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Cardiovascular magnetic resonance: Stressing the future

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Abstract

Non-invasive cardiac stress imaging plays a central role in the assessment of patients with known or suspected coronary artery disease. The current guidelines suggest estimation of the myocardial ischaemic burden as a criterion for revascularisation on prognostic grounds despite the lack of standardised reporting of the magnitude of ischaemia on various non-invasive imaging methods. Future studies should aim to accurately describe the relationship between myocardial ischaemic burden as assessed by cardiovascular magnetic resonance imaging and mortality.

Key words: Coronary artery disease; Myocardial ischaemic burden; Non-invasive imaging; Cardiac stress; Magnetic resonance imaging

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Core tip: Further studies should aim to accurately describe the relationship between myocardial ischaemic burden as assessed by stress cardiovascular magnetic resonance and mortality.

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INTRODUCTION

Non-invasive cardiac stress imaging plays a central role in guiding the treatment of patients with known or suspected coronary artery disease (CAD). Stress testing techniques performed include stress echocardiography, single photon emission computed tomography (SPECT) myocardial perfusion imaging and more recently cardiovascular magnetic resonance imaging (CMR). All functional tests support diagnosis, risk stratification and subsequent management decisions^[1] and thus allow myocardial ischaemia to play a crucial role in the management of patients with CAD^[2]. As the availability and use of CMR increases, it is increasingly emerging as the gold standard method of safe, radiation-free perfusion imaging providing functional assessment and tissue characterisation.

In this editorial, we focus on a recent article by Heitner *et al*^[3] published in JAMA Cardiology as we feel it is an important study adding credence to the growing role of pharmacological stress CMR in the assessment of patients with known or suspected CAD. We will also provide our perspective for the future direction of stress CMR.

STUDY ANALYSIS

Heitner *et al*^[3] provided real-world data for 9151 patients referred for evaluation of myocardial ischaemia with stress CMR across 7 participating centres followed for a total of 48000 patient-years. Their analysis demonstrated a strong association of abnormal CMR results with all-cause mortality over long-term follow-up up to 10 years with a hazard ratio of 1.8 between the patients who had abnormal scans and those that did not. This hazard ratio remained significant in all 8 patient subpopulations (presence/absence of history of CAD, normal/abnormal left ventricular ejection fraction (LVEF), presence/absence of typical chest pain, presence/absence of Late Gadolinium Enhancement). The multivariate analysis also showed that addition of stress CMR in two different models significantly increased the χ^2 from 581.8 to 687.4 ($P < 0.001$) and from 620.7 to 721.1 ($P < 0.001$) respectively, indicating that the addition of stress CMR in the model significantly predicts mortality over and above the other variables (including age, sex, diabetes, hypertension, hyperlipidaemia, smoking status, history of CAD or Myocardial Infarction, body mass index, family history of CAD and LVEF).

Whilst this was not a randomised control trial, it crucially provides real-world data and demonstrated for the first time that stress CMR is significantly associated with mortality. The major strengths of the study lie in the large number of patients included and the high number of outcomes over long-term follow up. It is important to consider however, that there were certain limitations. The cause of death is not known in the study and future studies will have to investigate if stress CMR is able to predict specific cardiovascular events rather than all-cause mortality. Nevertheless, as discussed by the authors, all-cause mortality is an objective, unbiased and clinically relevant hard end point. The authors also acknowledged that they had not been able to determine if patients were revascularised after the stress CMR. They reasonably anticipated that revascularisation would occur more commonly in patients with abnormal stress CMR and that revascularisation would improve prognosis and not increase mortality. Another important limitation is that the study CMRs did not assess the extent of ischaemic burden but instead categorised ischaemia into “negative” or “positive” even if just one segment showed abnormal perfusion. Although full quantified perfusion^[4] is not yet part of routine practice, visual semi-quantitative methods have been described^[5] and might have further improved the association with mortality. Furthermore, information about patient revascularisation in combination with myocardial ischaemic burden (MIB) might have allowed estimation of a threshold for MIB, similarly to the way it was estimated in the SPECT studies originally^[6], providing valuable information regarding the threshold of ischaemic burden as assessed with stress CMR.

Hachamovitch *et al*^[6] for the first time in 2003 successfully estimated the 10% MIB threshold with SPECT above which revascularisation offers a survival benefit over medical therapy, using propensity match scoring of observational data. In 2011, the same group used SPECT to demonstrate in a slightly larger observational series that patients with significant ischaemia but without extensive scar were likely to benefit from revascularisation in contrast to patients with minimal ischaemia^[7]. The 10% threshold for myocardial ischaemia based on SPECT has correlated with perfusion defect in 2/16 segments on CMR^[8] and has been incorporated in the ESC 2018 guidelines as a criterion for revascularisation on prognostic grounds and in the ACC/AATS/AHA/ASE/ASNC/SCAI/SCCT/STS 2017 guidelines as a high-risk

indicator^[1,9]. Despite the significance of ischaemia in decision making, there is a lack of standardized reporting of the magnitude of ischaemia on non-invasive testing, which contributes to the variability in translating the severity of ischaemia across stress imaging modalities^[8]. Given the high diagnostic and prognostic yield of pharmacological stress CMR with regards to CAD, it will be valuable for future studies to attempt to delineate the relationship between MIB and prognosis. Nonetheless, Heitner *et al*^[3] should be highly commended for contributing to the medical literature; a very well undertaken and described study including a significant number of patients and an extended follow up, supporting the prognostically beneficial use of CMR perfusion in the routine evaluation of patients with suspected coronary artery disease.

FUTURE DIRECTIONS

Over the last few years, adenosine stress CMR has been established as a highly accurate non-invasive and radiation-free method for the diagnosis and prognosis of CAD. The initial CE-MARC study demonstrated that stress CMR was superior to SPECT regarding the diagnostic accuracy for CAD^[10]. It has also been shown that compared with stress echocardiography, stress CMR was the strongest independent predictor of significant CAD among patients with intermediate probability of CAD presenting to emergency department^[11]. The 5-year follow up data from CE-MARC study demonstrated that stress CMR was the only significant predictor of MACE in addition to major cardiovascular risk factors, angiographic findings or the effect of initial treatment^[12]. Even though stress CMR is not universally, easily available currently, the increasing number of studies demonstrating its cost effectiveness over other non-invasive imaging modalities indicate that it will become more widely available in the near future^[13-15]. In addition to accurate assessment of ischaemia, stress CMR offers accurate localisation of ischaemic segments and the extent of myocardial scar, which have prognostic implications^[16]. It has been shown that ischaemia in ≥ 1.5 myocardial segments (in a 16 segment model) is significantly associated with poor prognosis as is the presence of myocardial scar, albeit to a lesser degree^[17]. Two potential drawbacks of stress CMR perfusion include the visual assessment of perfusion defects as well as the incomplete myocardial coverage. The continuous development of quantified myocardial perfusion reserve aims to reduce the inherent interpreter-bias of visual assessment and to increase the diagnostic ability in the presence of triple-vessel disease. Comparison of quantitative myocardial perfusion reserve with qualitative assessment of stress CMR has demonstrated that quantitative assessment differentiates significantly better the MIB particularly in the context of triple-vessel disease^[18]. More recently, it was also shown that quantitative assessment of MIB was superior to visual assessment with respect to prognosis^[4]. The ongoing development of whole-heart perfusion aims to address the limited, non-contiguous coverage of 2D stress CMR and ultimately provide a non-invasive, non-ionizing radiation method for accurate measurement of MIB. It has been demonstrated that whole-heart perfusion CMR has high diagnostic accuracy for the detection of significant CAD as defined by Fractional Flow Reserve, while estimation of MIB by whole-heart perfusion has very good correlation with SPECT^[19,20]. Comparison of whole-heart perfusion with high-resolution 2D perfusion has shown that there is strong correlation between the two techniques for the estimation of MIB however, there is still uncertainty around the clinically relevant threshold of 10%^[21].

In summary, non-invasive accurate assessment of myocardial ischaemic burden is a clinical necessity with significant implications for prognosis and clinical decision making. In the near future, further development of stress CMR perfusion techniques may reveal that quantified, whole-heart perfusion is the most accurate non-invasive method for the diagnosis and prognosis of CAD.

CONCLUSION

Heitner *et al*^[3] showed for the first time that stress CMR is significantly associated with worse mortality in a large study of real-world data. This is an important study that confirms the prognostic significance of stress CMR in terms of mortality in the real world. The study is a valuable addition to the growing volume of data that supports the central role of CMR in the diagnosis and stratification of CAD in routine clinical practice. However, as information about MIB as assessed by stress CMR was not available, future studies could aim to describe accurately the relationship between MIB, revascularisation and mortality.

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Retrospective Study

One-year outcomes of a NeoHexa sirolimus-eluting coronary stent system with a biodegradable polymer in all-comers coronary artery disease patients: Results from NeoRegistry in India

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Abstract

BACKGROUND

Biodegradable polymer drug-eluting stents (BP-DES) have shown to reduce restenosis rates and have low rates of stent thrombosis. The present postmarketing surveillance assessed 1-year clinical outcomes of patients who had received NeoHexa DES in real practice.

AIM

To investigate 1-year clinical outcomes of NeoHexa DES in real practice.

METHODS

Data obtained from a single-center cohort of patients who had received NeoHexa stents as part of routine treatment of coronary artery disease (CAD) were retrospectively investigated. The primary study endpoint was the rate of major adverse cardiac events (MACEs) defined as the composite of death, myocardial infarction (MI), and target lesion revascularization (TLR) during the follow-up at 1 mo, 6 mo, and 1 year after the index procedure.

RESULTS

A total of 129 patients with 172 lesions were enrolled. The most common comorbid conditions were hypertension (49.61%) and diabetes mellitus (39.53%). Procedural success was achieved in all patients, and no in-hospital MACE was reported. The incidence of composite MACE at 30 d, 6 mo, and 1 year was 0.78%,

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3.94%, and 4.87%, respectively. The rate of possible and probable late stent thrombosis was 0.78%. The cumulative incidences of death, MI, and TLR at 1 year were 2.44%, 0.81%, and 1.63%, respectively.

CONCLUSION

The relatively low rates of MACE and stent thrombosis in this study support safety and performance of NeoHexa stents, suggesting it to be an effective alternative to other contemporary stents for the treatment of de novo lesions in native coronary arteries.

Key words: Sirolimus; Drug-eluting stent; Myocardial infarction; Thrombosis; Coronary artery disease

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Core tip: Reports have indicated the use of stents in patients with coronary artery disease has reduced the rates of restenosis. Biodegradable polymer drug eluting stents, have shown to reduce restenosis rates and lower the stent thrombosis rate. Our study assessed 1-year, single-center cohort for clinical outcomes of patients who had received NeoHexa sirolimus drug-eluting stents in real practice. It showed relatively low rates of major adverse cardiac event and stent thrombosis supporting safety and performance of NeoHexa stent and supporting its use as an effective alternative to other existing stents.

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INTRODUCTION

The prevalence of cardiovascular diseases, particularly coronary artery disease (CAD), is ever-increasing in India and has reached epidemic proportions^[1]. Approximately 17% of total deaths were attributed to coronary heart disease in 2001–2003, which increased to 23% in 2010–2013 in India^[1,2]. Percutaneous coronary intervention (PCI) is one of the most commonly performed cardiac procedures aimed at improving symptoms and quality of life of patients with CAD^[3–5].

The unceasing research over decades in the field of PCI has led to improved devices and treatment strategies. Bare-metal stents (BMS) are able to reduce the rates of restenosis and acute occlusion compared with balloon angioplasty. Subsequently, the advent of drug-eluting stents (DES) has further decreased the rates of restenosis. Of note, first-generation DES were durable polymer DES, and delayed re-endothelialization due to the polymer raised concerns regarding late and very-late stent thrombosis (ST). Despite several efforts to reduce the ST rates of durable polymer DES such as alteration of stent platforms to increase tissue compatibility, modification of the outer layer of the stent surface, and using effective antiproliferative drugs and appropriate polymer carriers, the issue of inflammatory response still persists. Therefore, biodegradable polymer drug-eluting stents (BP-DES) were introduced with anticipation to reduce ST^[6–8]. As expected, long-term clinical evidence has demonstrated superiority of BP-DES in reducing very-late ST events compared with durable polymer DES^[9–11].

NeoHexa is one of such BP-DES designed with the aim to reduce rates of late ST and was launched in July 2015. The present study investigated the 1-year clinical outcomes of patients who had received this new DES in real clinical practice.

MATERIALS AND METHODS

Study design and patient selection

Data obtained from a single-center cohort of patients who had received NeoHexa stents as part of routine treatment for CAD between July 2015 and July 2016 at the

Cauvery Heart and Multispecialty Hospital, Mysore, were retrospectively investigated in January 2017. The study was conducted in accordance with the Helsinki Declaration and was approved by an independent ethics committee. Verbal informed consent was obtained before collecting data from patients who were contacted to participate in this study. This investigator initiated trial was registered with Clinical Trial Registry of India (CTRI/2018/03/012522)

Description of device

NeoHexa is a cobalt-chromium sirolimus-eluting coronary stent system. It is a premounted, balloon expandable DES with a persistent coating of BP carrier, loaded with 1.0 µg/mm² sirolimus in a slow-release formulation. It is mounted on a rapid exchange percutaneous transluminal coronary angioplasty balloon catheter. It has two radiopaque markers beside the mounted stent for accurate placement. It is available in diameters of 2.25, 2.5, 2.75, 3.0, 3.5, 4.0, and 4.5 mm and in stent lengths of 7, 10, 13, 15, 17, 20, 24, 28, 33, 38, 42, and 45 mm.

Study procedure and data collection

This was an all-comer study, and the indications for the angioplasty procedure and technique of stent implantation were as per the discretion of the treating physician. All patients were advised to receive dual antiplatelet therapy with clopidogrel and aspirin. Patients who were not pretreated received a bolus dose of 300-600 mg of clopidogrel or 60 mg of prasugrel and ≥ 100 mg of soluble aspirin just before the procedure.

Data were sourced from clinical notes, including inpatient progress notes and outpatient notes and letters, angiogram reports, and procedural angiographic images. Case report forms were completed for all patients, and data were stored in a secure, off-site database. Follow-up data were collected using either clinical visits or telephonic interactions by using structured questionnaires developed for this study to determine endpoint status at 1 mo, 6 mo, and 1 year after the index procedure. Supporting clinical documents were sought when necessary. Patients with incomplete clinical notes or who were noncontactable *via* telephone were excluded from the analysis.

Endpoint definitions

The primary endpoint of the study was the rate of major adverse cardiac events (MACEs) defined as the composite of death, myocardial infarction (MI), and target lesion revascularization (TLR) during the follow-up period after the index procedure. Deaths were categorized as cardiac or noncardiac. Stent thrombosis was evaluated according to the Academic Research Consortium criteria^[12]. Procedural success was defined as successful stent placement at the desired position with < 30% residual stenosis.

Sample size and statistical analysis

A random sample size of 129 patients was calculated based on the primary endpoint of the study. Categorical data are presented as numbers and percentages. Continuous variables are presented as the mean ± SD. All data were processed using the statistical analysis software SPSS, version 21 or higher (SPSS Inc., Chicago, IL, United States).

RESULTS

Baseline demographic and clinical characteristics

In total, 129 patients with 172 lesions were enrolled in the study. Baseline demographics and clinical characteristics are summarized in **Table 1**. Mean age of patients was 56.57 ± 11.73 years, and the majority were men (76.74%). The most common comorbid conditions were hypertension (49.61%), followed by diabetes mellitus (39.53%). Over 70% of patients presented with angina class II and above.

Lesion and procedural characteristics

Most lesions were located in LAD (42.44%), RCA (32.56%), and LCx (21.51%), and a majority of them were positioned proximal (48.26%), mid (31.39%), or distal (12.79%) (**Table 2**). Approximately 72% of patients had a lesion length ranging 20–40 cm. The average stenosis rate was 88.12%. Bifurcation and thrombotic lesions comprised approximately 11% of all lesions. Approximately 95% lesions were moderate- to high-risk lesions as per ACC/AHA criteria, and most (96.51%) lesions had a TIMI flow grade below 3. The average length and diameter of the stent was 27.30 ± 9.20 and 2.98 ± 0.69, respectively. Average stent per patient was 1.34 ± 0.53, and pre- and post-dilation was performed in 97.67% and 26.16% of patients, respectively. Procedural success was achieved in all patients, and no in-hospital MACE was reported.

Table 1 Demographic and baseline clinical characteristics

Characteristics	n = 129 patients
Patient demographics	
Age, yr	56.57 ± 11.73
Male	99 (76.74)
Baseline medical history	
Diabetes mellitus	51 (39.53)
Hypertension	64 (49.61)
Smoking	11 (8.53)
Family history of coronary artery disease	04 (3.10)
History of alcohol consumption	05 (3.88)
Renal disease	01 (0.77)
Atrial fibrillation	01 (0.77)
Cardiac status - Angina class	
I	08 (6.20)
II	26 (20.15)
III	71 (55.04)
IV	23 (17.83)
Unknown	01 (0.77)

Data presented as mean ± SD or n (%).

Clinical outcomes during follow-up

The incidence of composite of MACE at 30 d was 0.78% with one cardiac death. MACE rates during the follow-up duration are depicted in [Table 3](#). In brief, MACEs were reported in 6 (4.87%) patients at 1 year, consisting of 2 cardiac deaths, one noncardiac death, one (0.81%) MI, and 2 (1.63%) TLR events. Both TLR events were PCI, and the patients recovered after treatment. As shown in [Table 4](#), the cumulative rate of ST was 1.55% (2/129) at 1 year and late ST was ARC-possible ST.

DISCUSSION

The present postmarketing surveillance study was conducted to support the safety of NeoHexa stents for treatment of coronary artery lesions in real-world clinical practice. One-year follow-up results demonstrated the favorable safety and performance of the stent with low rates of MACE and ST of 4.87% and 1.55%, respectively.

We evaluated real-world data of NeoHexa in an unselected clinical practice population with diverse clinical profiles, which included diabetes (39.53%), hypertension (49.61%), bifurcation and thrombotic lesions (11.04%), and ACC/AHA type B and C lesions (94.77%). The presentation of patients was similar to that reported in studies of other similar stents^[13,14]. The NeoHexa stent is designed to have thin struts (60 µm) on a cobalt-chromium platform with a unique and innovative “s” link and an alternate “C” link, which provides high radial strength and no foreshortening, making it ideal for all lesion locations including ostial lesions.

The first-generation DES were built on bulky stent platforms, making deliverability quite challenging^[15]; however, the thin struts and growth of 8% from nominal pressure to rated burst pressure of this new-generation NeoHexa DES offer good deliverability and conformability, thereby allowing complete deployment and good wall apposition. The design leads to a minimal balloon overhang, minimizing the risk of edge dissection/injury, which is a common procedural complication of PCIs. The finding that procedural success was achieved in 100% of patients in this study supports these claims.

Compared with BMS, first-generation DES with a durable polymer have reduced the rate of restenosis but are associated with higher late ST^[11]. Delayed endothelial healing secondary to a hypersensitivity reaction to the durable polymer could be responsible for the observed high rate of ST with such DES^[16-18]. BP-DES were developed to address this potential limitation of durable polymer DES. The drug encapsulated in polymer is completely released within 3–9 mo, and the polymer also gradually degrades into carbon dioxide and water molecules. Therefore, BP-DES

Table 2 Lesion and procedural characteristics (n = 129 patients and 172 lesions)

Characteristics	n = 172 lesions
Target vessel location	
LAD	73 (42.44)
LCx	37 (21.51)
RCA	56 (32.56)
Ramus	03 (1.74)
Other	03 (1.74)
Target lesion location	
Ostial	05 (2.91)
Proximal	83 (48.26)
Mid	54 (31.39)
Distal	22 (12.79)
Unknown	08 (4.65%)
Lesion length	
< 20 mm	39 (22.67)
20–40 mm	124 (72.09)
> 40 mm	08 (4.65)
Stenosis	88.12
Bifurcation	3 (1.74)
Thrombotic lesions	16 (9.30)
ACC/AHA lesion type	
A	09 (5.23)
B	92 (53.49)
C	71 (41.28)
TIMI flow grade at baseline	
0	45 (26.16)
1	49 (28.49)
2	72 (41.86)
3	05 (2.91)
Unknown	01 (0.58)
Average stent length	27.30 ± 9.20
Average stent diameter	2.98 ± 0.69
Average stent per patient	1.34 ± 0.53
Predilation	168 (97.67)
Postdilation	45 (26.16)

Data presented as mean ± SD or n (%). ACC: American College of Cardiology; AHA: American Heart Association; LAD: Left anterior descending; LCx: Left circumflex; RCA: Right coronary artery; TIMI: Thrombolysis in myocardial infarction.

initially provide antiproliferative benefits similar to durable polymer DES and later behave like BMS once drug delivery and polymer biodegradation are complete^[19]. Given the importance of ST in evaluating the overall performance of DES, we estimated the ST rate in our study. The rates of both possible and probable late ST was 0.78% in the present study, which are comparable to those of other standard BP-DES such as sirolimus-eluting Orsiro stents (0.4%), biolimus-eluting Nobori stents (1.2%), and Biolimus A9 stents (0.2%) at 1-year follow-up^[14,20]. The low rate of ST observed in our study could be attributed to complete wall apposition of the NeoHexa stent and appropriate endothelial healing over the 1-year period.

Although there is no scientific difference between indigenously developed DES *vs* those developed and marketed by global manufacturers, cost effectiveness remains a key factor in the decision-making process for patients and health care providers in India^[21]. The most promising results of this retrospective study are 100% procedural success rate and low rates of MACE (4.87%). MACE rates in our study are comparable to previously reported incidence rates for other BP-DES: Endeavor stent (12.9%), NOBORI stent (11%), and Metafor SES (1.6%)^[13,22,23]. Moreover, our results are comparable to the rate observed in the SPIRIT II trial (7.2%)^[7].

Table 3 Mortality, morbidity, and major adverse cardiac event, *n* (%)

Events	In-hospital	1 mo	6 mo	1 yr
MACE	0	01 (0.78)	05 (3.94)	06 (4.87)
Death	0	01 (0.78)	03 (2.36)	03 (2.44)
Myocardial infarction	0	0	01 (0.79)	01 (0.81)
Clinically driven TLR	0	0	01 (0.79)	02 (1.63)

MACE: Major adverse cardiac event; TLR: Target lesion revascularization.

A major limitation of the present study is the observational design and retrospective analysis of data. However, observational data allow true representation of all-comer population unlike randomized trials with restricted enrollment criteria. In addition, a 1-year follow-up period might not be adequate to evaluate the safety and performance of NeoHexa DES. Therefore, our results must be further substantiated in well-designed studies with longer follow-up duration.

In conclusion, the relatively low rates of MACE and ST in this cohort of patients after 1 year of follow-up support the favorable safety and performance of NeoHexa stents. Product characteristics such as advanced stent design with the use of biodegradable polymer that provides high radial strength, minimal balloon overhang, low recoil, and uniform scaffolding could be responsible for these results. NeoHexa could be suggested as an effective alternative to other contemporary stents available in the market for the treatment of *de novo* lesions in native coronary arteries.

Table 4 Stent thrombosis, *n* (%)

Timing of stent thrombosis	Incidence	Type of stent thrombosis	Incidence
Early	0	Definite	0
Late	01 (0.78)	Probable	02 (1.55)
	01 (0.78)	Possible	

ARTICLE HIGHLIGHTS

Research background

Biodegradable polymer drug-eluting stents have been shown to reduce restenosis rates and have low rates of stent thrombosis. Thus, this post-marketing surveillance assessing outcomes after 1 year of treatment shows the real implications of biodegradable drug eluting stents.

Research motivation

Proving the real-life reduced restenosis rates of biodegradable stents was the motivation behind this study. Key problems were the rates of major adverse cardiac events (MACEs) myocardial infarction, and target lesion revascularization. Solving this would increase patient survival rate.

Research objectives

The main objective was to identify the rate of MACE during the follow-up period at 1 mo, 6 mo, and 1 year after the procedure completion.

Research methods

This was a retrospective analysis of a single-centre cohort of patients who had received NeoHexa stents as part of routine treatment for CAD.

Research results

Procedural success was achieved in all patients, and no in-hospital MACE was reported. The incidence of composite MACE at 30 d, 6 mo, and 1 year was 0.78%, 3.94%, and 4.87%, respectively.

Research conclusions

Relatively low rates of MACE and stent thrombosis in this study support the safety and performance of NeoHexa stents, suggesting that it is an effective alternative for treatment of *de novo* lesions.

Research perspectives

Our results must be further substantiated in well-designed studies with longer follow-up duration.

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Successful minimal approach transcatheter aortic valve replacement in an allograft heart recipient 19 years post transplantation for severe aortic stenosis: A case report

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Abstract

BACKGROUND

Aortic stenosis is one of the rare valvular complications in a transplanted heart. Over the past 8 years, transcatheter approach for aortic valve replacement (TAVR) has been slowly evolving to be the preferred approach in these patient population when compared to the surgical approach. We report a second case in the United States with successful transfemoral minimal approach with minimal sedation for TAVR in a heart transplant recipient 19 years post transplantation for severe symptomatic calcified aortic stenosis.

CASE SUMMARY

We present a case of 73-year-old male who has undergone successful minimal approach transcatheter aortic valve replacement in an allograft heart. Patient had received orthotopic heart transplantation 19 years ago for non-ischemic cardiomyopathy. Follow up transthoracic echocardiograms as per routine protocol did not show any aortic valve disease until 15 years post transplantation. Aortic valve was noted to be mildly sclerotic at that time and gradually progressed to severe symptomatic aortic stenosis over the next 4 years. Patient had complaints of worsening shortness of breath that limited his functional capacity. Overall his post heart transplantation period has been mostly uneventful except for allograft non occlusive vasculopathy and aortic stenosis. His Society of Thoracic Surgery risk score was 12.205% and he was considered to be a high-risk surgical candidate by surgeon. Decision was made to undergo transcatheter aortic valve replacement.

CONCLUSION

With the improved survival of these patients, we think it is time to look into

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pathophysiology of valvular disease in transplant heart recipients. Some other unanswered questions include, underlying donor and recipient risk factors for valvular diseases in heart transplant recipients.

Key words: Transcatheter aortic valve replacement; Heart transplant; Minimal approach valve replacement; Severe aortic stenosis; Case report

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Core tip: We report a second case in the United States with successful transfemoral minimal approach with minimal sedation for transcatheter approach for aortic valve replacement in a heart transplant recipient. We believe, with the increase of number of reported cases with valvular diseases in heart transplant patients, it is time for further research in valvular disease in allograft heart recipients.

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URL: <https://www.wjnet.com/1949-8462/full/v11/i8/209.htm>

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INTRODUCTION

The survival of heart transplant recipients has significantly improved over the past few decades with advanced surgical techniques and immunosuppressive therapies. Valvular diseases like aortic stenosis is seen as one of the late complications in cardiac allograft recipients given improved long-term survival in these patient population^[1-3]. Aortic valve replacement through median or partial sternotomy has been considered to be the standard treatment of choice^[4-6]. Over the past decade transcatheter aortic valve replacement has been evolving given that it is less invasive in these high risk transplant recipients^[6-10]. On review of literature, only 6 case reports have been reported thus far, of which one has been reported in the United States^[2,7]. Most of the case reports comment only on immediate post-operative outcomes.

CASE PRESENTATION

Chief complaints

Progressive shortness of breath.

History of present illness

A 73-year-old male with history of hypertension, orthotopic heart transplantation 19 years ago has been followed closely for symptoms of worsening shortness of breath in the setting of severe aortic stenosis. His functional capacity has been gradually declined to NYHA Class IV (New York Heart Association).

History of past illness

Hypertension, status post heart transplantation, allograft non occlusive vasculopathy and aortic stenosis.

Personal and family history

Included above.

Physical examination

Physical examination upon admission: He was noted to have elevated jugular venous pulse, bibasilar lung crackles and bilateral pedal edema.

Laboratory examination

None.

Imaging examinations

Follow up transthoracic echocardiograms as per routine protocol did not show any aortic valve disease until 15 years post transplantation when the aortic valve was noted to be mildly sclerotic at that time and gradually progressed to symptomatic severe aortic stenosis over the next 4 years.

FINAL DIAGNOSIS

Symptomatic severe aortic stenosis.

TREATMENT

Transcatheter aortic valve replacement.

OUTCOME AND FOLLOW-UP

Patient had tolerated the procedure well and was discharged home on post procedure day 2. His symptoms of shortness of breath and functional capacity were noted to be significantly improved during post procedure follow up in the clinic.

DISCUSSION

Patient was minimally sedated with subcutaneous lidocaine in bilateral groin sites along with small dose of versed and fentanyl pushes per anesthesia protocol.

The left groin was accessed with a 6 French sheath. A pigtail was advanced for aortoiliac angiography and contralateral access guidance. Aortic root angiography was performed for guidance of valve deployment. A 6 French venous sheath was obtained in the left common femoral vein and a temporary pacemaker was advanced into the right ventricle. With contralateral guidance, a 6 French sheath was placed into the right common femoral artery. Two Preclose devices were deployed and a 16 French sheath was placed. An Amplatz catheter and a Newton wire was advanced, across the aortic valve into the left ventricle followed by advancing a preshaped stiff amplatz wire. Later, the prosthetic aortic valve was advanced across the aortic valve. Once the valve was noted to be in proper position, a 29-mm Sapien 3 valve was deployed in the usual sequence of rapid pacing, balloon inflation and balloon deflation. Once the valve was deployed, transthoracic echocardiography was done that confirmed adequate valve function. No aortic regurgitation was noted. The delivery system and the 16 French sheath and hemostasis was achieved successfully. The left common femoral access sheath was removed and a 6 French Mynx device was placed. No immediate complications were seen. Patient did tolerate the procedure well and was discharged on post op day 2 ([Figure 1](#)).

CONCLUSION

Minimal approach transcatheter aortic valve replacement has proven to have good outcomes in high risk patients. Its use in allograft heart is also showing to have good immediate post-operative outcomes. All the case reports thus far have commented on immediate post-operative outcomes, but more data is needed in regard to long-term prognosis. There is inadequate data in regard to valvular diseases in heart transplant recipients. Vasculopathy is a well-known complication in this patient population. With the improved survival of these patients, we think it is time to look into pathophysiology of valvular disease in transplant heart recipients. Some other unanswered questions include, underlying donor and recipient risk factors for valvular diseases in heart transplant recipients.

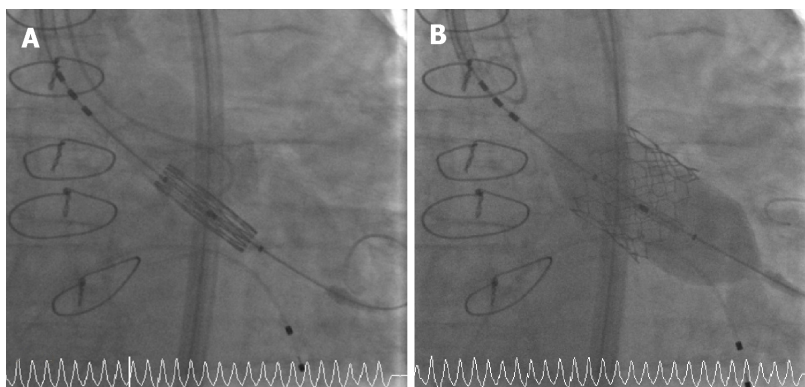


Figure 1 Fluoroscopic pictures. A: The fluoroscopic pictures of pre deployment of the Transcatheter Aortic Valve B: The fluoroscopic pictures of post deployment of the TAVR valve.

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