical centre significantly reduced both the time to TAVI and rejection rates from a Heart Valve Centre. If adopted across the other centres, this approach may help improve access to TAVI.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Severe aortic stenosis is a major cause of morbidity and mortality, with a prevalence that is expected to increase significantly in the next 30 years. Transcatheter aortic valve implantation (TAVI) is a safe and effective treatment option, but current pressure outstrips NHS capacity. Novel pathways that improve present referral systems and access to TAVI are therefore paramount to cope with this increasing demand.

WHAT THIS STUDY ADDS

⇒ This study demonstrates that a novel pathway, where comprehensive patient workup and assessment was performed locally at a non-surgical centre, prior to TAVI at a Heart Valve Centre, can significantly reduce the time to TAVI and improve patient selection.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Similar pathways could be adopted across the NHS, improving access to TAVI.

INTRODUCTION

Across Europe and North America, aortic stenosis (AS) is the most common primary valve disease requiring either catheter or surgical intervention.[1] Disease prevalence increases with age and by the age of 75 as many as one in eight will have moderate to severe AS on imaging.[2–4] Furthermore, models forecast that the number of patients with clinically significant heart valve disease, including severe AS, will double by 2050.[5 6] The natural history of severe symptomatic AS without treatment is poor, with a 50% 2-year mortality and only 3% survival at 5 years: a prognosis that is worse than a number of metastatic cancers. Valve intervention, in the form of surgical aortic valve replacement (SAVR) or transcatheter aortic valve implantation (TAVI), is currently the only therapy offering prognostic benefit.[7 8]

Since the inaugural TAVI in 2002, the procedure has evolved to be an established, effective and safe treatment for severe AS, particularly for elderly patients and those deemed high risk or unsuitable for open surgery: a cohort which accounts for over 30% of patients.[8] Current guidelines recognise TAVI as a safe and effective treatment option in all patients, regardless of surgical risk, with a favourable safety profile.[9] TAVI is not presently recommended as the first-line intervention in the lower-risk surgical cohort, but this area remains under research and there are a growing number of patients who may express a preference for the less invasive approach.[10 11] When compared with SAVR, TAVI is not only less invasive, but on average, requires a shorter hospital stay and affords patients a quicker recovery, with less postprocedural discomfort.[11 12]

Over 5000 TAVI procedures were performed in England in 2019, however, the high demand for TAVI in the National Health Service (NHS) outstrips capacity. In the 2019 UK TAVI survey, 50% of centres struggled to meet the British Cardiovascular Intervention Society (BCIS) treatment target of 18 weeks (126 days).[13] As studies have shown a 6-month delay to TAVI translates to up to 23% preprocedural mortality and as the number of required TAVI procedures is expected to grow 4–10 fold over the next decade, there is a clear need to tackle this deficit and expand existing TAVI services, in order to avoid excess morbidity and mortality.[14 15] Accordingly, the Valve for Life Initiative, launched by the European Association of Percutaneous Cardiovascular Interventions in 2015, aims to improve access to transcatheter valve intervention. The UK was selected to be the fourth country to participate in the programme in 2020.[2]

The main goal of this study was to evaluate the efficacy of a novel referral pathway, with emphasis on comprehensive patient workup and assessment locally at a non-surgical centre, with the ultimate aim of reducing the time to TAVI.

METHODS

Optimising the local pathway

The novel pathway centred primarily around the provision of a dedicated structural clinic in a single non-surgical centre - a model proposed by Valve for Life UK - and comprehensive local workup for proposed TAVI candidates (as detailed below). This allowed for direct triage to a TAVI MDT (multidisciplinary team meeting), followed by intervention at the Heart Valve Centre, without the need for further clinical review or investigations there. This approach was made possible by a strong collaboration with the established Heart Valve Centre, which provided the necessary mentorship and ensured at least weekly access to an appropriate MDT for case discussion.

The first key change made locally was direct triage to the dedicated structural interventionalist in the non-surgical centre, performed by cardiac physiologists at the time of echocardiographic diagnosis of severe AS. This eliminated the delay to receiving a written referral from a general practitioner or medical specialist and negated the need for assessment by a general cardiologist. The dedicated structural interventionalist would then initiate a clinical review and comprehensive local workup. Standard workup included gated cardiac TAVI CT in all patients. The utilisation of a specialist CT analysis software (3-Mensio) allowed the CT images to be both acquired and analysed locally: this reduced the time required for individual case discussions, and therefore, improved MDT capacity at the Heart Valve Centre. Invasive coronary angiography was not performed as standard, but was undertaken where additional information was required post-CT imaging, or where pre-TAVI percutaneous coronary intervention was deemed necessary. Low-dose dobutamine stress echocardiography was also performed in cases where there was a need to confirm the presence of severe AS, particularly in cases of low flow AS on standard transthoracic echocardiography. Finally, the TAVI procedure was often carried out by a team including the structural interventionalist from the non-surgical centre, improving continuity of care.

Overall, these steps enabled comprehensive TAVI workup and assessment to be performed locally in the non-surgical centre, thus reducing the demand on finite tertiary centre resources.

Evaluating the pathway

To evaluate the efficacy of this novel referral pathway, data were collected retrospectively for all patients referred for consideration of TAVI to the respective Heart Valve Centre over a 12-month period, from November 2020 to November 2021. The tertiary centre kept a comprehensive electronic record of all referrals, allowing these patients to be identified. All data were collected and verified from the appropriate electronic systems in the respective hospitals. Data were collected for a number of variables where possible, including: age, sex, date of referral, any subsequent investigations and date of procedure or final outcome of the referral.

The main outcome was to compare the time to TAVI in the single centre performing local workup to that in all other referring centres. The time to TAVI was calculated as the time from Heart Valve Centre referral to TAVI (or alternative intervention) for all centres, expressed in days. For the centre performing local workup, the referral time was defined as the date of MDT discussion, as this is when all data were collated and proposed TAVI candidates were officially referred to the Heart Valve Centre. Additionally, the total pathway time from echocardiographic diagnosis to TAVI or alternative intervention was calculated for the centre performing local workup. A secondary outcome of the proportion of referrals from each group proceeding to TAVI at the Heart Valve Centre was also analysed.

The data were tested for normality using the Kolmogrov-Smirnov test. Results are presented as mean±SD. The differences in proportions were tested with the χ^2 test

and differences between the data for the two groups were tested with the Mann-Whitney U test for non-parametric data to assess statistical significance. Significance was defined as a p<0.05.

RESULTS

Demographics

Over the study period, from November 2020 to November 2021, a total of 227 patients were referred to the Heart Valve Centre for consideration of TAVI. Referrals were received from 28 separate centres: 27 following a traditional referral pathway and a single centre performing comprehensive TAVI workup locally. No patients were excluded from analysis.

In total, 45 patients (19.8%) were referred from the non-surgical centre performing local workup and 182 (80.2%) were referred from all other centres combined. The mean age for all referrals was 81.6±7.9 years (range 36–103 years). The mean age for referrals from the centre performing local workup was 82.6 years and in all other referring centres was 80.8 years. Men accounted for 135 (59.5%) of all referrals and women for 92 (40.5%). For the centre performing local workup, 28 were male (62.2%) and 17 were female (37.8%). For all other referring centres, 107 were male (58.8%) and 75 were female (41.2%).

Time to TAVI

The mean time from Heart Valve Centre referral to TAVI (or alternative intervention) for all referrals was 93 days. When the centre performing local workup was excluded from analysis, the mean time from referral to treatment was 126±257 days (range 20–384 days). The mean time from referral to TAVI in the centre that performed local workup was significantly lower at 32.4±64 days (range 6–97 days), p<0.00001 (figure 1). The average total pathway time from echocardiographic diagnosis to TAVI for the centre performing local workup was 89.9±67.6 days (range 10–373 days), which was also significantly shorter than the referral to TAVI time for all other centres (p<0.003).

The TAVI workup

For the centre performing local workup, 18 patients (40%) underwent invasive coronary angiography in addition to TAVI CT. Six patients (33.3% of this cohort) required percutaneous coronary intervention at the referring centre prior to TAVI. A further two patients (4.4%) underwent invasive coronary angiography at the Heart Valve Centre. For referrals from all other centres, 48 patients (26.4%) underwent invasive coronary angiography at the Heart Valve Centre.

Stress echocardiography was undertaken in two patients (4.4%) in the centre performing local workup. The Heart Valve Centre undertook stress echocardiography in 20 of the patients (10.9%) referred from all other centres. In this group, there were also three patients (1.6%) who underwent a myocardial perfusion scan.

Apart from the need for these additional cardiac investigations, other factors identified that prolonged the workup time were: logistical factors leading to a delay in clinical review, need for further evaluation of other clinically significant heart valve disease and in some cases the requirement for other specialist opinions (particularly cardiac surgery and vascular surgery).

Referral outcomes

Overall, a total of 134 (59.0%) patients underwent TAVI; 4 (1.8%) patients underwent SAVR; 4 (1.8%) patients underwent balloon aortic valvuloplasty; 27 (11.9%) patients had a watch and wait strategy; 11 (4.8%) patients were deemed unfit for TAVI and were recommended for palliative treatment; 44 (19.4%) patients required repeated MDT discussion and 3 (1.3%) patients died awaiting intervention.

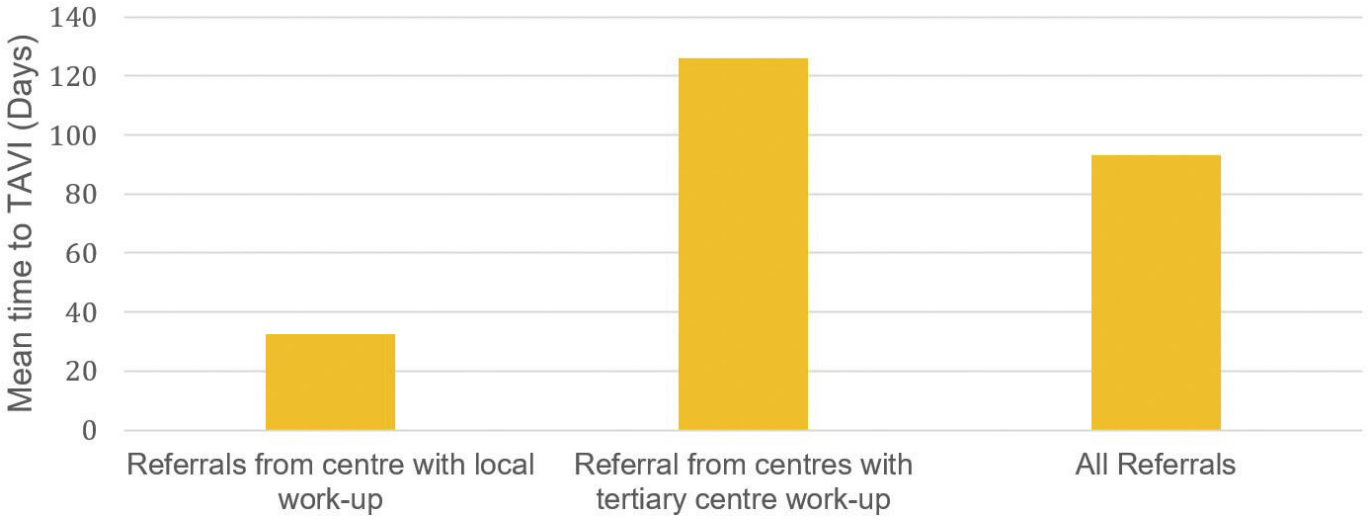

Figure 1 Bar graph of mean time (in days) from Heart Valve Centre referral to TAVI. TAVI, transcatheter aortic valve implantation.

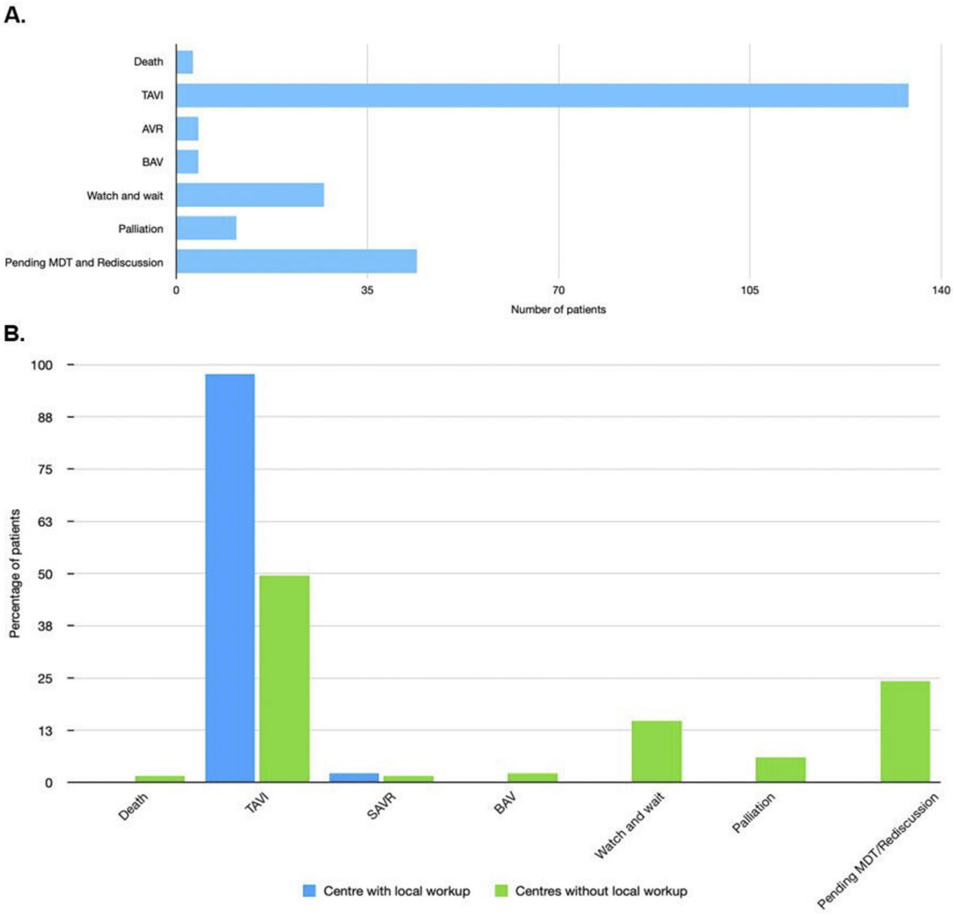

Figure 2 (A) Referral Centre intervention outcomes from all centres. (B) Comparison of patient outcomes from centres with local workup and centres that relied on tertiary centres. BAV, balloon aortic valvuloplasty; SAVR, surgical aortic valve replacement; TAVI, transcatheter aortic valve implantation.

When the referrals from the centre that performed local workup were analysed independently, 44 patients (97.8%) underwent TAVI and 1 patient (2.2%) underwent SAVR, with 0 deaths or recorded complications while awaiting intervention.

In the cohort of patients from all other referral centres, only 90 patients (49.5%) underwent TAVI and thus this group accounted for almost all of the alternative outcomes listed. Reasons for a watch or wait strategy were primarily the absence of symptoms to warrant intervention, exclusion of severe AS on stress echocardiography or patient preference for this approach. Those that required repeated MDT discussion mostly required further investigations or a surgical evaluation prior to consideration of TAVI. The palliative approach was adopted primarily on the grounds of frailty or prohibitive comorbidities including, significant cognitive impairment and active malignancy, either pre-existing or identified during TAVI workup.

Overall, a significantly higher proportion of patients were deemed suitable for and proceeded to TAVI within the local workup cohort (97.8% vs 49.5%, p<0.00001). These findings are illustrated in figure 2.

DISCUSSION

The UK perspective

The UK lags behind its European counterparts in TAVI provision. The UK performed 78 TAVI procedures per million (ppm) in 41 TAVI centres in 2019: only half the European average of 141 ppm and in around one-third of the Western European average of TAVI centres (by population).[13] Additionally, significant geographical inequity in access to TAVI exists, with up to an 11-fold discrepancy by region. In 2019, there were 299 deaths in patients awaiting TAVI in the UK: if extrapolated to all 35 TAVI centres in England, this would equate to over 500 potentially avoidable deaths.[2] These data demonstrate that prompt treatment is key to reducing the morbidity and mortality associated with severe AS and that the Valve for Life Initiative to improve access to TAVI is imperative.

Results analysis

In our study, the major patient demographics were similar across both patient referral groups. Stress echocardiography was more frequent among those patients referred from all centres than those undergoing local workup (10.9% vs 4.4%), however, this difference is likely accounted for by the fact that those identified as having

moderate or pseudosevere AS at the centre performing local workup would not have gone on to be referred to the Heart Valve Centre. Invasive coronary angiography was performed in a higher proportion of those undergoing local workup than in all other referrals (40% vs 26.4%), suggesting that this novel pathway was not associated with a more limited approach than that of the Heart Valve Centre. However, it is important to recognise that additional invasive procedures carry prospective risk, particularly in the TAVI patient population. Proposed explanations for this discrepancy could include the small sample size but also potentially a comparative lack of specialism in the local centre within this specific setting. This would require further analysis to understand the possible implications of widespread pathway implementation.

The primary outcome of this study clearly demonstrates that comprehensive local TAVI workup and clinical assessment is not only feasible, but also saves valuable time and resources at a tertiary centre level. The mean time from referral to the Heart Valve Centre to definitive treatment was reduced from 126 to 32.4 days ($p<0.00001$), when comparing referrals from all centres to those from the single centre performing local workup. The average total pathway time from echocardiographic diagnosis to TAVI for the centre performing local workup was 89.9 days, which was again significantly shorter than the Heart Valve Centre referral to TAVI time for all other centres ($p<0.003$): notably this underestimates total time saved, as the delay from echocardiographic diagnosis to Heart Valve Centre referral for all other centres is not accounted for. Importantly, this demonstrates that the local workup approach reduced the overall time to TAVI, not solely the time from Heart Valve Centre referral to definitive intervention.

This novel pathway exhibits that the BCIS treatment target of 126 days is eminently achievable and that with dedicated specialists and pathways, the Valve for Life target of 56 days from Heart Valve Centre referral to TAVI is also within reach: our data set was considerably within these targets at 89.9 and 32.4 days, respectively.[2 5]

Though the numbers are relatively small, the results also demonstrate that a significantly higher proportion of patients underwent TAVI in the group referred from the centre performing comprehensive local workup, when compared with those referred from all other centres (97.8% vs 49.5%, $p<0.00001$). This suggests that this novel pathway, including the provision of a dedicated structural clinic locally—run by a cardiologist with experience in the TAVI procedure and workup—can earlier identify the patients who do not require or would not benefit from a referral to a Heart Valve Centre. These may be patients who can remain under local follow-up if they do not currently meet criteria for intervention (eg, if they are asymptomatic or subsequent testing confirms moderate or pseudosevere AS). It may include patients who would best suited for an alternative intervention, for example, SAVR, or patients that are unsuitable for TAVI on the grounds of frailty, comorbidities or patient preference. These findings are important, as the symptom and survival benefit of TAVI is only seen in patients that are appropriately selected to undergo the procedure.[11] Furthermore, it critically aids the preservation of valuable Heart Valve Centre resources for those that would benefit most.[11]

Future perspectives

Multiple factors are often cited as barriers to expansion of structural disease programmes, including access to catheter/hybrid labs to perform procedures and bed availability for preprocedural and postprocedural care. Importantly, access to cardiac CT was also named as a substantial issue by 45% of TAVI centres in the UK and this is a key area where local TAVI workup can help ease the burden on Heart Valve Centres.[12] Timely and high-quality CT imaging is vital, as it is the optimal modality for assessing the availability of suitable vascular access, valve characteristics and sizing, as well as predicting potential complications.[14] Thus, a 'hub-and-spoke' model should be considered, where local centres offer CT-TAVI, alongside shared reporting with tertiary centres. This model decreases CT imaging demands on Heart Valve Centres and has shown success in other specialties that rely on accurate CT imaging.[16]

Current guidelines propose that TAVI should be performed solely in Heart Valve Centres, which perform a large number of TAVI procedures and have an established multidisciplinary heart team, including access to cardiac surgery and additional specialties.[1] All cardiac surgical centres in the UK currently offer a TAVI service, therefore, the ability to increase the number of TAVI centres would mandate expansion out of centres with an on-site cardiac surgical service. This approach has been proposed as a potential solution to the TAVI deficit, on the basis that the TAVI procedure is now safer and that most complications today relate to vascular access, rather than the need for emergency cardiothoracic surgery.[17]

A recent review of German and Austrian registries evaluated the safety of TAVI without on-site cardiac surgery. There are also data from a multicentre registry in Spain. In all cases, TAVI in non-surgical centres was performed with visiting cardiothoracic surgery on-site. It was concluded that patient selection, outcomes and complication rates were not statistically different to those with a permanent on-site cardiac surgical service and that complications requiring surgical intervention were rare.[17 18] However, studies have also suggested a higher periprocedural mortality in lower volume TAVI centres, which ultimately would support the current Heart Valve Centre approach.[1 2 13] The authors propose that our model provides an alternative hybrid method, that could be adopted by other centres and which reduces the demand on tertiary centres by performing clinical evaluation and TAVI workup locally, but also maintains a safe approach to TAVI by performing the procedure in an established Heart Valve Centre.

Limitations

The study is limited due to small sample size. The writers acknowledge that the pathways compared are not identical, but the time points selected were felt to represent the best comparators. The incorporation of total pathway time from echocardiographic diagnosis in the centre performing local workup was included to help balance any potential discrepancy.

The study was undertaken during the COVID-19 pandemic. In the associated Heart Valve Centre, the impact of COVID-19 on referral numbers was small as the centre remained one of two main referring centres for cardiac surgery throughout and a prioritisation system was used to ensure that symptomatic severe AS patients were still treated promptly due to the nature of the disease. Therefore, no future significant differences in the referring times or numbers are anticipated.

CONCLUSIONS

A novel TAVI pathway with emphasis on comprehensive local workup in a non-surgical centre, alongside collaboration with an established Heart Valve Centre, led to a significant reduction in the time to treatment. This minimised the dependence on tertiary centre resources, while maintaining safe patient care. This model also led to lower rejection rates for TAVI from the Heart Valve Centre. Implementation of similar novel pathways across the NHS could help improve and standardise the access to TAVI, improving the overall outcomes for TAVI candidates and maximising efficiency from a health economics perspective.

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Contributors LJH and SC contributed equally to this paper and submit as joint first authors. LJH, SC, SA-S, SF, VP and HR designed the study, collected, analysed and interpreted the data, drafted and revised the manuscript critically for important intellectual content. HR also acted as the guarantor. AA, GA, EB, AB, SB, BC, MD, PF, MH, DH, ELH, TH, TK, AK, SM, WM, MP, Roxy S, DS, Robert S, MS and MW revised the manuscript critically for important intellectual content. All authors approved the final version of the manuscript.

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