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AsiaIntervention

CORONARY INTERVENTIONS

INTERVENTIONS FOR VALVULAR DISEASE AND HEART FAILURE

EDITORIAL

NATIONAL SOCIETY

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Abstracts of INDIALIVE 2018

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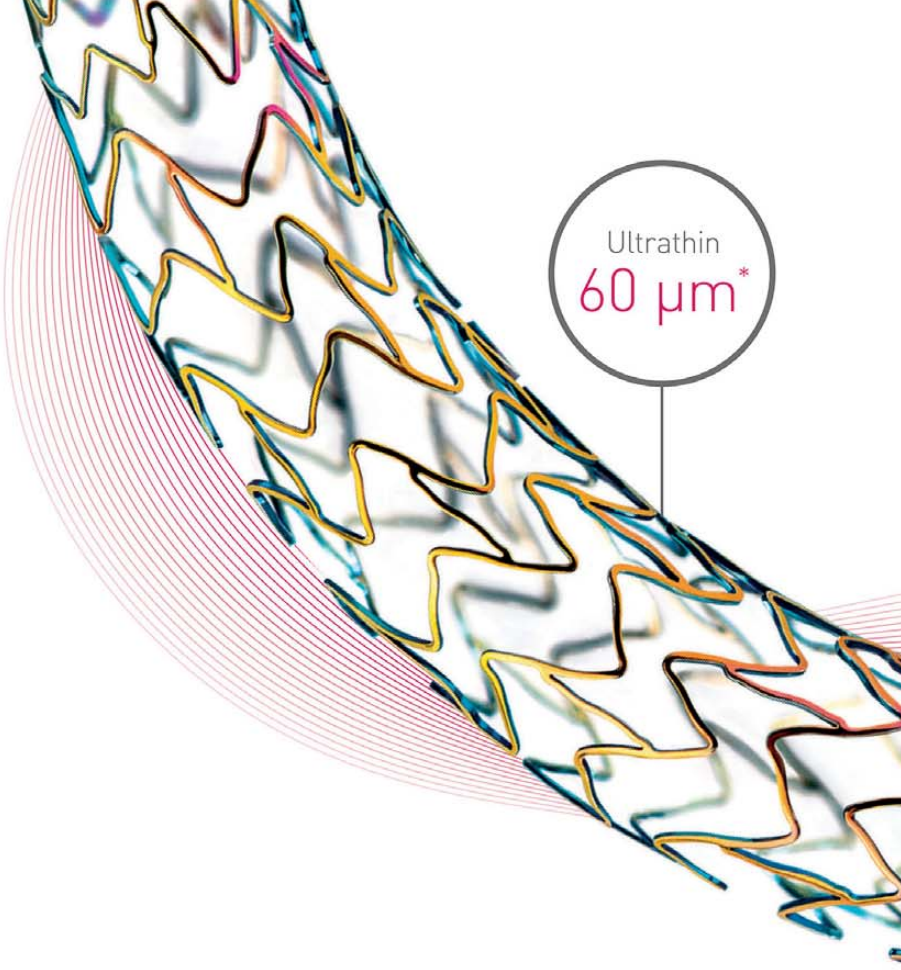

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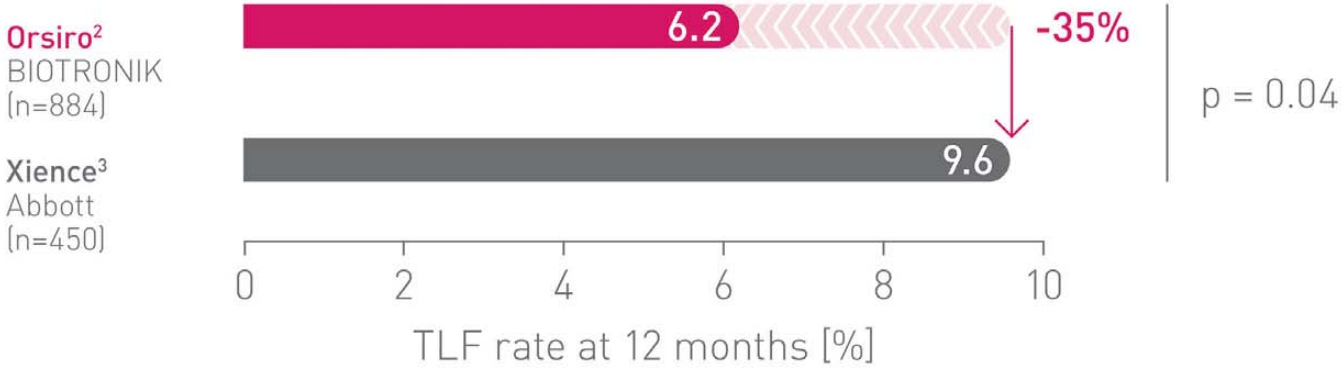

1. ø 2.25 – 3.0 mm; 2. CAUTION - Investigational device. Limited by United States law to investigational use.; 3. Xience is a registered trademark of Abbott Cardiovascular Systems Inc. Reference: Kandzari O. Ultrathin Bioresorbable Polymer Sirolimus-Eluting Stents versus Thin Durable Polymer Everolimus-Eluting Stents in Patients Undergoing Coronary Revascularisation [BIOFLOW V]: A randomized trial The Lancet. 2017.

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ABSTRACTS

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AsiaIntervention Journal is an international, English language, peer-reviewed journal whose aim is to create a forum of high quality research and education in the field of percutaneous and surgical cardiovascular interventions.
It is released twice a year, in paper and electronic formats. AsiaIntervention has applied for indexation in Science Citation Index® (ISI), SciVerse Scopus, MEDLINE®/PubMed®.
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AsiaIntervention 2018;4:5-6

AsiaIntervention: the voice of clinical research and publications of the region

Upendra Kaul, *Course Director INDIA LIVE and Chief Editor AsiaIntervention*

It is very appropriate that AsiaIntervention is bringing out this special issue to mark the 9th INDIA LIVE being held in Chennai starting on 28 February 2018. The Interventional Cardiology Foundation of India (ICFI) named this journal the official journal of INDIA LIVE in 2017. This was followed by the Asia Pacific Society of Interventional Cardiology (APSIC) making it their scientific voice. The journal was planned by the thought leaders of this region to become a forum of high-quality research and education in the field of percutaneous and surgical cardiovascular interventions from the Asia-Pacific region.

This young journal is growing remarkably well and is becoming a forum for cardiologists who specialise in this area to publish their scientific data. As one of the Chief Editors of AsiaIntervention and one of the Course Directors of INDIA LIVE, it is a proud moment for me to introduce this issue to the interventional cardiologists of the region. We have articles from India, Japan, Singapore and other countries. Transcatheter aortic valve replacement (TAVR) is finding an increasing space in the journal in line with what is happening all over the globe. Chronic total occlusion revascularisation, which has been a speciality of this part of the world, is also being addressed in the form of an interesting predictive model for success.

Contributions of India and INDIA LIVE

Interventional cardiologists of this region need to know that India has been a leader in the field of invasive cardiology in the entire Asia-Pacific Rim. Invasive cardiology began here in 1962 when Dr Sujoy Bhushan Roy set up the first laboratory and performed the first cardiac catheterisation in the All India Institute of Medical Sciences, New Delhi. The department also helped start this speciality in several other countries including Singapore. Selective coronary angiography was initiated in India in the 1970s with the start of a coronary artery bypass programme in a few selected centres. With the advent of coronary angioplasty in Europe pioneered by Andreas Grüntzig in 1977 and its subsequent spread across Europe and America in the early 1980s, the numbers and centres started increasing. By April 1985 angioplasty programmes had started in a few cities in India, namely Chennai, Delhi, Hyderabad and Mumbai. In order to have an audit of this new procedure, and also to disseminate teaching and training of the technique and selection of cases, a National PTCA Registry was started in India by the author, and regular scientific meetings were held twice a year. With the start of mitral balloon valvotomy in 1984 and other non-surgical therapies, the registry was expanded to become the National Interventional Council (NIC), a subsidiary of

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the Cardiology Society of India in 1985. The number of coronary procedures has continued to increase steadily from around 3,000 in 1992 in 103 centres to close to 500,000 in 2016 in approximately 1,000 centres – a substantial increase. The NIC has an annual meeting, highlighting live demonstrations, various teaching and academic aspects of coronary and non-coronary interventions, including the presentation of annual data.

It was in 2010 that INDIA LIVE was conceived by its five founding members, currently the Course Directors, under the banner of the Interventional Cardiology Foundation of India (ICFI). The aims were to showcase the strength of Indian interventional cardiologists and to hold an annual meeting along with thought leaders from all over the world with live demonstrations and targeted didactic presentations on various contemporary topics in the field of cardiovascular and structural heart disease. The course has become a popular regular international meeting held in February/March each year in New Delhi, Chennai or Mumbai, three of the well-known cities of India. Live cases of complex interventions both of coronary and structural heart disease with educative features, various imaging technologies, physiological basis of interventions and research papers from various investigators form the basis of the three days of deliberations. More than 2,000 cardiologists participate in this course annually. There are special sessions entitled "How to do", "Meet the Experts", "Complications and their management" and "Scientific paper presentations". The scientific abstracts received for the meeting will be published in this special edition of AsiaIntervention. The best abstracts will be rewarded. Authors of these abstracts will then be invited to submit full manuscripts which, after peer review, could be published in future issues of the journal.

Interestingly, as a coincidence in the same year (2010), a renowned interventional meeting, EuroPCR (Paris Course on Revascularisation), chose to partner with the National Heart Centre Singapore (NHCS) to launch jointly the first AsiaPCR-SingLive, a cardiology conference, from 21 to 23 January 2010. Singapore Live was a course started by Dr Arthur Tan of the NHCS in 1989. The same course continued under Professor Koh Tian Hai until the partnership with EuroPCR began in 2010. There is a special session of INDIA LIVE at these meetings.

The way ahead

The goal of the journal is to provide an opportunity to the interventional cardiologists of the Asia-Pacific region to publish scientific material highlighting the techniques and innovations developed by them. For this, we require the support of our colleagues in India and neighbouring countries to submit their work to the journal which is owned by all of us. It is we who are going to be responsible for maintaining its academic standards and bringing it up to par with already well-established international journals. The editorial board plans to assist those who want help in writing their manuscripts or wish to improve their paper-writing skills by connecting them with the appropriate professionals.

We remain committed to the quality, excellence and showcasing of the strengths of academics and research in the Asia-Pacific region and solicit participation from all of you to contribute to the growth of this young and upcoming journal in whatever way possible.

AsiaIntervention 2018;4:7-9

Significance of verification of IVUS-guided stent optimisation

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During percutaneous coronary intervention (PCI), intravascular ultrasound (IVUS) provides anatomic information for the coronary artery lumen, wall, and plaques, which can help the accurate evaluation of the lesion with vessel sizing[1]. Moreover, post-PCI stent underexpansion, malapposition, or edge dissections can be detected for stent optimisation, resulting in improved clinical outcomes[1-4]. Recently, much evidence demonstrating the clinical usefulness of IVUS has become available, particularly for complex lesions, such as left main disease, chronic total occlusions, and diffuse long lesions[2-4]. According to the recent large randomised study of the IVUS-XPL (Impact of Intravascular Ultrasound Guidance on Outcomes of Xience Prime Stents in Long Lesions) trial, IVUS-guided drug-eluting stent (DES) implantation, particularly for diffuse long lesions, compared with angiography-guided DES implantation resulted in a significantly lower rate of the composite endpoint of major adverse cardiac events (a composite of cardiac death, myocardial infarction, or target lesion revascularisation) at one year (2.9% vs. 5.8%, hazard ratio [HR] 0.48, p=0.007)[2]. These differences were primarily due to a lower risk of target lesion revascularisation (2.5% vs. 5.0%, HR 0.51, p=0.02). Also, the results of a meta-analysis with individual patient-level data from 2,345 randomised patients showed that IVUS-guided new-generation DES implantation vs. angiography-guided DES implantation was associated with a favourable outcome, particularly the occurrence of the hard clinical endpoint (the composite of cardiac death, myocardial infarction, or stent thrombosis) for complex lesions[3]. Of note, the primary endpoint of this meta-analysis did not include target lesion revascularisation. Therefore, different from the IVUS-XPL trial showing the benefit of IVUS due primarily to less frequent TLR events[2], major adverse cardiac events, even excluding the target lesion revascularisation events in this meta-analysis, were less frequent with IVUS guidance than with angiography guidance[3]. Lastly, according to the ADAPT-DES (Assessment of Dual AntiPlatelet Therapy With Drug Eluting Stents) study, the largest all-comers observational study (n=8,583)[5], IVUS was utilised in 3,349 patients (39%), and larger-diameter devices, longer stents, and/or higher inflation

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pressure were used in the IVUS-guided cases. At one year, propensity-adjusted multivariable analysis revealed that IVUS guidance vs. angiography guidance was associated with reduced definite/probable stent thrombosis (0.6% vs. 1.0%, p=0.003), myocardial infarction (2.5% vs. 3.7%, p=0.004), and a composite of adjudicated major cardiac events (cardiac death, myocardial infarction, or stent thrombosis) (3.1% vs. 4.7%, p=0.002). The benefits of IVUS were especially evident in patients with acute coronary syndromes and complex lesions[5].

Contrary to these findings[2-5], in this issue of AsiaIntervention, Watanabe et al in their study failed to demonstrate the clinical usefulness of IVUS guidance for target vessel revascularisation in the patients treated with first-generation DES[6].

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They sought to evaluate the clinical impact of IVUS use in first-generation DES implantation from the Coronary REvascularisation Demonstrating Outcome study in Kyoto (CREDO-Kyoto) PCI/CABG registry cohort-2. As a retrospective cohort study, they selected the patients treated with first-generation DES without acute myocardial infarction, and compared clinical outcomes between the two groups of patients with or without IVUS use (IVUS-guided group [n=2,768] vs. angiography-guided group [n=2,000]). There was no significant difference between the groups in the cumulative incidence of target vessel revascularisation (21.5% vs. 22.2%, p=0.57). Even after adjustment for confounders, the risk of IVUS guidance relative to angiography guidance for target vessel revascularisation remained neutral (HR 1.09, 95% CI: 0.90-1.32, p=0.37). Thus, they concluded that IVUS-guided PCI as compared with angiography-guided PCI was not associated with a lower risk for target vessel revascularisation in patients treated with first-generation DES.

Failure to demonstrate the clinical usefulness of IVUS-guided DES implantation in this study might be attributed to the following reasons. First, the definition of IVUS usage was too obscure. They did not differentiate the use of IVUS according to the timing of IVUS examination, and included the IVUS usage for pre-stent deployment, post-stent deployment, or both strategies. Thus, the effect of IVUS usage particularly for stent optimisation, which can be most important during PCI, was not accurately addressed. According to the previous IVUS-XPL trial[1], even among the patients with IVUS guidance, the clinical outcomes were totally different between the patients meeting the IVUS criteria for stent optimisation and those who did not meet the IVUS criteria (1.5% vs. 4.6%; HR 0.31, 95% CI: 0.11-0.86, p=0.02). Thus, the study evaluating the clinical efficacy of IVUS requires appropriate analyses of the measurements of IVUS parameters after DES implantation. Moreover, the lack of analyses of IVUS parameters raises the question of the extent to which the stent optimisation by IVUS was achieved in the IVUS-guided group. It is not a simple matter of usage or non-usage of IVUS, but whether the improvement of clinical outcomes is accompanied by "appropriate use of IVUS", i.e., the extent of stent optimisation by IVUS usage. The interpretation of IVUS images is not intuitive, but requires a careful understanding of what is important[1]. Second, this study was not a randomised study but an observational study with a modest sample size. Third, the authors only included patients treated with first-generation DES, which are not widely used in current practice. Fourth, in this study, all-comers treated with DES were included. Patients with chronic total occlusions were only 15.9% in the IVUS group, and the proportion of patients with a larger than 28 mm stent was 52.8%. However, rather than routine use of IVUS for stent optimisation, IVUS usage (particularly for complex lesions) could be more beneficial. Although they tried subgroup analyses, the number of patients could be too small to detect the clinical efficacy of IVUS for each subgroup, something which was different from the previous ADAPT-DES study[5].

However, it is notable that there was a trend towards a beneficial effect in small vessels in subgroup analyses, indicating the beneficial effect of IVUS particularly for small vessels. Also, the final balloon pressure was statistically greater in the IVUS group at 20 atm vs. 18 atm (p<0.0001), although the authors did not include the analyses of quantitative coronary angiography after stent implantation, which would be essential to confirm the differences in angiographic results between the two groups. Lastly, although the authors failed to demonstrate the superiority of the IVUS-guided group for target vessel revascularisation, the superiority of the IVUS-guided group was observed for all-cause death (HR 0.85, 95% CI: 0.73-0.99, p=0.04), myocardial infarction (HR 0.75, 95% CI: 0.59-0.95, p=0.02), and major adverse cardiac events (HR 0.88, 95% CI: 0.79-0.97, p=0.01) for the propensity score-matched cohort.

Taken together, the present study provides valuable lessons in terms of (i) the importance of appropriate IVUS usage in selected patients rather than routine usage along with appropriate interpretation of the IVUS images[1], (ii) the necessity of well-designed randomised trials, (iii) the need for cautious interpretation of negative findings of retrospective analyses with modest sample sizes, and (iv) the requirement for analyses of the parameters of quantitative coronary angiography and IVUS measurements.

Conflict of interest statement

The authors have no conflicts of interest to declare.

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Transcatheter aortic valve implantation in rheumatic aortic stenosis

Paul T.L. Chiam, *Deputy Editor, AsiaIntervention*

Transcatheter aortic valve implantation (TAVI) has become an established treatment for patients with severe aortic valve stenosis (AS) who are inoperable or at high surgical risk[1-6], and an attractive alternative in intermediate surgical-risk patients[7,8]. Two years after TAVI achieved European commercial approval (CE mark), the technology became established in Asia[9]. As with the global experience, TAVI has been increasingly applied in Asia to off-label indications such as bicuspid AS[10], degenerated surgical bioprosthesis (valve-in-valve TAVI)[11], non-calcific AS[12], and pure aortic regurgitation[13].

Rheumatic heart disease (RHD), although declining in incidence over the past few decades, is still relatively prevalent in many parts of Asia. With better treatment of patients with RHD, their life expectancy is expected to increase, and it is likely that we in Asia may face more patients with rheumatic AS. It is not uncommon for patients with rheumatic AS to have had several episodes of heart valve surgery for mitral and tricuspid valve pathologies. Due to the previous sternotomies, longstanding cardiac disease and advancing age, many of these patients will be at elevated risk for aortic valve replacement. Thus, TAVI may have a unique role in such patients.

The pathology of rheumatic AS is, however, quite distinct as it is due to commissural fusion, leaflet fibrosis and thickening, without significant calcification. One of the concerns of using TAVI in such patients is whether the transcatheter heart valve can be well anchored. Our group has previously demonstrated that, in a patient with systemic lupus erythematosus-associated AS (where the pathology was leaflet thickening without valve calcification), a SAPIEN XT valve (Edwards Lifesciences, Irvine, CA, USA) was implanted in a stable position[12]. As rheumatic AS involves a similar pathology to that of leaflet thickening and fibrosis, it is likely that a transcatheter valve could be successfully anchored. What remains uncertain is if the commissural fusion would be "split", as with mitral valvuloplasty, or if the annulus would merely be stretched to accommodate the new valve. There have been very few reports of TAVI in rheumatic AS[14,15], and the latest report by Gunasekaran et al[16] in this issue of AsiaIntervention adds to the growing knowledge of this niche application.

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In their report, Gunasekaran et al[16] describe a 70-year-old lady with mitral valve surgery on two previous occasions and severe comorbidities, presenting with symptomatic severe rheumatic AS. Due to her high surgical risk, TAVI was chosen as the preferred treatment option by the local Heart Team despite a lack of leaflet or annular calcification, and a SAPIEN 3 valve (Edwards Lifesciences) was successfully implanted without paravalvular leak and with satisfactory valve function at six months.

It appears that TAVI is a feasible alternative in rheumatic AS. In this author's experience of seven cases of rheumatic AS (unpublished data), TAVI, using either the SAPIEN or CoreValve (Medtronic, Minneapolis, MN, USA) prostheses, was successful in all cases with durable results at one year. With newer-generation TAVI devices which have an outer skirt (to reduce paravalvular leak) or recapturability (to enhance accurate deployment), the outcomes of TAVI in rheumatic AS can be expected to improve.

As the benefit-risk ratio of TAVI in rheumatic AS becomes more favourable, TAVI may become the first treatment choice for many patients with RHD who have undergone various interventions for mitral or tricuspid disease. This will have a significant impact in Asia where more patients with chronic RHD may present with severe rheumatic AS due to a general rise in longevity.

There are, however, questions that remain unanswered. What is the exact mechanism of the transcatheter valve expansion when deployed within a rheumatic AS, and what is the durability of TAVI in these rheumatic patients who are generally younger and may still have an ongoing low grade inflammatory response? This is one area of TAVI where Asia should and could take the lead to understand better the role(s) of TAVI in rheumatic AS.

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Antegrade approach to cross a native aortic valve

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Transcatheter aortic valve implantation (TAVI) has become a well-established treatment for patients with high and intermediate surgical risk symptomatic severe aortic stenosis (AS)[1,2]. With the widening of the indications for TAVI, the incidence of bicuspid valve in the TAVI cohort is now increasing[3]. Sometimes we encounter difficulty in crossing a bicuspid aortic valve, due to its anomalous anatomy, severe calcification, and enlarged ascending aorta. It is important to have a bail-out solution for cases where there is difficulty in crossing a native aortic valve in order to accomplish transfemoral TAVI successfully.

In this issue of AsiaIntervention, Tay et al report a novel technique for crossing a Sievers type 0 bicuspid stenotic aortic valve[4].

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Multiple attempts were performed with various catheters and wires; however, it remained difficult to cross the aortic valve. Therefore, the authors performed a transseptal puncture and guided the wire and the catheter to the left ventricle, crossing the aortic valve to the aorta via the antegrade approach. After externalisation of the wire to the sheath in the femoral artery, the valve was finally implanted via the retrograde transfemoral approach.

The antegrade approach has been used for percutaneous mitral commissurotomy[5] since 1982 using the Inoue Balloon™ (Toray Industries, Inc., Tokyo, Japan), and is also predominantly used in antegrade balloon aortic valvuloplasty in Japan[6]. Furthermore, this approach was also used in the first TAVI case[7] by Cribier et al. Therefore, using this approach it is easy to cross a stenotic calcified aortic valve and natural to use it for TAVI. This antegrade transseptal approach is also used for some mitral procedures such as percutaneous mitral valve repair (MitraClip™ [Abbott Vascular, Santa Clara, CA, USA], etc.)[8], and for left appendage closure devices[9]. Therefore, in the current era, it is of the utmost importance for interventional cardiologists to learn this technique for the future development of this field.

Despite the advent of smaller-profile sheaths in the current era, the transfemoral approach still has some limitations, namely difficulty in crossing a severely calcified aortic valve, and the potential to cause vascular complications[10]. The TAVI devices currently available cannot be used via the antegrade approach, because they are designed only for the retrograde transfemoral approach and the rigidity of the devices hinders their antegrade use. To solve the current limitations of the transfemoral approach, TAVI devices more compatible with the antegrade approach, with softer, more flexible, and lower profiles, may be developed in future. This case report has not only provided us

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with a useful bail-out technique that we should keep in our toolbox, but has also given us a glimpse into the future in terms of the development of ideal TAVI devices.

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Korean Society of Interventional Cardiology (KSIC)

Hweung-Kon Hwang, President

Hyo-Soo Kim, Chairman

The history of the national society

The Korean Society of Interventional Cardiology (KSIC) is an academic association representing Korean interventional cardiologists. As of December 2017, it has 585 active members and nine working groups including CTO, TRI, Bifurcation, Imaging and Physiology, Stent Failure, Platelet Research, Complication and Structural Heart Disease.

KSIC was founded as a working group under the Korean Society of Cardiology on 19 June 1997, and has served as the largest group in the field of cardiology. Currently, KSIC has become a representative academic association of interventional cardiological practice in Korea, both in name and reality, since its independence from the Korean Society of Cardiology in 2012. The current leadership of the KSIC comprises Professor Hyo-Soo Kim (Seoul National University Hospital) who is working as the Chairman of the Board of Directors since 2016, and Professor Hweung-Kon Hwang (Konkuk University Medical Center) who has been the President since 2017.

The mission of the KSIC is to promote research and development in the field of interventional treatment for cardiovascular disease, to facilitate mutual understanding among members, and to protect patients with cardiovascular disease in Korea. These objectives prompt us to hold an international academic conference twice a year, to have joint academic research, and to enforce a KPCI Certification System with the Korean PCI (Percutaneous Coronary Intervention) Registry and the Korean TAVI (Transcatheter Aortic Valve Implantation) Registry.

In particular, KSIC makes every effort to provide international scholars and domestic researchers with opportunities to interact with each other through the international academic conferences held in January and June/July every year, to report on the advances and excellence of domestic cardiovascular intervention, and to introduce the latest overseas research results.

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Next meetings
KSIC 2018, the 14th International Winter Conference, will be held 11-13 January 2018 in Seoul.
The KSIC Summer Conference 2018 will be held 22-23 June 2018 in Busan.

What does APSIC membership mean for the national society?

Since the academic and research fields of KSIC have grown rapidly over the last ten years, Korea has emerged as the most influential country in interventional cardiology in the Asia Pacific region. Thus, KSIC and APSIC are partners of growth and development in this field, maintaining a mutual friendship.

KSIC hopes to continue communication with Asian interventional cardiology societies through APSIC in the future. In particular, KSIC is conducting a joint session with several Asian academic associations at international academic conferences, and would like to invite APSIC, if possible.

What are the current issues related to the national society?

In recent decades, thanks to the development of therapeutic materials and drugs as well as the efforts of domestic cardiovascular intervention doctors, the management quality of cardiovascular diseases in Korea has greatly improved. The Korean national health insurance system allows Korean patients to receive PCI at a low cost because the government has cut the medical costs. Thus, the economic status of hospitals and the income of doctors in Korea is getting worse. Another issue in interventional practice here is

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the government's restriction on the number of guidewires and balloon catheters being used, leading to substantial stress being imposed on interventionists during procedures. KSIC is trying to negotiate with the government to solve these issues in order to achieve the independence of interventional doctors in the care of their patients.

The domestic field of cardiovascular disease therapy has grown rapidly with the help of the academic and industrial communities. It is now time for the academic association to play a more active public role. Reflecting this domestic situation, KSIC implemented the KPCI Certification System some 8 years ago, and implemented the Korean PCI Registry in 2014 and the Korean TAVI Registry in 2017. Regarding scientific activities, KSIC holds two conferences annually in order to provide high-quality educational opportunities to its members. About 1,500 Koreans participate in each academic conference, which means that most practitioners in the national field of cardiovascular disease attend. In addition to the private international live courses in Korea such as ENCORE-SEOUL and ASAN-LIVE, KSIC organises two nationwide conferences and is doing its best to improve the ability of Korean doctors in the field of cardiovascular disease.

What are the future vision/expectations/hopes related to the national society?

As a representative academic association of cardiovascular intervention in Korea, KSIC aims to provide its members with the high-quality educational opportunities described above, as well as to promote the stable development of domestic cardiovascular disease treatment methods, and ultimately to protect the interests of its members and patients.

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A weighted angiographic scoring model (W-CTO score) to predict success of antegrade wire crossing in chronic total occlusion: analysis from a single centre

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KEYWORDS

- chronic total occlusion
- multiple vessel disease

Abstract

Aims: The aim of this study was to derive a weighted score model predicting success/failure of antegrade wire crossing in chronic total occlusion (CTO) percutaneous coronary intervention (PCI).

Methods and results: Four hundred and four consecutive CTO cases (408 lesions) undergoing CTO-PCI between January 2009 and March 2015 were included. Data were divided into two sets, namely "derivation" and "validation", in a 70:30 ratio. The score was derived using multivariate analysis to identify independent predictors of wire crossing failure from the derivation set (n=285 lesions) and validated on the remaining 123 lesions (validation set). The overall procedural success rate was 83.6%. Independent predictors of CTO-PCI failure and their contribution to the weighted score were a blunt stump (beta coefficient 2.12), length of occlusion >20 mm (beta coefficient 1.71), presence of calcification (beta coefficient 0.72), presence of tortuosity (beta coefficient 1.06) and collateral with Rentrop grade <2 (beta coefficient 1.06). The respective scores allotted were +2.0, +1.5, +1, +1, +1 (total 6.5), rounding the coefficient to the nearest 0.5. Score values of 0-2, >2-4 and >4 were classified as low, intermediate and high levels of difficulty for CTO-PCI success and were associated with 98%, 74.2%, and 42.5% ($p<0.0001$), respectively, of antegrade wire crossing success in the derivation set. This was also validated on the validation set with CTO success in the three derived difficulty levels being 100%, 82.4% and 48.4%, respectively.

Conclusions: Our weighted angiographic CTO score is a strong predictor of final antegrade wire crossing success and could be used in day-to-day clinical practice of CTO interventions.

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Abbreviations

β	beta coefficient
CAD	coronary artery disease
CTO	chronic total occlusion
J-CTO score	Japanese chronic total occlusion score
OR	odds ratio
PCI	percutaneous coronary intervention
TIMI	Thrombolysis In Myocardial Infarction
W-CTO score	weighted chronic total occlusion score

Introduction

With improving techniques and hardware for percutaneous coronary intervention (PCI) and the increasing role of PCI in the management of obstructive coronary artery disease (CAD), chronic total occlusions (CTO), being the most challenging subset, remain the last or unconquered frontier[1-4]. Success in CTO-PCI, in addition to operator expertise, also depends on detailed angiographic analysis of the CTO lesion[5]. The Japanese chronic total occlusion score (J-CTO score) identifies five independent parameters which could predict antegrade wire crossing success/failure with an equal contribution for each predictor[6].

We hypothesised that all independent angiographic predictors may not have an equal contribution in predicting antegrade wire crossing success/failure and therefore a weighted score might be more accurate and useful for case selection in day-to-day practice. We therefore aimed to study the lesion characteristics of our cohort of about 400 CTO patients over the last six years and to establish a weighted score model predicting the level of difficulty of antegrade wire crossing.

Methods

Consecutive CTO-PCI cases between January 2009 and March 2015 were included in this study. The study protocol was approved by the local ethics committee, and all procedures were performed according to current international guidelines[7]. Baseline clinical and angiographic parameters were recorded. Lesions were defined as chronic total occlusion if the duration of occlusion was estimated to be three months or more with TIMI 0 antegrade flow. The duration of occlusion was determined from the time of onset of clinical symptoms, including timing of myocardial infarction or worsening of chest symptoms. When the duration of occlusion was uncertain and there was angiographic evidence of chronic occlusion it was labelled as of indeterminate duration.

DEFINITIONS OF ANGIOGRAPHIC PREDICTORS

Detailed specific angiographic features of the CTO lesions are described below.

1. Proximal stump/entry point: angiographic morphology of the entry point was described as “tapered” in its favourable format if the occluded segment started as a funnel-shaped ending of the leading vessel or “blunt” in its adverse format.
2. Calcification: the presence of fluoroscopic calcification on either still or moving images within the CTO segment was assigned positive for calcification.
3. Bending/tortuosity: tortuosity was defined as bending of at least >45° as assessed by angiography within the occluded segment or the vessel in close proximity.
4. Occlusion length: occlusion length was measured from the proximal end of the occlusion site to the most proximal point of retrograde filling from the ipsilateral/contralateral collateral. A simultaneous contralateral injection technique was used if distal filling was not clear on a single antegrade shot. Occlusion length was categorised into either <20 mm (favourable) or >20 mm (negative predictor) as per the consensus of the EuroCTO Club[8].
5. Presence of side branch at occlusion site: a side branch was defined as being present if a branch originated within 3 mm from the proximal endpoint of the occlusion (conventionally a negative predictor for CTO wire crossing).
6. Ostial location: an ostial location was identified if the occlusion was within 5 mm of the origin of the vessel (conventionally a negative predictor for CTO wire crossing).
7. Collateral filling of the distal segment: the grade of collateral filling of the distal vessel was based on a collateral grading system of 0 to 3, according to the Rentrop and Cohen classification[9]. For the purpose of analysis, collateral filling grades 0-1 were combined into one category while grades 2 and 3 were combined into another category using filling of the distal vessel as the primary criterion irrespective of the source of the collateral. Finally, a good opacification of the distal vessel (grades 2 and 3) vs. poor collateral filling (grade 0, 1) was compared.
8. Antegrade trickle was defined as a faint delayed trickle beyond the proximal stump in a frame-by-frame analysis, which often equates to the presence of microchannels in the absence of bridging collaterals.

Technical success was defined as the ability to cross the occluded segment successfully with a CTO wire antegradely, and <20% residual stenosis with TIMI 3 flow. The primary endpoint was final antegrade guidewire crossing success irrespective of the time required in a single procedure. In cases of antegrade failure, and the procedure was completed by the retrograde technique either in the same or in a second sitting, the case was still considered as an antegrade failure. Cases which previously failed, but succeeded in the second antegrade attempt were on the contrary categorised as CTO success.

STATISTICAL ANALYSIS

For each angiographic adverse predictor, considering a baseline probability of success of 0.25 with its presence in a negative format and an alternative probability of success of 0.5 in its absence at 95% power, and 5% level of significance, the minimum sample size was estimated to be 190. Adding a design effect of 1.5, a total of 285 cases were required for the study.

As failure of antegrade wire crossing was the primary event, predictors of failure were identified using binary logistic regression analysis. The variables were not pre-specified and were

identified using univariate analysis considering antegrade wire crossing failure as the final outcome. Such identified univariate variables were then used for multivariable logistic regression.

At the outset, the data were divided into two sets in a ratio of 70:30, the first set being the "derivation set" and the second set being the "validation set", based on simple random sampling. A weighted score was then derived for each identified multivariate predictor in proportion to the respective beta coefficient obtained for the same, rounded off to the nearest 0.5. A level of difficulty score for a CTO procedure was then determined for each case in the derivation set by assigning points for each of these predictors present and then summing them all into a weighted CTO score (W-CTO). As a next step, the derived scores were then applied to each individual patient in the derivation data set and a hypothetical level of difficultly determined using cut-offs for probability of success of more than 90%, 50-89% and <50% and assigning them difficulty levels of low, intermediate and high, respectively. The score model thus derived was then validated using a computation of the W-CTO score for each patient in the validation set and matched for consistency using a Z-test. A p-value <0.05 was considered significant. A goodness of fit was derived using the Hosmer-Lemeshow test.

Having validated the W-CTO score, as a second step, our derived W-CTO score was additionally applied to the entire data set again and a level of difficulty for individual cases worked out using this score model. The J-CTO score was also simultaneously computed for each patient in the entire data set using the methodology described by Morino et al[6].

The real-time predictability of the two scores was then compared using receiver operating characteristic (ROC) curve analysis[10]. All computations were carried out using SPSS, Version 22 (IBM Corp., Armonk, NY, USA).

Results

Between January 2009 and March 2015, a total of 404 consecutive patients with 408 CTO lesions underwent PCI at our centre and formed the study cohort.

BASELINE DEMOGRAPHICS AND CTO ANGIOGRAPHIC DETAILS

Table 1 shows the baseline demographics of the entire patient subset including the age/sex distribution, risk factor profile, clinical parameters and the CTO angiographic details and the success and failure in the entire patient cohort. The mean age of subjects was 57.1±9.4 years, with the majority (88.5%) male. About one third of patients were diabetic, half were hypertensive, and two fifths were smokers. About half of our patients had stable angina alone. History of previous myocardial infarction was present in 14.5%. The majority (80.9%) of cases had a relatively preserved left ventricle ejection fraction (LVEF >50%). Single-vessel disease was present in 57%, double-vessel disease in 36%, and only 7% had triple-vessel disease. One hundred and eighty-two (44.6%) of our patients had a total occlusion duration of less than one year, while 192 (47.1%) had occlusion of more than a year, and 34 (8.3%) had an indeterminate duration of occlusion.

LESION CHARACTERISTICS

Table 1 also presents a summary of the different angiographic characteristics of the CTO lesions in the entire patient subset and the related procedural success. The left anterior descending (LAD) artery was the most common CTO vessel (42.6%), followed by the right coronary artery (RCA: 40%) and left circumflex (LCx: 17.4%). An occlusion length of >20 mm was present in 46.8%, 36.8% had a blunt stump, 31.1% had a bend of >45° and 32.1% of lesions had calcification. Bridging collaterals were seen in 13% and the presence of a side branch at the proximal stump was present in 26.5% of lesions. Previously attempted lesions were only 5.4%.

Classifying the lesions in accordance with the J-CTO score, 22.3% of lesions were classified as easy, 27.5% as intermediate, 30.4% as difficult, and 19.9% as very difficult with their J-CTO scores being 0, 1, 2 or ≥3, respectively, as depicted in **Table 2**. Antegrade wire crossing success at the first attempt was obtained in a total of 334 (81.9%) CTO lesions. Amongst lesions where an antegrade attempt failed (T4), a retrograde attempt was made in 30 cases of which 24 cases (80%) were successful and a second antegrade attempt was made in twenty-two (22) lesions, of which 17 (77.2%) were successful. Primarily 22 lesions were kept on medical follow-up alone.

PROCEDURAL CHARACTERISTICS

The procedural characteristics are presented in **Table 3**. The femoral approach was used in 13% of cases, the radial approach in 43%, a combined radial and femoral approach in 17% of cases, and a bilateral femoral approach in 26%. Contralateral injection to visualise the occluded segment filling through contralateral collaterals was carried out in 285 (69.8%). In the remaining 31.2% of cases, the distal vessel was visualised either through ipsilateral collaterals or antegrade trickle through a recanalised segment or bridging collaterals. In all cases, the antegrade approach was tried initially with a wire escalation strategy followed by parallel wiring if the wire went subintimal. If both techniques failed, then it was perceived as CTO antegrade failure and a retrograde approach was carried out depending upon the operator decision. Microcatheter support plus a Fielder XT (Asahi Intecc, Aichi, Japan) wire technique was used in 244 (59.6%) with success achieved in 164 (40.2%) cases. A parallel wire technique was attempted in 72 (17.6%) cases and a penetration technique to cross the CTO lesion was attempted in 99 (24.3%) cases. Gaia wires (Asahi Intecc) were available for use only after August 2013 (the last one and a half years) so the experience to a large extent is from the pre-Gaia era. In total, 24 (5.8%) cases had a Gaia wire used, with success achieved in 22 (91.6%). Crusade catheter-based parallel wiring (Kaneka, Osaka, Japan) was also available only after August 2013. The antegrade dissection re-entry technique using the CrossBoss™ and Stingray™ coronary CTO crossing and re-entry devices (Boston Scientific, Marlborough, MA, USA) were not available during this study.

Table 1. Clinical and angiographic lesion characteristics in the study patients.

Variables		Total population, N=408 (%)	Derivation set, N=285 (%)	Validation set, N=123 (%)	*p*-value
Age (years)		57.1±9.4	57.7±9.5	56.1±9.3	0.18*
Male sex		361 (88.5%)	251 (88.1%)	110 (89.4%)	0.69
Diabetes		131 (32.1%)	84 (29.5%)	47 (38.2%)	0.08
Hypertension		204 (50%)	141 (49.5%)	63 (51.2%)	0.75
Smoking		173 (42.1%)	119 (41.8%)	54 (43.9%)	0.69
LVEF	>50%	330 (80.9%)	18 (6.3%)	11 (8.9%)	0.45
	30-50%	49 (12%)	37 (13%)	12 (9.8%)	
	<30%	29 (7.1%)	230 (80.7%)	100 (81.3%)	
Clinical symptom	CSA	233 (57.1%)	155 (54.4%)	78 (63.4%)	0.08
	ACS	116 (28.4%)	82 (28.8%)	34 (27.6%)	
	MI	59 (14.5%)	48 (16.8%)	11 (9.0%)	
Lesion site	LAD	174 (42.6%)	114 (40%)	60 (48.8%)	0.26
	LCx	71 (17.4%)	52 (18.2%)	19 (15.4%)	
	RCA	163 (40%)	119 (41.8%)	44 (35.8%)	
Duration of occlusion	3 months to 1 year	182 (44.6%)	132 (46.3%)	50 (40.7%)	0.33
	>1 year	192 (47.1%)	133 (45.9%)	61 (49.5%)	
	Indeterminate	34 (8.3%)	22 (7.7%)	12 (9.7%)	
Proximal cap blunt		150 (36.8%)	97 (34%)	53 (43.1%)	0.08
Side branch present		108 (26.5%)	71 (24.9%)	37 (30.1%)	0.28
Bridging collaterals present		53 (13%)	37 (13%)	16 (13%)	0.99
Length of occlusion >20 mm		191 (46.8%)	131 (46%)	60 (48.8%)	0.60
Calcification present		131 (32.1%)	92 (32.3%)	39 (31.7%)	0.91
Tortuosity present		127 (31.1%)	90 (31.6%)	37 (30.1%)	0.76
Ostial		53 (13%)	34 (11.9%)	19 (15.4%)	0.33
Antegrade trickle present (microchannels)		148 (36.3%)	107 (37.5%)	41 (33.3%)	0.42
Rentrop grade <2		355 (87%)	243 (85.3%)	112 (91.1%)	0.11
Ipsilateral collateral present		189 (46.3%)	134 (47%)	55 (44.7%)	0.67
Contralateral collateral present		184 (45.1%)	124 (43.5%)	60 (48.8%)	0.33
In-stent lesion		14 (3.4%)	9 (3.2%)	5 (4.1%)	0.77
Previous failed attempt		22 (5.4%)	17 (6%)	5 (4.1%)	0.44
J-CTO score		1.52±1.1	1.5±1.1	1.6±1.2	0.52*
Total AG success		341 (83.6%)	235 (82.5%)	106 (86.2%)	0.35

*Mann-Whitney test. ACS: acute coronary syndrome; AG: antegrade; CSA: chronic stable angina; LAD: left anterior descending artery; LCx: left circumflex artery; MI: myocardial infarction; RCA: right coronary artery

DERIVATION AND VALIDATION SET ANALYSIS AND DEVELOPMENT OF WEIGHTED SCORES

The baseline clinical characteristics of cases stratified into two data sets in a proportion of 70:30 with n=285 in the "derivation set" and n=123 in the "validation set" are shown in **Table 1**. The two sets were matched for all independent variables.

Table 2. The J-CTO score distribution and related success in the entire patient data set.

J-CTO score	Number of patients (%) N=408	CTO success (%)
0	91 (22.3%)	100%
1	112 (27.5%)	95.5%
2	124 (30.4%)	81.5%
≥3	81 (19.9%)	51.9%

UNIVARIATE/MULTIVARIATE PREDICTORS

Table 4 shows the univariate predictors of antegrade wire crossing failure in the derivation set. Factors with a significant p-value on univariate analysis were then assessed by multivariate analysis. The multivariate predictors including their beta coefficients (β) and odds ratio (OR) predicting failure are shown in **Table 5**. Blunt stump (β=2.07; OR 7.9, 95% CI: 3.66-17.08; p<0.001), length of occlusion >20 mm (β=1.54; OR 4.68, 95% CI: 2.09-10.47; p<0.001), presence of calcification (β=0.81; OR 2.25, 95% CI: 1.06-4.77; p=0.036), presence of tortuosity (β=1.11; OR 3.02, 95% CI: 1.43-6.39; p=0.004), and collateral with Rentrop grade <2 (β=1.09; OR 2.97, 95% CI: 1.22-7.21; p=0.016) emerged as independent predictors of CTO-PCI failure.

The score assigned to each independent variable was derived in proportion to its beta coefficient **(Table 5)**. For each CTO lesion,

Table 3. Procedural characteristics in the study patients.

		N=408 (%)
Approach	Bilateral femoral	157 (39%)
	Radial	123 (30%)
	Femoral+radial	128 (31%)
Contralateral injection needed		285 (69.8%)
CTO wiring technique (microcatheter)		408 (100%)
Microcatheter	+Fielder XT (loose tissue tracking)	244 (59.6%)
	+Penetration technique	99 (24.3%)
	+Parallel wire technique	72 (17.6%)
	+Gaia wire	24 (5.8%)
Balloon crossing difficulty		36 (8.8%)
	Anchoring balloon technique	10 (2.5%)
	Rotablation	2 (0.5%)
GuideLiner		5 (1.2%)
Tornus		6 (1.4%)
Newer devices (after August 2013)	Gaia wire	24 (5.8%)
	Crusade	17 (4.2%)
Mean contrast volume (ml)		295 (150-800)
Mean number of stents per patient		1.68

all applicable score values were then summed to obtain a total difficulty level of that lesion as per our new score model (W-CTO). The total weighted score thus derived with a maximum of 6.5 (W-CTO score) was then segregated into three levels of difficulty as per predefined criteria in methodology. The difficulty levels thus derived ascribed a low level of difficulty to 0-2, intermediate to 2.5-4 and high >4. The success rate of CTO-PCI was 98%, 74.2% and 42.5%, in low, intermediate and high levels of difficulty W-CTO scores, respectively.

The levels of difficulty cut-offs as derived from the new score model in the derivation set were then applied to the validation set and a predictive value for CTO-PCI success was worked out on the validation set. **Figure 1** shows the matching of the difficulty level computation in the derivation and validation sets using the Z-test. The goodness of fit for our model using the Hosmer-Lemeshow test was significant at a level of 0.86 with an x^2 of 2.594.

COMPARISON OF THE WEIGHTED W-CTO SCORE WITH THE J-CTO SCORE

Figure 2 shows the predictive accuracy of our weighted score model (W-CTO) and the existing J-CTO score by applying both the scores on the entire data set **(Figure 2)**. The predictability

Table 4. Univariate predictors amongst clinical and lesion-related variables in the "derivation" data set.

Variables		OR	95% CI	β coefficient	*p*-value
Age (years)		1.03	0.99-1.06	0.03	0.07
Male sex		2.38	0.69-8.12	0.87	0.17
Diabetes		0.92	0.47-1.81	–0.09	0.80
Hypertension		1.25	0.68-2.29	0.22	0.48
Smoking		1.23	0.67-2.28	0.21	0.50
Presenting problem (ref: CSA)	ACS	0.53	0.25-1.11	–0.63	0.09
	MI	0.31	0.11-0.93	–1.17	0.036
	Duration (ref: <1 year) ≥1 year	1.68	0.89-3.15	0.52	0.109
Lesion (ref: LAD)	RCA	1.35	0.69-2.64	0.29	0.386
	LCx	0.97	0.39-2.4	–0.03	0.947
LVEF fraction (ref: >50%)	30-50%	1.31	0.56-3.08	0.27	0.535
	<30%	0.59	0.13-2.68	–0.52	0.498
Proximal cap blunt		8.30	4.14-16.66	2.12	<0.001
Side branch present		2.68	1.41-5.09	0.99	0.003
Bridging collaterals present		1.62	0.71-3.69	0.48	0.249
Length of occlusion >20 mm		5.51	2.69-11.31	1.71	<0.001
Calcification present		2.05	1.10-3.82	0.72	0.024
Tortuosity present		2.89	1.55-5.41	1.06	<0.001
Ostial present		2.60	1.17-5.76	0.96	0.019
Antegrade trickle present		4.55	1.96-10.54	–1.5	<0.001
Rentrop grade <2		4.55	1.38-5.98	1.06	0.005
In-stent		0.58	0.07-4.74	–0.55	0.61
Previous attempt		1.48	0.46-4.76	0.39	0.506

ACS: acute coronary syndrome; CI: confidence interval; CSA: chronic stable angina; LCx: left circumflex artery; LVEF: left ventricular ejection fraction; MI: myocardial infarction; OR: odds ratio; RCA: right coronary artery

Table 5. Independent predictors for CTO-PCI failure on multivariate analysis and their weighted contribution to W-CTO score.

Variables	β coefficient	*p*-value	OR (95% CI)	Score
Proximal cap blunt	2.07	<0.0001	7.90 (3.65-17.08)	+2
Length of occlusion >20 mm	1.54	<0.0001	4.68 (2.09-10.47)	+1.5
Tortuosity present	1.11	0.004	3.02 (1.43-6.39)	+1
Rentrop grade <2	1.09	0.016	2.97 (1.22-7.21)	+1
Calcification present	0.81	0.036	2.25 (1.06-4.77)	+1
Total score (W-CTO)				+6.5

CI: confidence interval; OR: odds ratio

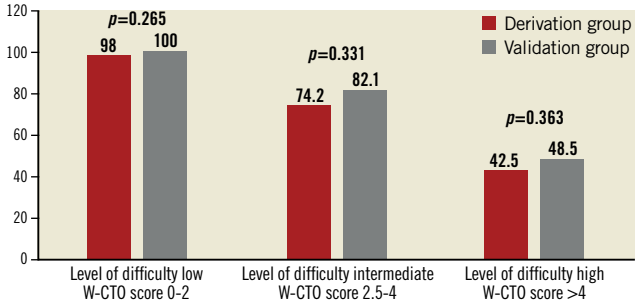

Figure 1. *Matching of success rate in different lesions in the "derivation" and "validation" sets stratified into three levels of difficulty, namely low, intermediate and high, using the derived W-CTO scores.*

of antegrade wire crossing success was demonstrated to be better with the W-CTO score as compared to the J-CTO score (ROC AUC of 0.82 [J-CTO] vs. 0.86 [W-CTO], p=0.009).

PROCEDURE-RELATED COMPLICATIONS

In-hospital death occurred in a total of four cases (1%). Coronary perforation leading to pericardial tamponade occurred in four cases (1%). No patient required temporary or permanent haemodialysis and no cases of radiation-induced cutaneous injury occurred in our study population. No patient required emergency CABG.

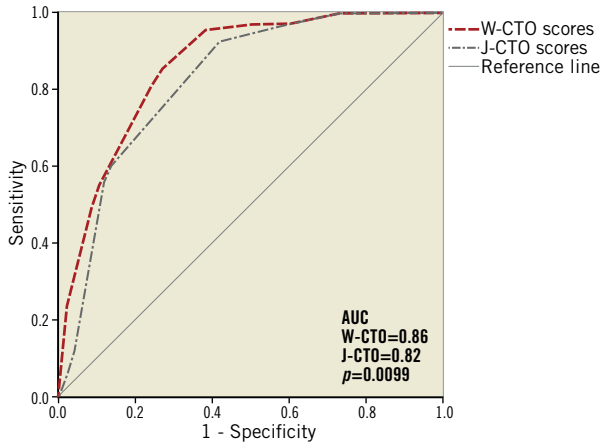

Figure 2. *ROC curves comparing the predictive value of guidewire crossing success/failure using the W-CTO and J-CTO scores from the entire data set.*

Discussion

This is a single-centre analysis of 404 consecutive patients who underwent antegrade CTO-PCI. An angiographic scoring system to predict CTO-PCI success/failure has been attempted before[5,6,11-15]. A large proportion of this data is from a Japanese or European population and none from Indian patients, who have smaller calibre vessels, more diffuse disease and a younger age at presentation[16,17]. The J-CTO score is a commonly used scoring model and was derived from a study on 479 CTO cases. Our data included an almost equally large number of CTO lesions (n=408), if not more. However, the time duration during which the cases were collected was about two years in the J-CTO registry and six years in our study, ours being a single-centre study.

Our total success rates of 100%, 95.5%, 81.5% and 51.9% for lesions with J-CTO levels of difficulty of 0, 1, 2, and >3, respectively, were in line with the success rates observed in the J-CTO registry of 97.8%, 92.3%, 88.4%, and 73.3% with levels of difficulty 0, 1, 2 & ≥3, respectively. The distribution pattern of the level of difficulty of different lesions in our data set using the already published J-CTO scores conformed to the spectrum of CTO cases in the J-CTO registry, suggesting no major difference of lesion types in terms of the level of difficulty between the two data sets.

WHY A WEIGHTED SCORE

Predictors of antegrade wire crossing may not contribute equally to the outcome of the CTO success. The weighted contribution of each variable was also evident through the differing beta coefficients and odds ratios observed in the multivariate regression analysis of the J-CTO registry data, a point which was brought out by the authors in discussion but was somehow discarded in working out the score model considering the different coefficients to be in close proximity. However, on in-depth analysis of the J-CTO results, one finds that a few of the coefficients were at least twice the minimum, giving a relative importance of at least two times. In the light of the same thought, our weighted score model (W-CTO score), with a total score of 6.5 and individual values as shown in **Table 3**, could be more accurate when used on a wider patient base by different operators in different patient subsets in day-to-day clinical practice.

OTHER SCORE MODELS

In a recent study, Alessandrino et al proposed a clinical and lesion-related (CL) score which included two clinical variables (history of CABG and history of MI) and four lesion-related variables (blunt stump, lesion calcification, non-LAD CTO, and lesion length >20 mm) as independent predictors of unsuccessful CTO-PCI with a weighted score given to each parameter[11]. In our study, since there were only two cases of history of CABG, this did not affect the outcome analysis.

Recently, Galassi et al developed a weighted predictive score model for technical failure in CTO-PCI. The ORA score included three predictors of CTO failure: ostial location, Rentrop collateral grade <2, and age >75, assigning 1, 2, and 1 points, respectively[18]. However, this study included cases carried out via both the antegrade and retrograde techniques, which was different from our study which evaluated only antegrade wiring. As such, the requirement for retrograde success could be somewhat different from antegrade success.

PREDICTORS AS OBSERVED IN OUR STUDY VS. PREDICTORS OBSERVED IN THE J-CTO REGISTRY

In this study, multivariate predictors of failure included a proximal blunt cap, lesion length >20 mm, presence of calcification and tortuosity or bending within the lesion, similar to those noted in the J-CTO registry. A "previous failed attempt", which was a predictor in the J-CTO score, did not however stand out in our data set, which might have been because of a difference in the types of repeat cases or numbers of those being accepted for repeat attempts by us vs. those in the J-CTO registry. Also, Syrseloudis et al did not find a correlation between a previously failed attempt and final CTO success[12].

In addition to the J-CTO score predictors, one important predictor of failure in our study was a poor distal target vessel and/or its poor opacification with collaterals, i.e., collaterals with Rentrop grade <2. Louvard et al had also observed a mean Rentrop collateral grade to be significantly higher in cases with CTO success compared to failure (1.5+1 vs. 1.3+0.7, p=0.002), making it a predictor of CTO antegrade wire crossing failure. We summed Rentrop collaterals grade 2 and 3 together as a group with better collateral filling and better distal vessel visualisation: this turned out to be a favourable predictor for CTO success as compared to poor distal vessel filling (Rentrop collateral grade 0-1 only) which proved to be negative.

There was no significant difference in the CTO-PCI success rate with respect to the artery involved. This is different from one of the earlier studies by Hasegawa et al, which showed lower procedural success rates in RCA (71.8%) followed by LAD (74.8%) and LCx (79.0%)[13]. Maeremans et al showed a similar success rate of CTO-PCI in all three vessels, as in our study[19]. The periprocedural complication rates were also comparable to the earlier studies[20-22].

Limitations

Firstly, this study included only those cases which, as per the operator, qualified to be managed interventionally as a whole. It is likely that cases with very heavy calcification, very long occlusions, or occlusion as part of diffuse TVD may have been left out, leading to selection bias. Secondly, being a single-centre and a single primary operator study there could be a case selection bias and results could differ because of the different complexity of cases selected for analysis. However, as mentioned earlier in the discussion, our data set and the J-CTO registry data set were not dissimilar with respect to distribution of level of difficulty of the lesions and total success rates, both features helping to override the above limitation to a large extent, if not completely.

Conclusions

We conclude that the weighted angiographic CTO score model (W-CTO) derived by us is highly predictive of final antegrade wire crossing success/failure and could be used as a predictive tool in day-to-day practice in elective CTO-PCI patients.

Impact on daily practice

We believe that our weighted CTO score model, with a predictive capacity as good as or even better than the prevalent J-CTO score, could prove useful in prospective selection of cases for CTO intervention. It should, however, be kept in mind that, with rapidly advancing technology, new scoring models will need to include the newer approaches and hardware.

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Conflict of interest statement

The authors have no conflicts of interest to declare.

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Intravascular ultrasound-guided versus angiography-guided percutaneous coronary intervention with drug-eluting stents: five-year outcomes from the CREDO-Kyoto PCI/CABG registry

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KEYWORDS

- drug-eluting stent
- intravascular ultrasound
- stable angina

Abstract

Aims: We sought to investigate the clinical impact of intravascular ultrasound (IVUS) use in first-generation drug-eluting stent (DES) implantation as compared with angiography guidance only.

Methods and results: From the CREDO-Kyoto registry cohort-2, the current study population consisted of 4,768 patients treated with first-generation DES only without acute myocardial infarction (AMI) at enrolment. As a retrospective cohort study, we compared clinical outcomes between the two groups of patients with or without IVUS use during the procedure (IVUS group: N=2,768, angiography group: N=2,000). The outcome measures were target vessel revascularisation (TVR), target lesion revascularisation (TLR), all-cause death, myocardial infarction, stent thrombosis, and major adverse cardiovascular events. There was no significant difference between the groups in the cumulative incidence of TVR (21.5% vs. 22.2%, p=0.57). Even after adjusting the confounders, the risk of IVUS use relative to angiography guidance for TVR remained neutral (HR: 1.09, 95% CI: 0.90-1.32, p=0.37).

Conclusions: IVUS-guided PCI as compared with angiography-guided PCI was not associated with a lower risk of TVR in non-AMI patients treated with first-generation DES.

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Abbreviations

AMI	acute myocardial infarction
BMS	bare metal stent
CABG	coronary artery bypass grafting
CI	confidence interval
DES	drug-eluting stent
HR	hazard ratio
IVUS	intravascular ultrasound
MI	myocardial infarction
PCI	percutaneous coronary intervention
RCT	randomised controlled trial
STEMI	ST-elevation myocardial infarction
TVR	target vessel revascularisation

Introduction

Intravascular ultrasound (IVUS) has been utilised in percutaneous coronary intervention (PCI) not only for obtaining more accurate information about the coronary anatomy and the implanted stents, but also for earlier detection of procedure-related complications and suboptimal stent expansion[1-3]. Accordingly, previous observational and randomised studies have demonstrated the clinical efficacy of IVUS-guided PCI in the bare metal stent (BMS) era[1,4]. However, with the advent of drug-eluting stents (DES), several recent studies have reported inconsistent results regarding the advantage of IVUS guidance in PCI[5-8]. Therefore, we aimed to investigate the long-term clinical outcomes of IVUS-guided PCI as compared with angiography-guided PCI using DES in a large Japanese observational database of patients undergoing first coronary revascularisation.

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Methods

STUDY POPULATION

The Coronary REvascularization Demonstrating Outcome Study in Kyoto (CREDO-Kyoto) PCI/CABG registry cohort-2 is a physician-initiated, non-company sponsored, multicentre registry which enrolled consecutive patients who underwent first coronary revascularisation in 26 centres in Japan between January 2005 and December 2007 **(Supplementary Appendix 1)**. The relevant review boards or ethics committees in all participating centres approved the research protocol. Because of retrospective enrolment, written informed consent from the patients was waived; however, we excluded those patients who refused to participate in the study when contacted at follow-up. This strategy is in accordance with the guidelines for epidemiological studies issued by the Ministry of Health, Labor and Welfare of Japan.

Among 15,939 patients enrolled in this registry, the current study population included 4,768 patients without acute myocardial infarction (AMI) at enrolment, who underwent PCI using DES only, after excluding 86 patients who refused study participation, 2,795 patients who underwent coronary artery bypass grafting (CABG), 4,721 AMI patients, 601 patients who had both DES and BMS implantation, 2,502 patients who received BMS only, and 466 patients who had no stent implantation **(Figure 1)**. The

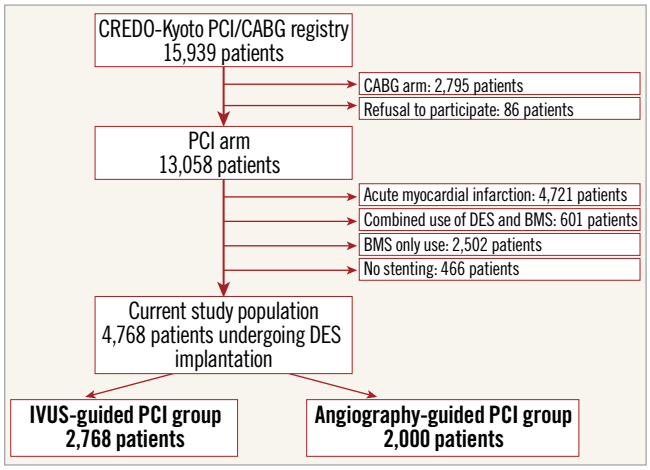


Figure 1 *Study flow chart. CABG: coronary artery bypass grafting; CREDO-Kyoto registry: Coronary REvascularization Demonstrating Outcome Study in Kyoto registry; DES: drug-eluting stent; IVUS: intravascular ultrasound; PCI: percutaneous coronary intervention*

study patients were classified into two groups according to the use of IVUS during the procedure: 2,768 patients (58.1%) who underwent IVUS-guided DES implantation (IVUS group) and 2,000 patients (41.9%) who underwent angiography-guided DES implantation without the use of IVUS (angiography group).

DEFINITIONS AND ENDPOINTS

Definitions of baseline clinical characteristics have been described in detail previously[9]. IVUS-guided PCI was defined as PCI with the use of IVUS regardless of the type of IVUS catheter(s) or the timing of IVUS examination (pre- or post-stent deployment or both). Angiography-guided PCI was defined as PCI performed without IVUS use.

The outcome measures for the current analysis were target vessel revascularisation (TVR), clinically driven TVR, target lesion revascularisation (TLR), clinically driven TLR, all-cause death, myocardial infarction (MI), definite stent thrombosis (ST), and major adverse cardiac events (MACE), defined as a composite of all-cause death, MI, or TVR. TVR was defined as any repeat revascularisation for the coronary vessels stented at the index PCI procedure. TLR was defined as either repeat percutaneous or surgical revascularisation for a lesion anywhere within the stent or the 5 mm borders proximal or distal to the stent. Death was regarded as cardiac in origin unless obvious non-cardiac causes could be identified. MI was defined according to the definition in the Arterial Revascularization Therapy Study[10]. Definite ST was defined as thrombosis at the target lesion, confirmed by angiography or autopsy in accordance with the criteria of the Academic Research Consortium[11].

DATA COLLECTION FOR BASELINE CHARACTERISTICS AND FOLLOW-UP EVENTS

Demographic, angiographic, and procedural data were collected from hospital charts or hospital databases according to

the pre-specified definitions by experienced clinical research co-ordinators from the study management centre (Research Institute for Production Development, Kyoto, Japan) **(Supplementary Appendix 2)**. In this retrospective cohort study, data collection for follow-up events was performed in 2010 and 2012. Collection of follow-up information was mainly conducted through review of the in-patient and out-patient hospital charts by the clinical research co-ordinators, and additional follow-up information was collected through contact with patients, relatives and/or referring physicians by sending mails with questions regarding vital status, subsequent hospitalisations, and status of antiplatelet therapy. Death, MI, ST, and stroke were adjudicated by the clinical events committee **(Supplementary Appendix 3)**. Median follow-up duration was 1,864 (interquartile range [IQR]: 1,589-2,143) days.

STATISTICAL ANALYSIS

We expressed categorical variables as numbers and percentages, and continuous variables as the mean±standard deviation. We compared categorical variables with the χ^2 test when suitable. Otherwise, we used Fisher's exact test. We compared continuous variables with the Student's t-test or the Wilcoxon rank-sum test based on their distributions. We used the Kaplan-Meier method to estimate cumulative incidences of the clinical events and evaluated the difference with the log-rank test. Consistent with our previous reports, we used a multivariable Cox proportional hazards model stratified by participating centres to estimate the effects of PCI under IVUS use for the outcome measures by incorporating 37 clinically relevant risk-adjusting variables, as listed in **Table 1** and **Table 2**, together with IVUS use. Proportional hazard assumptions for the risk-adjusting variables were assessed on the plots of log (time) versus log (-log [survival]) stratified by the variable and it was confirmed that the assumptions were acceptable for all the variables. We calculated adjusted hazard ratios (HR) and their 95% confidence intervals (CI). We could not conduct multivariable adjustment for definite ST due to the small number of events. Furthermore, as observational studies inevitably involve the inherent limitations of measured and unmeasured confounders, a propensity score-matching analysis was additionally performed as a sensitivity analysis. A logistic regression model was used to compute the propensity score for the use of IVUS with 13 independent variables relevant to the use of IVUS **(Table 1, Table 2)**. Using the propensity score, patients in the IVUS group were matched to ones in the angio group. Clinical outcomes were compared between the IVUS and the angio groups in the propensity score-matched cohorts. Cumulative incidence was estimated by the Kaplan-Meier method and the difference was assessed with the log-rank test. As all the clinically relevant variables were not well matched, we conducted an adjusted comparison using Cox proportional hazard models with 10 clinically relevant adjusting variables **(Table 1, Table 2)**. As in our previous reports, we dichotomised continuous variables by using clinically relevant reference values or median values. We also evaluated the effect of IVUS use on TVR in several clinically relevant subgroups including diabetes

Table 1. Baseline patient characteristics.

Variables	IVUS group N=2,768	Angiography group N=2,000	*p*-value
Clinical characteristics			
Age	68.5±9.8	68.5±10.2	0.91
*>75 years	845 (30.5%)	602 (30.1%)	0.75
*Male gender	1,979 (71.5%)	1,433 (71.7%)	0.91
Body mass index	23.7±3.4	23.9±3.5	0.03
*<25.0 kg/m²	1,855 (67.0%)	1,308 (65.4%)	0.24
*Hypertension	2,347 (84.8%)	1,664 (83.2%)	0.14
Diabetes mellitus	1,148 (41.5%)	861 (43.1%)	0.28
*requiring insulin therapy	286 (10.3%)	241 (12.1%)	0.06
*Current smoking	672 (24.3%)	530 (26.5%)	0.08
*Heart failure (current and prior)	404 (14.6%)	310 (15.5%)	0.39
*Multivessel disease	1,669 (60.0%)	1,188 (59.4%)	0.53
*Mitral regurgitation 3-4/4	82 (3.0%)	88 (4.4%)	0.009
*Previous myocardial infarction	378 (13.7%)	348 (17.4%)	0.0004
*Previous stroke	342 (12.4%)	226 (11.3%)	0.27
*Peripheral vascular disease	236 (8.5%)	196 (9.8%)	0.13
Left ventricular ejection fraction	61.5±12.5 (2,556)	60.0±13.1 (1,658)	0.0003
≤40%	173/2,556 (6.8%)	154/1,658 (9.3%)	0.003
*eGFR <30, without haemodialysis	99 (3.6%)	80 (4.0%)	0.45
*Haemodialysis	139 (5.0%)	104 (5.2%)	0.78
*Atrial fibrillation	225 (8.1%)	160 (8.0%)	0.87
*Anaemia (haemoglobin <11.0 g/dl)	322 (11.6%)	246 (12.3%)	0.48
*Thrombocytopaenia (platelet <100*109/L)	37 (1.3%)	27 (1.4%)	0.97
*COPD	87 (3.1%)	83 (4.2%)	0.07
*Liver cirrhosis	64 (2.3%)	49 (2.5%)	0.76
*Malignancy	243 (8.8%)	186 (9.3%)	0.54
Medication at discharge			
Aspirin	2,732 (98.7%)	1,971 (98.6%)	0.66
Thienopyridine	2,759 (99.7%)	1,995 (99.8%)	0.63
*Cilostazole	264 (9.5%)	138 (6.9%)	0.001
*Statin	1,603 (57.9%)	961 (48.1%)	<0.0001
*ACE-I/ARB	1,474 (53.3%)	962 (48.1%)	0.0004
*β-blocker	720 (26.0%)	521 (26.1%)	0.98
*Calcium channel blocker	1,458 (52.7%)	1,005 (50.3%)	0.10
*Nitrate	940 (19.7%)	838 (17.6%)	<0.0001
*Nicorandil	656 (23.7%)	401 (20.1%)	0.003
*PPI	648 (23.4%)	365 (18.3%)	<0.0001
*H2 blocker	630 (22.8%)	390 (19.5%)	0.007
*Warfarin	217 (7.8%)	149 (7.5%)	0.62

Categorical variables are expressed as number (%) unless otherwise indicated. Continuous variables are shown as mean±SD. *Risk-adjusting variables selected for the multivariable analysis. ACE-I/ARB: angiotensin-converting enzyme inhibitor/angiotensin receptor blocker; COPD: chronic obstructive pulmonary disease; eGFR: estimated glomerular filtration rate; IVUS: intravascular ultrasound; PPI: proton pump inhibitor

Table 2. Angiographic and procedural characteristics.

Variables	IVUS group N=2,768	Angiography group N=2,000	*p*-value
Target lesion			
*Unprotected LMCA	117 (4.2%)	62 (3.1%)	0.04
*Proximal LAD	1,827 (66.0%)	1,167 (58.4%)	<0.001
LAD	1,892 (68.4%)	1,218 (60.9%)	<0.001
LCX	799 (28.9%)	659 (33.0%)	0.003
RCA	993 (35.9%)	789 (39.5%)	0.01
*Bifurcated lesion	1,208 (43.6%)	770 (38.5%)	0.0004
*Chronic total occlusion	353 (12.8%)	383 (19.2%)	<0.0001
*Side branch stenting	142 (5.1%)	128 (6.4%)	0.06
Sirolimus-eluting stent use	2,537 (91.7%)	1,892 (94.6%)	<0.0001
Implanted stents	2 (1-2)	2 (1-2)	0.26
Total stent length (mm)	36 (23-56)	33 (18-56)	0.14
*>28 mm	1,570 (56.7%)	1,053 (52.7%)	0.005
Minimal stent diameter (mm)	2.75 (2.5-3.0)	2.5 (2.5-3.0)	0.004
*<3.0 mm	1,425 (51.5%)	1,082 (54.1%)	0.07
Final balloon pressure (atmosphere)	18.4±3.5 (3,752/3,984)	17.2±3.6 (2,631/2,830)	<0.0001

Categorical variables are expressed as number (%) unless otherwise indicated. Continuous variables are shown as mean±SD or median (interquartile range). *Risk-adjusting variables selected for the multivariable analysis. IVUS: intravascular ultrasound; LAD: left anterior descending coronary artery; LCX: left circumflex coronary artery; LMCA: left main coronary artery; RCA: right coronary artery

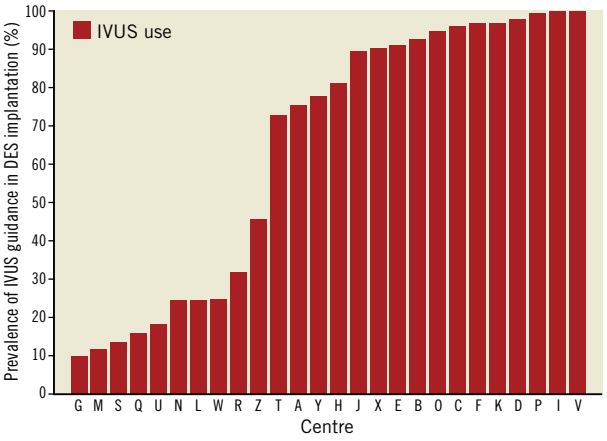


Figure 2. *Prevalence of IVUS use according to centre. DES: drug-eluting stent; IVUS: intravascular ultrasound*

mellitus, total stent length (≤28 mm and >28 mm), multivessel disease, minimum stent diameter (≥3 mm or <3 mm), and the frequency of IVUS use in each centre (>70% or ≤70%). Statistical analyses were performed by a physician (H. Watanabe) with JMP 10.0 (SAS Institute Inc., Cary, NC, USA) software and by a statistician (T. Morimoto) with SAS 9.4 (SAS Institute Inc.) software. All the statistical analyses were two-tailed. P-values <0.05 were considered statistically significant.

Results

BASELINE CHARACTERISTICS

Among the 4,768 study patients for the current analysis, 2,768 patients (58%) received DES implantation under IVUS use. There was a sharply bipolar division regarding the prevalence of IVUS use among the 26 participating centres with median of 79%: more than 70% of the total PCI procedures were performed under IVUS use in 16 centres (62%), while less than 30% of the total PCI procedures were performed under IVUS use in eight centres (31%) **(Figure 2)**. The baseline characteristics are not very different between the IVUS and the angiography groups, except for the higher prevalence of patients with greater body mass index, severe mitral regurgitation, previous myocardial infarction, and left ventricular ejection fraction ≤40% in the angiography group than in the IVUS group **(Table 1)**. As for the medications at discharge, cilostazole, statins, angiotensin-converting inhibitors/angiotensin receptor blockers, nitrate, nicorandil, proton pump inhibitors and H2 blockers were more often used in the IVUS group than in the angiography group **(Table 1)**. Regarding angiographic and procedural characteristics, patients in the IVUS group more often had the target lesions in an unprotected left main artery, and proximal left anterior descending artery, as well as bifurcation lesions, but less often had chronic total occlusion, and the target lesions in the left circumflex artery, and right coronary artery **(Table 2)**. The IVUS group had larger minimal stent diameter, higher final balloon pressure, and a greater prevalence of long (>28 mm) stent use than the angiography group **(Table 2)**.

LONG-TERM CLINICAL OUTCOMES

The cumulative five-year incidence of TVR was not significantly different between the IVUS and the angiography groups (21.5% versus 22.2%, log rank p=0.57) **(Table 3, Figure 2)**. Even after adjusting the confounders, the risk of IVUS guidance relative to angiography guidance for TVR remained neutral (HR: 1.09, 95% CI: 0.90-1.32, p=0.37) **(Table 3)**.

The adjusted risks of IVUS guidance relative to angiography guidance for all-cause death and MACE were also neutral (HR: 0.93, 95% CI: 0.87-1.17, p=0.65, HR: 0.82, 95% CI: 0.65-1.02, p=0.08, and HR: 0.96, 95% CI: 0.83-1.11, p=0.64, respectively), although the cumulative five-year incidences of all-cause death and MACE were significantly lower in the IVUS group than in the angiography group **(Table 3)**. There was no significant difference in the cumulative five-year incidences of clinically driven TVR, TLR, clinically driven TLR, MI and definite ST between the two groups **(Table 3)**.

The neutral adjusted risk for TVR between the IVUS and the angiography groups was observed consistently across the subgroups stratified by diabetes mellitus, total stent length, minimum stent diameter, the number of coronary lesions, and the frequency

Table 3. Crude and adjusted 5-year clinical outcomes: IVUS group versus angiography group.

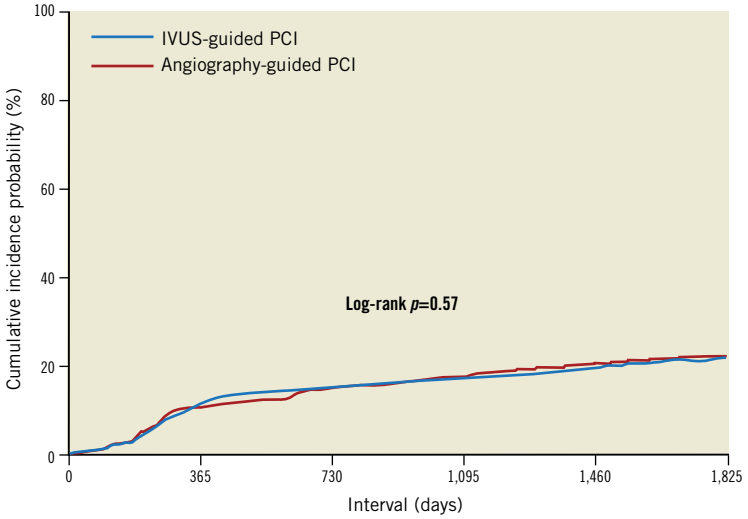
Variables	IVUS group Number of patients with events (cumulative 5-year incidence) N=2,768	Angio group Number of patients with events (cumulative 5-year incidence) N=2,000	Crude HR (95% CI)	*p*-value (log-rank)	Adjusted HR (95% CI)	*p*-value
TVR	556 (21.5%)	408 (22.2%)	0.97 (0.85-1.09)	0.57	1.09 (0.90-1.32)	0.37
Clinically driven TVR	281 (11.3%)	211 (11.8%)	0.94 (0.79-1.11)	0.44	1.01 (0.78-1.31)	0.93
TLR	413 (16.0%)	292 (15.9%)	1.01 (0.87-1.17)	0.93	1.04 (0.89-1.20)	0.65
Clinically driven TLR	192 (7.9%)	134 (7.7%)	1.00 (0.81-1.23)	0.97	1.00 (0.80-1.24)	0.99
All-cause death	368 (14.1%)	303 (16.0%)	0.85 (0.74-0.98)	0.02	0.82 (0.65-1.02)	0.08
Myocardial infarction	177 (6.8%)	143 (7.4%)	0.84 (0.68-1.04)	0.12	0.87 (0.62-1.22)	0.41
Stent thrombosis (definite)	31 (1.2%)	20 (1.1%)	1.14 (0.68-1.98)	0.62	–	–
MACE	905 (33.9%)	697 (36.2%)	0.90 (0.82-0.99)	0.02	0.96 (0.83-1.11)	0.64

Cumulative incidence was estimated by the Kaplan-Meier method. CI: confidence interval; HR: hazard ratio; IVUS: intravascular ultrasound; MACE: major adverse cardiac events; TLR: target lesion revascularisation; TVR: target vessel revascularisation

of IVUS in each centre **(Figure 3)**. There were no significant interactions between the subgroup factors and the effect of IVUS guidance relative to angiography guidance for TVR **(Figure 4)**.

SENSITIVITY ANALYSIS

We performed propensity score matching, which selected 1,932 patients in each group using 13 risk variables influencing the use of IVUS **(Supplementary Table 1-Supplementary Table 3)**. The result from the analysis for the primary outcome measure (TVR) was consistent with the result from the Cox model. We observed significant between-group differences in all-cause death as well as MI in the propensity score-matched analysis, which might be explained by the residual confounding related to the important between-group differences in the prevalence of previous MI, LVEF, and low LVEF after propensity score matching **(Supplementary Table 1)**.



Interval	0 day	1 year	3 years	5 years
IVUS-guided group				
No. of patients with at least one event		307	455	556
No. of patients at risk	2,768	2,375	2,051	1,198
Cumulative incidence probability		11.3%	17.0%	21.5%
Angio-guided group				
No. of patients with at least one event		205	334	408
No. of patients at risk	2,000	1,707	1,459	857
Cumulative incidence probability		10.6%	17.6%	22.2%

Figure 3. *Kaplan-Meier curve for the crude cumulative incidence of target vessel revascularisation in the IVUS group and the angio group.*

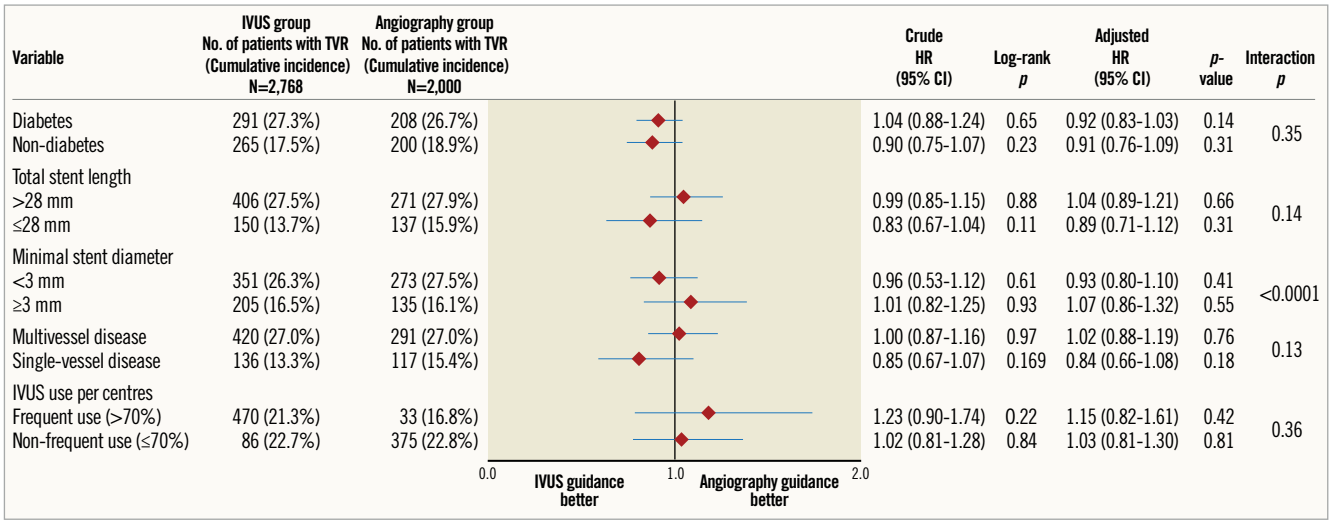


Figure 4. *Subgroup analyses and forest plots of hazard ratio for target vessel revascularisation (primary outcome measure). CI: confidence interval; HR: hazard ratio; TVR: target vessel revascularisation*

Discussion

The principal finding in the current analysis is that IVUS-guided PCI was not associated with a lower risk for TVR in non-AMI patients treated with first-generation DES.

No standardised criteria have been established for IVUS-guided PCI; however, our current IVUS guidance strategy is based on hypotheses extrapolated from previous IVUS studies[2,3]. In short, our current IVUS guidance strategy is to target the complete lesion coverage from "healthy" to "healthy" site and appropriate expansion of the stent matching the reference segment. However, this strategy was somewhat limited by the fact that the use of longer stents resulted in higher rates for stent thrombosis and restenosis[12,13]. It was sometimes difficult to find an optimal landing site with less plaque in severe atherosclerotic lesions as in diabetic patients, which might also weaken the efficacy of this strategy. Considering the balance between less plaque burden in the landing point and the shorter stent length, our arbitrary decision in IVUS-guided DES implantation might be unavoidable, which might influence the efficacy of the IVUS-guided DES implantation.

Concerning clinical data, available randomised and observational data are relatively scarce and the results are conflicting[5-8,14]. One of the recent trials indicating the advantage of IVUS use was the IVUS-XPL (Intravascular Ultrasound Guidance on Outcomes of XIENCE Prime Stents in Long Lesions) randomised trial, which was the largest one to date, randomising 1,400 study participants to IVUS-guided PCI versus angiography-guided PCI[8]. It demonstrated the usefulness of IVUS-guided DES implantation on long lesions. IVUS-guided everolimus-eluting stent (EES) implantation was associated with a lower rate of the composite of MACE at one year in comparison with angiography-guided EES implantation (2.9% vs. 5.8%, HR: 0.48, 95% CI: 0.28-0.83, p=0.007). The difference was mainly due to a lower risk of ischaemia-driven target lesion revascularisation (TLR) between the groups (2.5% vs. 5.0%, HR: 0.51, 95% CI: 0.28-0.91, p=0.02). Currently, this is the only adequately powered randomised trial to have evaluated the efficacy of IVUS guidance, but it may not be immune to some limitations, although "randomised" trials are generally regarded as providing the highest level of evidence. The open label trial design might introduce important biases particularly in this type of strategic trial. The final stent optimisation might not have been sufficient in the angiography-guided PCI group if the investigators had had the intention to get positive results for IVUS. The targeted procedural endpoint in the angiography-guided PCI group was less than 30% residual stenosis by visual estimation, and post-stent dilatation was not recommended if this procedural endpoint was satisfied. Actually, the prevalence of post-dilatation was lower in the angiography-guided PCI group than in the IVUS-guided PCI group (57% vs. 76%, p<0.001), resulting in greater residual diameter stenosis in the angiography-guided PCI group (13.74±8.05% vs. 12.79±8.66%, p=0.04). The use of TLR as an endpoint may not be without problems in this type of open label randomised trial, because the occurrence of TLR could be highly influenced by the physicians' decision.

As an observational study, ADAPT-DES (The Assessment of Dual Antiplatelet Therapy With Drug-Eluting Stents) is the largest study to date (enrolling 8,583 patients), which suggested the clinical efficacy of IVUS-guided DES implantation. IVUS guidance compared with angiography guidance was strongly associated with reduced one-year rates of definite/probable stent thrombosis (0.6% vs. 3.7%, adjusted HR: 0.40, 95% CI: 0.21-0.73, p=0.003), MI (2.5% vs. 3.7%, adjusted HR: 0.70, 95% CI: 0.55-0.88, p=0.004), and MACE, defined as a composite of cardiac death, MI, or stent thrombosis (3.1% vs. 4.7%, adjusted HR: 0.70, 95% CI: 0.55-0.88, p=0.004)[15]. However, we should note that the study population

was a mixture of AMI and non-AMI patients. The advantage of IVUS-guided PCI in patients with AMI also remains a subject of debate[16,17]. Furthermore, the median prevalence of IVUS use across the 11 enrolling sites was only 33% (ranging from 1% to 90%), which was much lower than that in the present study (79%). In the present study, there was a sharply bipolar division regarding the prevalence of IVUS use among the participating centres, indicating that both IVUS-guided and angiography-guided PCI procedures were largely performed in centres that are proficient in either strategy. These differences in the demographics and prevalence of IVUS use among different studies might lead to different results in the comparison of clinical outcomes between the IVUS-guided and angiography-guided PCI procedures.

In both randomised trials and observational studies, it would not be possible to draw a simple and generalised conclusion such as that IVUS-guided PCI is better than angiography-guided PCI, or vice versa. Achieving the optimal luminal outcome has been recognised as the most important determinant of stent-related clinical outcomes such as target lesion revascularisation and stent thrombosis, although DES are much more forgiving than BMS in terms of minimum requirement for the luminal outcome. Therefore, we should pursue achieving the optimal luminal outcome in both IVUS-guided and angiography-guided PCI procedures. IVUS guidance might be useful, for example, in detecting underexpansion of the stent that could not be easily recognised by angiography, while responding to those subtle IVUS findings such as malapposition and minor dissections may not improve clinical outcomes, but may result in just increasing the procedural time and cost. We might be able to compromise on the debate of IVUS-guided versus angiography-guided PCI by taking a balanced attitude towards using IVUS when something is in doubt by angiography.

Limitations

The current study has many limitations. First, this retrospective observational study could not exclude unmeasured confounders despite extensive multivariable adjustment. In particular, one of the major limitations is that we set no clear criteria for IVUS guidance, particularly about optimised stent implantation, in our analysis. The decision and timing of the IVUS examination (prior to and/or after stent deployment) and how to utilise the information from the IVUS images depended on the operator. Second, although our study targeted patients undergoing first-generation DES implantation, second-generation DES are currently being used for PCI in daily clinical practice. Third, no quantitative measurements in the IVUS or angiographic images were available and the effect of these parameters on clinical outcomes was not assessed in the current analysis. Furthermore, the angiograms of patients with TLR were not analysed by the independent angiographic core laboratory. Fourth, the degree of proficiency in IVUS examination in routine procedures differed from one hospital to another. Also, the procedural endpoint, practice patterns and clinical outcomes might have been different according to centre. Although our statistical adjustment included stratification by participating centre, a cautious attitude should be taken in generalising the results of this analysis to hospitals with limited experience of IVUS-guided PCI.

Conclusions

In this observational study, IVUS-guided PCI as compared with angiography-guided PCI was not associated with a lower risk for TVR in non-AMI patients treated with first-generation DES.

Impact on daily practice

As our study clearly suggested a neutral result as to IVUS use in non-AMI patients treated with first-generation DES, this topic requires further investigation. We should focus on stent optimisation guided by IVUS in the era of second- or third-generation DES.

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Conflict of interest statement

The authors have no conflicts of interest to declare.

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Supplementary data

Supplementary Appendix 1. List of participating centres and investigators for the CREDO-Kyoto PCI/CABG registry cohort-2.

Supplementary Appendix 2. List of clinical research co-ordinators.

Supplementary Appendix 3. List of clinical events committee members.

Supplementary Table 1. Baseline patient characteristics in the propensity score-matched cohorts.

Supplementary Table 2. Angiographic and procedural characteristics in the propensity score-matched cohorts.

Supplementary Table 3. Clinical outcomes in the IVUS and the angio groups.

The supplementary data are published online at: www.asiaintervention.org

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Left main bifurcation percutaneous coronary intervention using a drug-eluting stent and drug-coated balloon: optical frequency domain imaging follow-up

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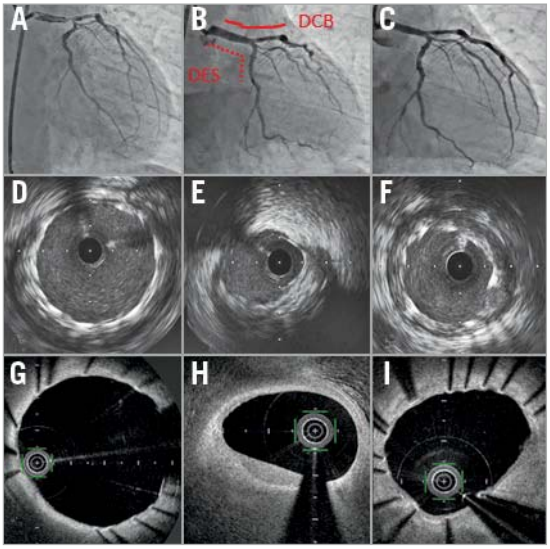

A 65-year-old man with stable angina pectoris was admitted for percutaneous coronary intervention. Coronary angiography (CAG) detected a left main artery (LM) true bifurcation lesion with the following stenotic percentages: 90%, distal LM; 90%, left circumflex artery (LCX); and 75%, left anterior descending artery (LAD) **(Panel A)**. A 3.5×18 mm Resolute Integrity® drug-eluting stent (DES) (Medtronic Vascular, Santa Rosa, CA, USA) was implanted between the LM and the proximal LCX. CAG was performed after kissing balloon inflation using a 3.0×15 mm SeQuent Please® drug-coated balloon (DCB) (B. Braun, Melsungen, Germany) for the LAD and delivery balloon for the LCX **(Panel B)**. Intravascular ultrasound showed a well-dilated stent in the LM **(Panel D)** and LCX **(Panel F)**, and a high echoic intimal layer at the intimal surface, considered paclitaxel in the LAD **(Panel E)**.

He was symptom-free at the 12-month follow-up. CAG detected no restenosis in the LM bifurcation lesion **(Panel C)**. Optical frequency domain imaging showed well-dilated, completely covered stent struts in the LM **(Panel G)** and LCX **(Panel I)**, and a sufficient lumen and smooth surface just proximal to the LAD treated with the DCB **(Panel H)**. Fractional flow reserve at the LAD was 0.81.

Further observation is necessary to monitor plaque progression; however, this strategy reduced the duration of dual antiplatelet therapy, radiation time, and use of contrast media without complex stenting, e.g., culotte stenting. A combination of DES and DCB is effective for treating an LM true bifurcation lesion.

Conflict of interest statement

The authors have no conflicts of interest to declare.

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SAPIEN 3 valve implantation in rheumatic aortic stenosis with a functioning mitral prosthesis: first case report from India

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Introduction

Transcatheter aortic valve implantation (TAVI) is a rapidly evolving therapeutic option for patients with severe aortic stenosis who are high risk for surgery or for inoperable patients[1]. Indications for TAVI are evolving as it is being used as an option for intermediate-risk and low-risk patients. Data on the use of TAVI in rheumatic aortic stenosis are not widely available and have not been reported from India.

Pathology in rheumatic aortic stenosis differs from calcific severe aortic stenosis[2] and is characterised by commissural fusion with restricted opening and no calcification. We present a case report of TAVI in rheumatic aortic stenosis and prior mitral valve replacement with multiple comorbidities.

Editorial, see page 11

Description

A 70-year-old lady presented with a history of rheumatic heart disease and closed mitral valvotomy in 1978, mitral valve replacement with a prosthetic mechanical mitral valve (27 mm Medtronic-Hall prosthesis; Medtronic, Minneapolis, MN, USA) and De Vega's tricuspid annuloplasty in 2003. She had a past history of culture negative infective endocarditis in 2005 (treated with six weeks of antibiotic therapy), was a known diabetic, hypertensive, with severe bronchial asthma and had atrial fibrillation. She also had 90% right internal carotid artery stenosis and normal pressure hydrocephalus. She was cleared by the neurologist for TAVI. In view of high morbidity (48.153%) and mortality (14.249%) STS risk scores, she was rejected by cardiothoracic surgeons for surgical aortic valve replacement. An echocardiogram revealed a normally functioning mitral prosthesis **(Figure 1)**, severe aortic stenosis with an aortic valve area of 0.5 cm^2 and a mean aortic pressure gradient of 45 mmHg, and normal left ventricular systolic function. The aortic valve was thickened with commissural fusion and had very minimal calcification. Computed tomography evaluation **(Figure 2)** showed tricuspid aortic leaflets with very minimal calcification, annulus diameter of 19.88 mm, and coronary height of 13.9 mm on the right side and 10 mm on the left side. Her epicardial coronaries were normal with adequately sized iliofemorals

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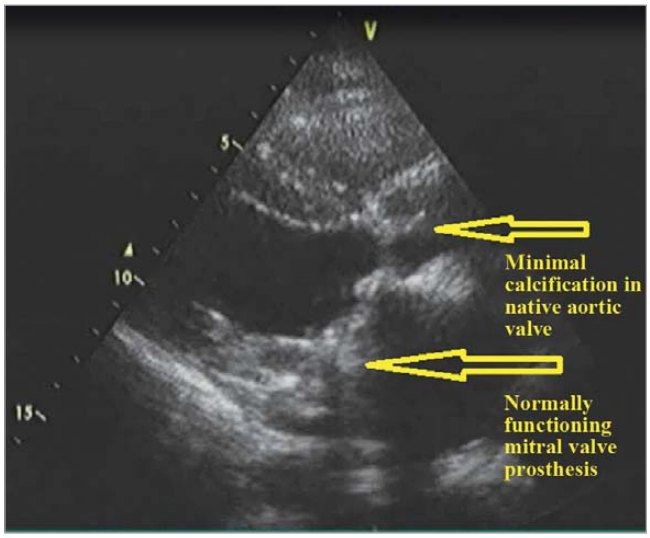

Figure 1. *Echocardiogram showing very minimal aortic valve calcification.*

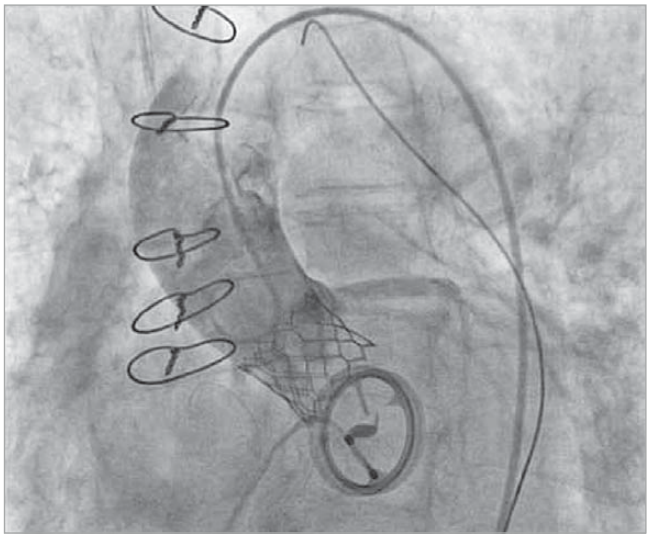

Figure 3. *Final result with a 23 mm SAPIEN 3 valve.*

and, after Heart Team discussion, she was considered for transfemoral TAVI. Although TAVI is usually indicated for degenerative aortic stenosis and not for rheumatic aortic stenosis, it was considered as an alternative in this case due to very high surgical risk.

Balloon aortic valvuloplasty and a simultaneous aortogram were carried out in order to assess annular size and also to look for coronary occlusion. A balloon-expandable SAPIEN 3 valve (Edwards Lifesciences, Irvine, CA, USA), oversized by 25%, was chosen to prevent valve embolisation and paravalvular leak. A 23 mm SAPIEN 3 valve was meticulously positioned, and slowly deployed during rapid ventricular pacing to achieve precise positioning. We achieved satisfactory haemodynamics and a final aortogram showed no paravalvular leak **(Figure 3)**. She was discharged in a stable condition after a week. She has completed six months of clinical follow-up with an echocardiogram showing excellent valve function.

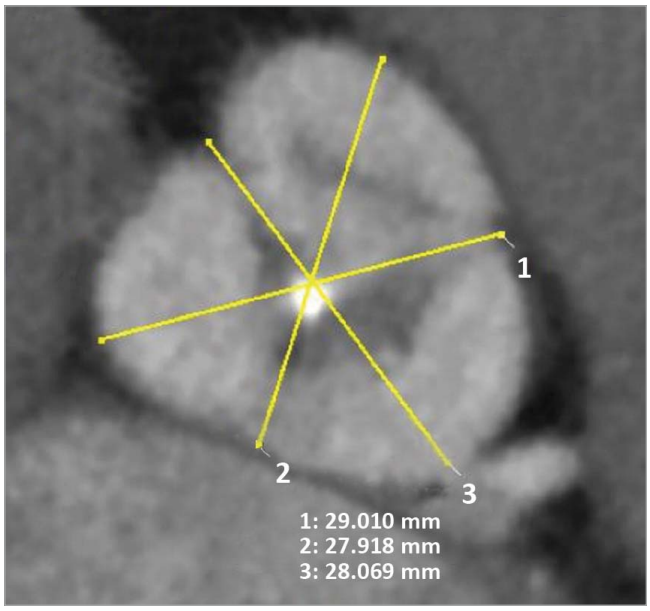

Figure 2. *Computed tomography of the aortic valve showing very minimal aortic valve calcification.*

Discussion and limitations

The use of TAVI as a therapeutic strategy is considered a relative contraindication in rheumatic aortic stenosis[3]. The presence of annular/leaflet calcium is essential for performing TAVI as it helps to anchor the valve and prevent valve embolisation. Our case was unique with extreme high risk. The anticipated challenges were minimal calcification, low coronary height on the left side and the presence of a functioning mitral prosthesis, all of which increased the risk of valve embolisation and coronary occlusion.

Recent reports have shown that about one in 10 patients in the USA have TAVI for an off-label indication, especially aortic or mitral regurgitation and bicuspid aortic valves. In multivariate analysis, one-year mortality was no different in patients who had TAVI for an off-label condition relative to those who had TAVR for an on-label indication[4]. Apart from degenerative aortic stenosis, other expanded indications include (i) patients with patent coronary bypass grafts, especially functioning internal thoracic arteries, (ii) failed aortic bioprosthesis, at least 23 mm in size, avoiding resternotomies for cardiac reoperation, and (iii) patients with contraindications for sternotomy (e.g., retrosternal oesophageal conduits).

As a transcatheter valve requires annular/leaflet calcification to anchor it, in this case we chose to oversize the valve to prevent device embolisation. Moreover, an oversized valve and the annular symmetry of the patient's native valve might in fact favourably decrease the development of residual paravalvular leak. Despite the limited height of the coronary ostium, adequate

sinus width and the absence of bulky leaflet calcification may also reduce the risks of coronary ostial occlusion. Regarding the choice of valve, both self-expanding and balloon-expandable were considered. The Medtronic Evolut™ R valve (Medtronic) would have the advantage of repositioning up to 80% deployment, but has to be implanted in a deeper position relative to other valves and may not only interfere with the mitral prosthesis but could also potentially cause displacement towards the aorta and lead to inadequate positioning. The SAPIEN 3 valve was chosen considering the lesser possibility of its interference with the mitral prosthesis. Coronary occlusion was not a major concern due to the absence of bulky leaflet calcium and also visualisation of patent coronaries during the simultaneous aortogram carried out along with balloon valvuloplasty. One can also consider newly available fully repositionable and completely recapturable devices in this situation.

The SAPIEN 3 valve, in view of its non-repositionable characteristics, should be precisely positioned in the aortic annulus, with adequate pacing and slow deployment of the valve which is critical to assure stable implantation. Although device embolisation usually occurs early, it may occur later and hence a stringent follow-up is necessary.

Finally, this is a good beginning to start clinical trials for rheumatic aortic stenosis, especially in developing countries where we still see patients with rheumatic valvular heart disease.

Conclusion

TAVI can be performed in patients with rheumatic aortic stenosis who are not candidates for surgery after meticulous planning. The presence of minimal annular calcium and/or slight oversizing of the valve might help to anchor the valve. In the presence of a functioning mitral prosthesis, adequate pacing, meticulous positioning and slow deployment are crucial to ensure that the valve is not too deep in order to avoid mitral paravalvular leak.

Impact on daily practice

The indications for TAVI may expand further, and proper planning and execution is vital in complex cases. It is time to start registries for TAVI in rheumatic aortic stenosis, particularly from developing countries.

Conflict of interest statement

The authors have no conflicts of interest to declare.

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Hybrid technique to bail out an unsuccessful transfemoral TAVR attempt

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Abstract

The most common route to perform transcatheter aortic valve replacement (TAVR) is via the transfemoral access. The success of this technique hinges on the successful passage of guidewires across the stenosed aortic valve. Although this is possible in the majority of cases, this case illustrates an occasional anomaly. In this report, we describe a novel hybrid technique involving a transseptal access as well as the formation of a continuous arteriovenous loop to complete the procedure successfully. This technique also has an additional advantage as it maintains the feasibility of performing the procedure under local anaesthesia and conscious sedation.

Abbreviations

AV loop	arteriovenous loop
BAV	balloon aortic valvuloplasty
LA	left atrium
LV	left ventricle
PTFE	polytetrafluoroethylene
TAVR	transcatheter aortic valve replacement
TF	transfemoral
VSD	ventricular septal defect

Introduction

Transcatheter aortic valve replacement (TAVR) via the transfemoral (TF) access is a well-established technique to treat anatomically suitable intermediate to high surgical risk patients with severe aortic valve stenosis. Prior screening with computed tomography ensures a high degree of technical success. Occasionally, cases may be aborted due to failure of the retrograde approach when guidewires are unable to cross the calcified aortic valve leaflets. In such situations, the case is aborted and an alternative access (e.g., transapical) needs to be contemplated. This case report describes a novel technique which may enable such cases to be completed successfully.

Editorial, see page 14

Discussion

A 64-year-old lady with a background of severe pulmonary arterial hypertension and lung disease was progressively dyspnoeic from severe aortic valve stenosis. Her resting oxygen saturation was 88% and she also had significant obstructive sleep apnoea. A TAVR was considered after discussion with the heart and respiratory team due to high surgical risks. She had a Sievers type 0 bicuspid aortic valve with mean gradient of 46 mmHg and an estimated aortic valve area of 0.8 cm^2. Computed tomography

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demonstrated a horizontal aorta with an annular perimeter of 80.4 mm.

We selected a 26 mm Evolut™ R valve (Medtronic, Minneapolis, MN, USA) for TAVR and performed the case under conscious sedation and local anaesthesia due to concern about worsening hypoxia. The procedure proceeded unremarkably initially with a Sentrant (Medtronic) 14 Fr sheath placed in the right femoral artery and a 6 and 5 Fr sheath placed in the left arterial and femoral artery, respectively. The latter two permitted the placement of a pigtail in the aortic root and a pacing wire in the right ventricle.

We then faced significant difficulty in the retrograde crossing of the aortic valve. Multiple attempts were performed with various catheters (6 Fr AL1, AL2, multipurpose, pigtail, Judkins right 3 and 4, Amplatz right) and both straight-tipped Terumo and polytetrafluoroethylene (PTFE) wires. Attempts using coronary wires were also futile.

We switched to a transseptal approach utilising another access on the right femoral vein. This was performed with a Fast-Cath™ SL0 sheath and BRK™ needle (Abbott, Abbott Park, IL, USA) **(Figure 1A)**. After the tip of the SL0 sheath was in the left atrium, an exchange length Terumo wire (Terumo Corp., Tokyo, Japan) was manoeuvred antegradely into the left atrium. Guided by this Terumo wire, a pigtail was positioned into the left atrium and, using this, we managed to direct the Terumo wire through the mitral valve into the left ventricle in an antegrade fashion and then further direct the Terumo wire to cross the aortic valve antegradely into the aorta (**Figure 1B**-**Figure 1D**). This Terumo wire was then snared using an Amplatz GooseNeck® Snare (Medtronic) placed through the 14 Fr Sentrant sheath and positioned at the level of the descending thoracic aorta. The Terumo wire was then externalised out of the Sentrant sheath to form a continuous arteriovenous loop **(Figure 1E)**. We decided not to use the continuous AV loop as a rail to deliver the EnVeo delivery system (Medtronic) due to significant tension on the inner curve of the aorta and the risk of a dissection. Instead, a 5 Fr 90 mm Flexor® Shuttle® Guiding Sheath (Cook Inc., Bloomington, IN, USA) was then tracked over the Terumo wire via the 14 Fr Sentrant arterial sheath to cross the aortic valve retrogradely supported by the AV loop **(Figure 1F)**. Once the shuttle sheath was in the left ventricle, the Terumo wire was removed and then a Confida™ wire (Medtronic) was placed through the shuttle sheath in the LV **(Figure 1G)**. The shuttle sheath was removed and exchanged for the EnVeo delivery system. The rest of the implant was unremarkable and the procedure was completed successfully **(Figure 1H)**.

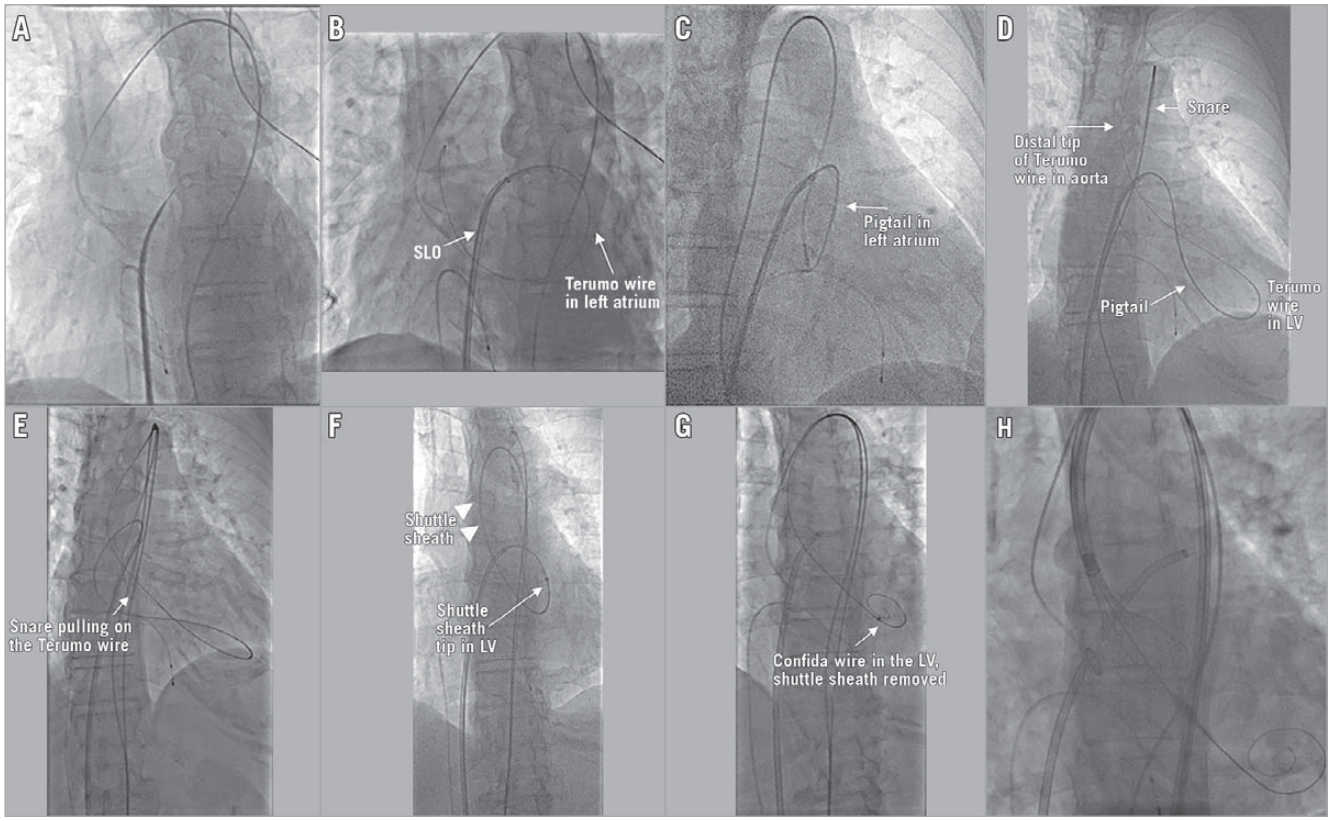

Figure 1. *Procedural steps for the hybrid technique. A) Transseptal puncture. B) SLO sheath placed in the LA with the exchange length Terumo wire looping within the LA. C) Using a pigtail to manoeuvre the wire into the ventricle antegradely. D) Manoeuvring the Terumo wire into the aorta. E) Snaring the Terumo wire and forming a continuous AV loop. Externalising the wire out of the femoral artery. F) Using the AV loop to deliver a Shuttle sheath (via arterial sheath in femoral artery) across the aortic valve retrogradely. G) Placing the Confida wire via the shuttle sheath into the LV. H) Implanting the 26 mm Evolut R valve.*

Crossing the aortic valve using the retrograde approach is a pivotal step in transfemoral TAVR. There have been very few data on failure rates; however, they are likely to be rare (<1%) but may be a cause of an aborted TAVR procedure[1]. In this case, the difficulty occurred due to the bicuspid and calcified morphology of the aortic valve **(Figure 2)**. Balloon aortic valvuloplasty (BAV) registries also do not mention this complication as only the outcomes of patients with successful BAV are reported. The alternative for a failed TF procedure could be a transapical approach. A full antegrade approach is also possible and was historically the first published approach for TAVR[2]. These are, however, more invasive and technically demanding.

A transseptal technique and forming a continuous AV loop are both well-established techniques (e.g., for VSD closure or paravalvular leak closures) and may be utilised in rare situations such as these. We would caution against using the AV loop as a rail for the larger and more rigid TAVR devices as there would invariably be tension placed on the inner curve of the aorta and passage of a large device may increase the risk of aortic dissection.

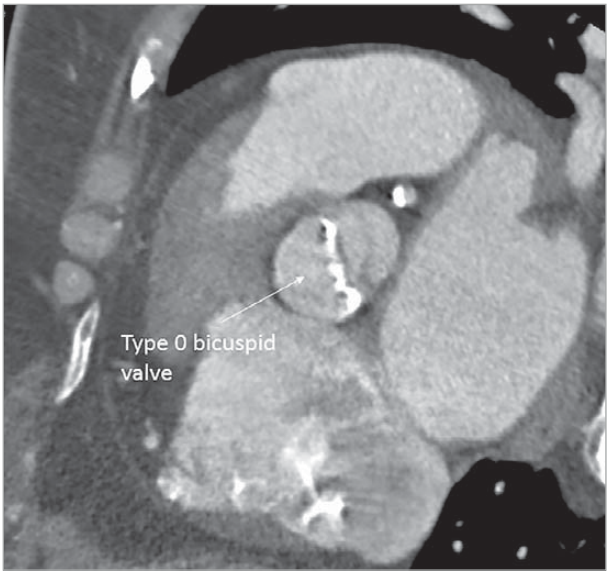

Figure 2. *Anatomy of the aortic valve (type 0) may have contributed to the difficulty in crossing.*

Conclusions

A novel hybrid transseptal with retrograde crossing technique can be considered during difficult retrograde entry of the aortic valve and will improve the rates of technical success during transfemoral TAVR.

Impact on daily practice

This technique enables operators to have an alternative technique to cross the aortic valve in TAVR situations where retrograde crossing is not possible.

Conflict of interest statement

The authors have no conflicts of interest to declare.

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Transfemoral aortic valve implantation using the reverse X-ray image in a patient with dextrocardia situs inversus

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KEYWORDS

- aortic stenosis
- conduction abnormalities
- femoral
- TAVI

Abstract

A frail 94-year-old man, who had dextrocardia situs inversus and symptomatic severe aortic stenosis, underwent transcatheter aortic valve implantation (TAVI) using the femoral approach. Computed tomography showed that there were no other cardiovascular malformations. Generally, it was difficult to maintain awareness of the position between his heart and ascending aorta during the procedure because of the inversion of these structures. Therefore, the reverse X-ray image was used to facilitate TAVI, and the procedure was successful without complications. However, nine days after TAVI, he developed complete atrioventricular block that was symptomatic. Therefore, he underwent cardiac pacemaker implantation using the reverse X-ray image to help position the atrial and ventricular leads.

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Abbreviations

AS	aortic stenosis
AVB	atrioventricular block
CT	computed tomography
PMI	pacemaker implantation
SVC	superior vena cava
TAVI	transcatheter aortic valve implantation

Introduction

Transcatheter aortic valve implantation (TAVI) is increasingly used in patients who have symptomatic aortic stenosis (AS) and have a high risk for an invasive operation or contraindications for surgery[1,2]. Generally, it is difficult to perform any cardiovascular interventions in patients with dextrocardia situs inversus, because this condition is rare and makes it difficult to understand the relative anatomical locations of the heart and great vessels. There have been few reports of TAVI in patients with dextrocardia situs inversus. We report a patient with dextrocardia situs inversus who underwent TAVI and then required pacemaker implantation (PMI) due to delayed onset complete atrioventricular block (AVB).

Methods and results

A 94-year-old man who had dextrocardia situs inversus was referred to our hospital with recurrent syncope. His medical history included congestive heart failure, hypertension and dementia. The electrocardiogram showed sinus rhythm and first-degree AVB without bundle branch block. Echocardiography showed a heavily calcified aortic valve with a mean gradient of 46 mmHg, normal left ventricular systolic function and no other significant valvular disease. Coronary angiography revealed no significant stenosis. In addition, computed tomography (CT) showed dextrocardia **(Figure 1)**, which consisted of a right-sided aorta and left-sided inferior vena cava. CT also showed an aortic annulus area of 416 mm^2 and a mean diameter of 23 mm. Furthermore, CT demonstrated suitable iliofemoral arteries without stenosis or calcification that could be used as an access route. Our Heart Team concluded that he was a candidate for transfemoral TAVI, because of his advanced age and frailty despite an intermediate surgical risk (logistic EuroSCORE 13.6% and Society of Thoracic Surgeons score 7.2%).

The procedure was performed under general anaesthesia. An 18 Fr Edwards arterial expandable sheath (Edwards Lifesciences, Irvine, CA, USA) was inserted from the left femoral artery. All procedures except for vessel puncture and sheath insertion were performed using the reverse X-ray image **(Figure 2)**. A pacing wire was inserted from the right femoral vein, and the tip was located in the right ventricle. A 0.035-inch super-stiff wire (Amplatz Extra-Stiff Wire; Cook Medical, Bloomington, IN, USA) was passed through the aortic valve. Balloon aortic valvuloplasty was performed with a 23 mm balloon (Edwards Lifesciences) under rapid pacing. The NovaFlex+ Delivery System (Edwards Lifesciences) was inserted into the expandable sheath after a 180° rotation so that the Edwards logo pointed downwards. This allowed the delivery system to pass smoothly through the inverted aortic arch **(Figure 3)**. A 26 mm Edwards SAPIEN XT valve (Edwards Lifesciences) was implanted under rapid pacing. After valve implantation, aortography and transoesophageal echocardiography showed an excellent valve position without aortic regurgitation.

At nine days after TAVI, the patient suddenly presented complete AVB. CT before TAVI showed a left-sided superior vena cava (SVC) draining into the right atrium and no other structural malformation such as persistent left SVC. Again using the reverse X-ray image during the procedure so that the anatomical orientation could be understood and the procedure performed with the usual image, the atrial and ventricular leads of a permanent pacemaker were successfully implanted into the right atrium and ventricle through the right subclavian vein. Eventually, he was discharged without any further events after TAVI.

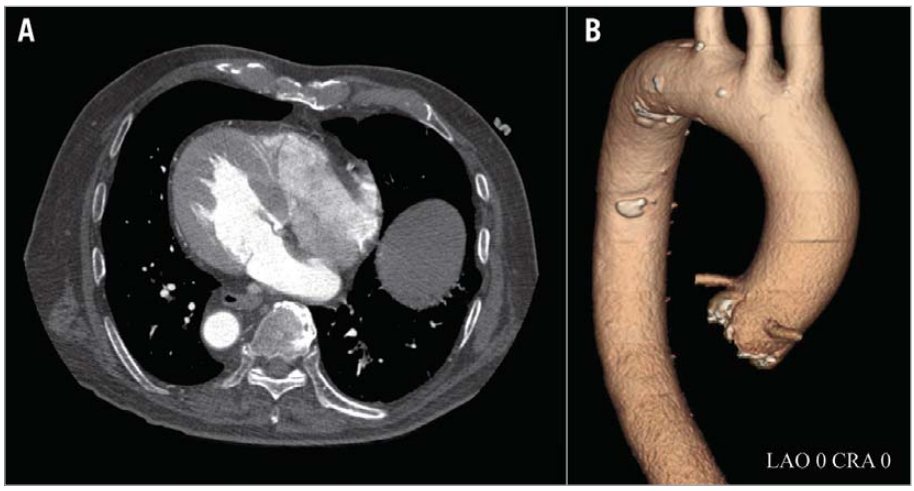

Figure 1. *Computed tomography. A) Right-sided left ventricle and descending aorta. B) 3D image of the right-sided aortic arch. CRA: cranial oblique; LAO: left anterior oblique*

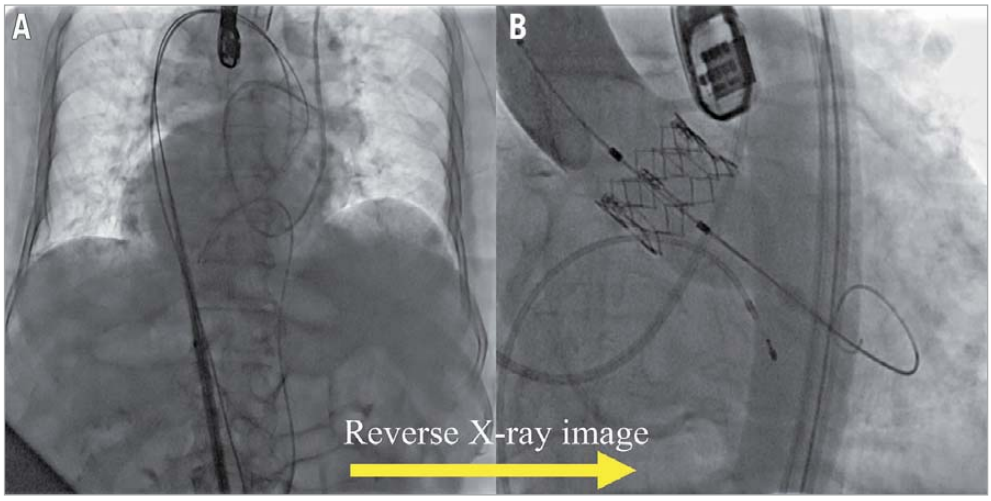

Figure 2. *X-ray image. A) Sheath insertion using a normal X-ray image. B) Deployment of a 26 mm Edwards SAPIEN XT valve using the reverse X-ray image.*

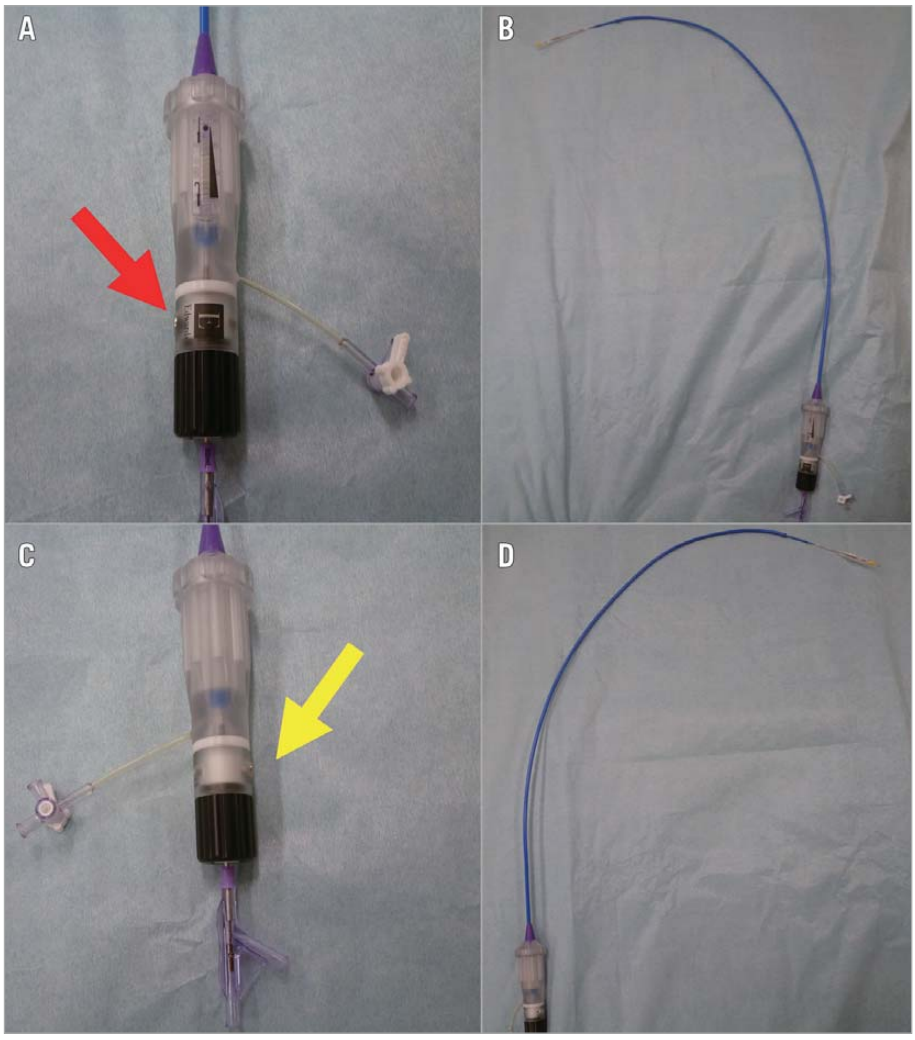

Figure 3. *NovaFlex+ Transfemoral Delivery System. In normal usage, (A) the Edwards logo faces upwards (red arrow) and (B) the delivery system flexes to the left. In this case, (C) the Edwards logo was rotated 180° (yellow arrow), so that (D) the delivery system flexed to the right and passed through the right-sided aortic arch.*

Discussion

To our knowledge, this is the first reported case of dextrocardia situs inversus to have TAVI using the reverse X-ray image.

Dextrocardia is a very rare congenital heart disease. A previous study reported that the incidence of dextrocardia is about one in 12,000 live births[3]. Dextrocardia is often associated with various structural malformations such as univentricular heart and bilateral SVC[3]. In this case, CT revealed a simple mirror image dextrocardia without other structural heart disease. There are few reports of TAVI in patients with dextrocardia situs inversus[4,5]. Dubois et al reported that an 84-year-old woman with situs inversus totalis and symptomatic AS underwent successful TAVI. Three-dimensional reconstruction of a preoperative cardiac angio CT before TAVI was useful to confirm the relative positions of the heart and great vessels[4]. In addition, Good et al showed that, when a patient with dextrocardia situs inversus undergoes TAVI, it is important to rotate the NovaFlex+ Transfemoral System by 180° when inserting it into the expandable sheath[5].

Understanding cardiac structure and appropriate modification of the procedure are mandatory in order to perform TAVI in patients with dextrocardia, because the structure of heart and arteries is different from normal. Two important issues for successful TAVI are: 1) insertion of the NovaFlex+ Delivery System into the expandable sheath after 180° rotation, and 2) the use of the reverse X-ray image. The correct insertion and advancement of the NovaFlex+ Delivery System into the expandable sheath is crucial, and this involves aiming the Edwards logo downwards instead of upwards. This should result in a smooth delivery of the device into the aortic valve through the right-sided aortic arch. Furthermore, the reverse structure of the arch and ascending aorta can lead to difficulty in performing TAVI. Therefore, the reverse X-ray image is very effective and useful for understanding the orientation of the device and simplifying the procedure. In addition, it also simplifies the pacemaker lead insertion into the right atrium and ventricle. In this case, the reverse X-ray image was used for both TAVI and pacemaker implantation.

Limitations

Our technique might not be applicable in patients with other structural malformations.

Conclusion

We need to understand the structure of the heart and great vessels in individual patients who have dextrocardia and who undergo TAVI. In cases of dextrocardia without other cardiovascular malformations, insertion of the NovaFlex+ Delivery System into the expandable sheath after 180° rotation and the reverse X-ray image are important in order to perform TAVI successfully. Theoretically, these methods can be applied when the Commander delivery system and Edwards SAPIEN 3 valve (Edwards Lifesciences) are used.

Impact on daily practice

Insertion of the NovaFlex+ Delivery System into the expandable sheath after 180° rotation, and the use of the reverse X-ray image are efficient in order to perform TAVI in a patient with dextrocardia situs inversus. These methods are theoretically useful for TAVI in the SAPIEN 3 era.

Conflict of interest statement

The authors have no conflicts of interest to declare.

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Abstracts of INDIALIVE 2018

CORONARY INTERVENTIONS

INTERVENTIONS FOR STRUCTURAL HEART DISEASE AND HEART FAILURE

MISCELLANEOUS

INDIALIVE 2018 Coronary interventions

PCI of unprotected left main: real-world experience of a solo cardiologist in a peripheral centre without IABP or IVUS

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Aims: To describe our experience in a peripheral centre with multiple constraints.

Methods and results: A total of 49 patients underwent PCI of unprotected LMCA from Nov 2008 till Nov 2017. Neither IABP nor IVUS was available. Initially PCI was carried out only as a lifesaving procedure (11 patients) but later it was also carried out in patients with comorbid conditions (38 patients). There were 36 males and 13 females (age 40-91, mean 65.49 years). Comorbidities included diabetes in 26 (53.06%), hypertension in 35 (71.42%), COPD in 4 (8.16%), renal failure in 5 (10.20%) and CVA in 2 (4.08%) patients. EF ranged from 25 to 73% (mean 45%). In 35 patients the lesion was ostial, in 3 in the shaft and in 11 patients it was in the terminal LMCA. SYNTAX score ranged from 11 to 41 (mean 15.34) and EuroSCORE ranged from 1.11 to 39.81 (mean 11.55). A total of 74 stents (mean 1.4 per patient) (2 BMS and 72 DES) were used. Follow-up physically or telephonically was available in all. Follow-up ranged from 1 month to 118 months with a mean of 23.34 months. Follow-up angiography was carried out in 6 patients (12.24%), one of whom had ACS due to in-stent stenosis and underwent CABG surgery. In total there were 9 deaths (18.36%), one in hospital and 8 at follow-up. In-hospital death was in a patient with cardiogenic shock due to STEMI who had LMCA and RCA lesions. Two patients died due to senility, 2 of progressive heart failure, one of renal failure and 3 had sudden cardiac death, possibly ischaemic.

Conclusions: LMCA PCI is feasible even in a peripheral centre with multiple constraints and is a choice of treatment in the emergency setting and a good option in a select group of patients with high surgical risk.

INDIALIVE 2018 Coronary interventions

CIN in elective PCI

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Aims: To decide whether the presence of metabolic syndrome increases the risk of CIN among non-diabetics undergoing elective PCI.

Methods and results: This was a prospective cohort study in which 500 non-diabetic patients undergoing elective PCI were enrolled. Two hundred and fifty (250) patients met the criteria for metabolic syndrome and 250 patients were in the control group. All the patients were evaluated for development of CIN. Contrast-induced nephropathy was defined as a post-PCI rise in creatinine ≥25% from baseline or an absolute increase ≥0.5 mg/dL. CIN developed in 42 patients out of 500 patients (8.4%), 29 (11.6%) of whom had metabolic syndrome and 13 (5.2%) of whom were in the control group. The development of CIN was significantly higher in patients with metabolic syndrome (p=0.01). Post PCI, rise in creatinine was significantly high from 0.92±0.19 mg/dL to 0.96±0.25 mg/dL (p=0.001) in the metabolic syndrome group while there was no significant change in the control group (p=0.127).

Conclusions: Metabolic syndrome is a risk factor for the development of CIN in non-diabetic patients undergoing elective PCI. Hence, patients should be screened for the presence of metabolic syndrome before elective PCI and appropriate preventive measures should be taken.

INDIALIVE 2018 Coronary interventions

Impact of stent overlap on clinical outcome in patients undergoing sirolimus-eluting coronary stent implantation: insights from en-ABL e-registry

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Aims: We analysed the impact of overlapping of a sirolimus-eluting stent, Abluminus DES+ (Envision Scientific), in patients with coronary artery disease.

Methods and results: The en-ABL e-registry is a prospective and multicentre post-marketing registry. We pooled the data of patients with overlapping of stents from this registry. A total of 162 patients were enrolled in this substudy. The primary endpoints of the study were incidence of major adverse cardiac events (MACE) and stent thrombosis (ST) at 1 year. MACE was defined as the composite of cardiac death, target vessel myocardial infarction, and target lesion/vessel revascularisation. A total of 338 Abluminus DES+ were employed to treat 164 lesions in a total of 162 patients. The study population was dominated by male patients (82.10%). Diabetes mellitus was present in 41.36% of patients while 40.12% of patients had hypertension. The mean stent diameter and mean stent length were 2.88±0.41 mm and 28.97±9.79 mm, respectively. One-year follow-up was available for 74.69% of the patients. The incidence of MACE was reported as 9.09% at 1 year. The MACE comprised TLR (4.13%), TV-MI (2.48%) and cardiac death (2.48%). ST was reported as 3.31% at 1 year. There was no late or very late stent thrombosis reported at 1 year.

Conclusions: The present study results indicate that, even in this highly complex cohort of patients, treatment with the Abluminus DES+ ensures good clinical outcomes at 1 year of follow-up.

INDIALIVE 2018 Coronary interventions

Safety and efficacy of sirolimus-coated balloon in in-stent restenosis in small coronary arteries

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Aims: To evaluate the performance of the MagicTouch sirolimus-coated balloon (Concept Medical) in high-risk patients with in-stent restenosis lesions in small vessels.

Methods and results: The study comprised 199 patients with in-stent restenosis (ISR). Amongst them, we sub-analysed 96 (48.24%) patients with ISR lesions in small calibre vessels (RVD ≤2.75 mm). The main study endpoint assessed was major adverse cardiac events (MACE) at 1 year. The MACE component comprised target lesion revascularisation (TLR), target vessel myocardial infarction (TV-MI) and cardiac death. A total of 105 ISR lesions were treated in 96 patients. Male patients accounted for the majority of the study population (79.17%). Half of the patients presented with diabetes mellitus (51.04%). Among 105 treated lesions, most lesions were focal (60.95%), followed by diffuse intra-stent (16.19%), diffuse proliferative (9.52%) and diffuse total occlusion (9.52%). DES-ISR (83.81%) was the most prevalent in the study group. Ninety-one (94.79%) patients completed 1-year follow-up. Follow-up for the rest of the patients is yet to come as this is an ongoing study. The occurrence of MACE was reported as 6.59%. The rate was mainly propelled by TLR (5.49%) and TV-MI (1.10%). There was no cardiac death reported at 1 year for this group.

Conclusions: The present study supports the use of the MagicTouch SCB for the treatment of a high-risk population such as patients with ISR in small calibre vessels and is associated with an optimal long-term clinical follow-up.

INDIALIVE 2018 Coronary interventions

SYNTAX plus score for outcomes in multivessel and left main angioplasty

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Aims: To develop an accurate risk system combining the SYNTAX angiographic score and clinical variables to predict the clinical outcomes for patients undergoing complex PCI.

Methods and results: The development set included 900 patients who underwent PCI from April 2011 to April 2015 and was retrospective. Their baseline, clinical, procedural characteristics and SYNTAX scores were assessed using univariate and forward stepwise logistic regression without intercept. Age >70 years, severe LV dysfunction, high and intermediate SYNTAX scores, branch vessel disease and GFR <60 ml/min/1.73 m^2 were the 6 most significant variables to predict the primary endpoint (MACE), which was the composite of cardiac death, MI, ischaemia-driven target lesion revascularisation and definite/probable stent thrombosis at 1 year. A formula was then developed with the 6 variables using a regression equation. The resultant score was employed in the prospective arm of 300 patients. Median age was 57.8 (SD=9.6) years. Males were 86%. Diabetes and hypertension were prevalent at 59.4% and 55%. Most patients presented with either acute coronary syndromes or recent myocardial infarction (62.9%). The median value of the SYNTAX score in the study group was 18 (15-40). Total MACE rate was 10.2%; it was 9.3% in the low (<23), 17.9% in the intermediate (23-32), and 13.3% in the highest (>33) SYNTAX score groups. The final SYNTAX plus score system calculated the risk of MACE from a possible 2% to 75%. The total risk of MACE was 11.3% in the validation group. The scoring model correlated well in the validation group (sensitivity 92.3%, specificity 82.1%, c statistic 0.85).

Conclusions: A simple risk scoring equation can be employed to predict the probability of major adverse cardiovascular events in patients undergoing complex PCI, developed by combining the SYNTAX score and clinical variables. Patients can be treated with an optimal and safe revascularisation procedure using this risk score.

INDIALIVE 2018 Coronary interventions

Long-term results of a novel sirolimus-eluting stent with biodegradable polymer for treatment of coronary stenoses

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Aims: To investigate the long-term results of the novel sirolimus-eluting stent, Abluminus DES+ (Envision Scientific), in patients with atherosclerotic lesions in coronary arteries.

Methods and results: The en-ABL e-registry is a multicentre, non-randomised, post-market registry. Patients presenting with either stable or unstable disease (including ST- and non-ST-elevation myocardial infarction) were enrolled. The main study endpoint was the rate of major adverse cardiac events (MACE) at two-year follow-up; MACE is a composite of cardiac death, target vessel myocardial infarction (TV-MI) and target lesion revascularisation (TLR). The rates of probable or definite stent thrombosis were also recorded. Enrolled in the study were 2,377 patients, with 2,821 lesions in total. The mean age of the study population was 57 years, with a high prevalence of diabetes mellitus (34.46%). Most of the patients (45.46%) presented with ST- or non-ST-elevation acute coronary syndrome. One-year follow-up was completed by 1,982 (83.38%) patients, while 5 (0.21%) patients were lost to follow-up. The follow-up for the rest of the patients is yet to come. MACE occurred in 2.67% of the patients. MACE components were reported as cardiac death (0.71%), TV-MI (0.40%) and TLR (1.56%). At 2 years, 1,498 (63.02%) patients had completed follow-up and the incidence of MACE was 3.60%. The probable and definite ST were reported as 9 (0.6%) and 4 (0.27%), respectively, at 2 years.

Conclusions: The present data support the use of the Abluminus DES+ stent in patients with coronary atherosclerosis with reduced revascularisation rates at long-term follow-up of 2 years.

INDIALIVE 2018 Coronary interventions

Sirolimus-eluting coronary stent in elderly patients with stenosis in coronary arteries: a subgroup analysis from the en-ABL e-registry

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Aims: To evaluate the performance of the Abluminus DES+ - a newer-generation biodegradable polymer sirolimus-eluting stent (Envision Scientific) - in this scenario.

Methods and results: A total of 658 patients aged ≥65 years having atherosclerosis in the coronary arteries were recruited into the en-ABL e-registry – a multicentre, prospective and real-world registry. The primary endpoint is major adverse cardiac events (MACE), a composite of cardiac death, target vessel myocardial infarction (TV-MI), or target lesion revascularisation (TLR) at one-year follow-up. Also, stent thrombosis (ST) was observed at one-year follow-up. A total of 799 lesions were treated with 893 Abluminus DES+ in 658 patients. The study population was predominantly male (70%). The mean age of the patients in this group was 70.05±9.42 years; 37.99% of patients had diabetes mellitus whereas almost half of the patients had hypertension (53.04%); 65.96% patients clinically presented acute coronary syndrome. At 1 year, follow-up was available for 528 (80.24%) patients. One (0.15%) patient was lost to follow-up and follow-up of the rest of the patients is yet to come. The cumulative incidence of MACE at 1 year was recorded as 3.78%. MACE components are reported as TLR (1.33%), cardiac death (1.70%) and TV-MI (0.76%). The rate of stent thrombosis was reported as 0.95% at 1 year.

Conclusions: The analysis suggests that the Abluminus DES+ is safe and efficacious in treating coronary artery disease in elderly patients with lower revascularisation rates at 1-year follow-up.

INDIALIVE 2018 Coronary interventions

Clinical outcomes of real-world diabetic patients treated with Abluminus DES: a multicentre en-ABL e-registry

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Aims: We sought to assess the performance of the Abluminus DES+ - a newer-generation biodegradable polymer sirolimus-eluting stent (Envision Scientific) - in diabetic patients with coronary stenosis.

Methods and results: This multicentre, prospective registry was conducted in 30 centres in India. The en-ABL e-registry enrolled 2,377 patients; 819 patients had documented history of diabetes mellitus (DM). The study endpoints were major adverse cardiac events (MACE), a composite of cardiac death, target vessel myocardial infarction (TV-MI), or target lesion/vessel revascularisation (TLR/TVR) and stent thrombosis (ST) at 1 year. We analysed two cohorts in this prospective study: DM (819) and non-DM (1,558). Patients with diabetes were more frequently treated for hypertension (60.32% vs. 33.70%, p<0.001). At 1 year, 84.86% and 82.61% of patients were available for follow-up for the DM cohort and non-DM cohort, respectively. The reported MACE rates at 1 year were 3.30% in the DM group and 2.33% in the non-DM group; (p=0.198). The MACE rate was mainly driven by TLR (2.01% vs. 1.32%, p=0.235), followed by TV-MI (0.43% vs. 0.39%, p=1.000) and cardiac death (0.86% vs. 0.62%, p=0.579). The rate of ST was recorded as 0.86% vs. 0.54% (p=0.397) at 1 year for the two groups.

Conclusions: At 1 year, diabetic patients had a low rate of MACE, actually similar to non-diabetic patients, supporting the safety and efficacy of the Abluminus DES+ - a newer-generation biodegradable polymer sirolimus-eluting stent that incorporates a unique coating technology.

INDIALIVE 2018 Coronary interventions

Impact of diabetes mellitus on the performance of a sirolimus-coated balloon in patients with coronary in-stent restenosis: insights from the Nanolute study

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Aims: We aimed to assess the impact of diabetes mellitus on the safety and efficacy of the MagicTouch sirolimus-coated balloon (Concept Medical) in patients with coronary in-stent restenosis.

Methods and results: A total of 199 patients with coronary in-stent restenosis (ISR) were included in the multicentre and prospective Nanolute study. Among these, we assessed two subgroups: ISR-DM (103) and ISR-non-DM (96). All patients were treated with a sirolimus-coated balloon. The clinical study endpoint was major adverse cardiac events (MACE) - a composite of cardiac death, target vessel myocardial infarction (TV-MI) and target lesion revascularisation (TLR) at 1 year. Among 199 patients with ISR, 103 (51.76%) patients had a diagnosis of diabetes mellitus, whereas 96 (48.24%) had no documented history of the disease. One-year follow-up was available for 94 patients and 84 patients in the DM and non-DM cohorts, respectively. The follow-up for the rest of the patients is yet to come as it is ongoing study. The incidence of MACE was reported as 4.25% and 8.33% for the DM cohort and non-DM cohort, respectively, with a p-value of 0.26. The MACE rate was broken down into TLR (4.25% vs. 7.14%, p=0.520) and TV-MI (0.0% vs. 1.19%, p=0.472). The clinical outcomes were not statistically different for both the DM and non-DM cohorts. There was no cardiac death reported at 1 year for both cohorts.

Conclusions: The present analysis suggested that diabetes mellitus does not appear to have a negative impact on the efficacy of SCB in patients with ISR lesions and is associated with good clinical outcome in this complex cohort.

INDIALIVE 2018 Coronary interventions

Revascularisation with a sirolimus-coated balloon in atherosclerosis in small coronary arteries: real-world experience from the Nanolute study

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Aims: We sought to investigate the clinical outcomes after treatment using the MagicTouch sirolimus-coated balloon (SCB) (Concept Medical) in patients with *de novo* lesions located in small coronary arteries.

Methods and results: The all-comers, multicentre, Nanolute registry enrolled patients with *de novo* lesions located in coronary vessels with a reference vessel diameter (RVD) ≤2.75 mm. We conducted the analysis at 1 year with the pre-specified primary study endpoint of major adverse cardiac events (MACE) which is composed of target lesion revascularisation (TLR), target vessel myocardial infarction (TV-MI) and cardiac death. We also assessed the procedural success, defined as technical and angiographic success in the absence of MACE at hospital discharge. A total of 196 patients with 204 lesions were treated with 217 SCB; 38.78% of patients presented with diabetes mellitus and 44.39% of patients with hypertension. Additional stenting was performed only in 6.12% of the patients. The mean diameter of the SCB was 2.33±0.26 mm. Procedural success was achieved in 99.49% of patients while only 1 patient had vessel dissection. One-year follow-up is available for 175 (89.29%) of the patients; MACE occurred in 3.43% of the patients. MACE was mainly propelled by TLR (2.86%) followed by cardiac death (0.57%). There was no TV-MI reported at 1 year in the study.

Conclusions: 1-year clinical results after treatment using the SCB demonstrated low rates of MACE in a small vessel cohort of the Nanolute registry, hence showing an adequate efficacy and safety in this setting. Adequately powered studies in a western population are ongoing.

INDIALIVE 2018 Coronary interventions

Two-year clinical follow-up of a multicentre Nanolute study assessing the safety and efficacy of a sirolimus-coated balloon in coronary artery stenosis

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Aims: We sought to evaluate the efficacy and safety of the MagicTouch sirolimus-coated balloon (Concept Medical) in patients with atherosclerotic lesions in coronary arteries.

Methods and results: Nanolute is a multicentre, prospective, real-world study of patients undergoing percutaneous coronary intervention (PCI) with the MagicTouch sirolimus-coated balloon (SCB) for in-stent restenotic (ISR) and/or *de novo* lesions in coronary vessels. The measured clinical endpoint was the occurrence of major adverse cardiac events (MACE), defined as a combination of cardiac death, target vessel myocardial infarction (TV-MI) and target lesion revascularisation (TLR) at 1 year. We also assessed the MACE rate at an extended follow-up of 2 years. Included in this ongoing study were 438 patients, with a total of 516 PCI procedures on 465 lesions, all treated with SCB. Diabetes mellitus accounted for 44.29% of the total study population; 48.40% of patients clinically presented with acute coronary syndrome. Of 465 lesions, 45.81% were ISR lesions whereas 54.19% were *de novo* lesions. One-year follow-up was available for 393 (89.73%) patients. The follow-up of the rest of the patients is yet to come. The occurrence of MACE was recorded as 4.33% at 1 year with TLR (3.82%), TV-MI (0.25%) and cardiac death (0.25%). We recorded MACE at an extended follow-up of 2 years. Two years of follow-up was completed by 333 (76.02%) patients, and the incidence of MACE was 5.10%. There was no increment in events at 2 years.

Conclusions: In this cohort of patients, SCB angioplasty delivered good clinical outcomes at 1 year. The results are very promising at 2 years of extended follow-up.

INDIALIVE 2018 Coronary interventions

HBA1c levels in patients with ST-elevation myocardial infarction and its correlation with severity of coronary artery disease (assessed by SYNTAX score) and short-term mortality

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Aims: To evaluate the correlation between HBA1c on admission and severity of coronary artery disease using the SYNTAX score and mortality in patients with ST-elevation myocardial infarction (diabetic and non-diabetic).

Methods and results: Three hundred and sixty-two (362) patients presenting with STEMI (within 48 hrs) were included in our study (96 diabetic and 266 non-diabetic). Data regarding patient characteristics were collected over 7 months. SYNTAX score was calculated by the online SYNTAX score calculator. All-cause mortality data were collected prospectively up to 6 months. Diabetics were older, predominantly male, and more hypertensive than non-diabetics. Mean HBA1c was greater in diabetics (8.01±1.50) than in non-diabetics (5.69±0.65) ($p<0.001$). SYNTAX score showed significant linear correlation with HBA1c values in all cases, diabetic and non-diabetic subgroups ($p<0.001$). HBA1c quartiles (<5, 5.1-5.5, 5.6-6, 6.1-6.4) showed increased mean SYNTAX scores (2.65, 5.53, 7.15, 13.42, respectively, $p<0.001$) and increased 6-month mortality (3%, 4.8%, 1.7%, 15.1%, respectively, $p=0.004$) with increased values in the non-diabetic group. In the diabetic group, increased HBA1c quartile (<7.5, 7.6-8.5, 8.6-9.5, >9.5) values correlated with increased mean SYNTAX scores (12.7, 16.5, 18.25, 22.5, respectively) ($p<0.001$) but not with mortality ($p=0.525$). Multivariate regression analysis showed HBA1c >6 as an independent predictor of 6-month mortality.

Conclusions: A significant correlation exists between HBA1c and angiographic SYNTAX score in STEMI patients (both diabetic and non-diabetic). It also significantly correlates with 6-month mortality.

INDIALIVE 2018 Coronary interventions

2D speckle tracking echocardiography as a predictor of significant coronary artery stenosis in female patients with effort angina who are treadmill test positive - an angiographic correlation

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Aims: 1. To determine the diagnostic accuracy (sensitivity and specificity) of 2D speckle tracking echocardiography (GLS score) in predicting the angiographic severity of coronary artery disease in female patients with effort angina who are TMT positive. 2. To risk stratify TMT positive female patients with effort angina based on longitudinal myocardial strain assessed by 2D speckle tracking echocardiography, in order to decide on the need for invasive management.

Methods and results: Female patients with effort angina who are TMT positive and are recommended for coronary angiogram based on standard treatment guidelines are subjected to 2D speckle tracking echocardiography and a global longitudinal strain (GLS) score is obtained. Following CAG, a correlation was sought between lesion severity and GLS score. Sensitivity and specificity of the GLS score in predicting the angiographic severity of coronary artery disease was also calculated. One hundred (100) patients were evaluated. The average age of patients included in the study was 55 years. All were TMT positive female patients, with the average Duke score being –2. Effort angina was the predominant symptom; 70% of patients were in NYHA Class II. The most common associated risk factor was HTN, with 66 patients being hypertensive; 63 patients were diabetic. Dyslipidaemia was observed in 46 patients. There was no RWMA or LV dysfunction in any of the patients. Sixty-three percent (63%) of patients had a GLS score greater than or equal to –17, with the average being –15; 56% of patients had a significant lesion of greater than 70% in at least one of the coronary arteries. Sensitivity of GLS in predicting significant CAD in TMT positive female patients was 94% and specificity 76%. The positive predictive value was 84% and the negative predictive value was 90%. The optimum cut-off value of the GLS score to predict a coronary lesion is –17.5. Patients with a GLS more than –20 had no significant coronary lesion and those with a GLS less than –12 had multivessel disease. Compared to the Duke TMT score, GLS showed better correlation with a significant coronary lesion and this was more evident in the age group 45 to 55 years.

Conclusions: GLS by 2D speckle tracking echocardiography correlates well with the angiographic severity of coronary artery disease and can predict a significant coronary lesion with a sensitivity of 94% and a specificity of 76% in female patients with effort angina.

INDIALIVE 2018 Coronary interventions

CT angiography: a distinguishing marker of coronary artery disease in comparison with conventional coronary angiography

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Aims: The present study was carried out to evaluate the diagnostic performance of CTA as compared with CIA in an Indian set-up.

Methods and results: A cross-sectional analytic study was carried out for a period of two years in 50 patients after obtaining written informed consent. Sixty-four (64) slice CT coronary angiography was performed prior to CIA. The angiograms were evaluated by an experienced observer. The total number of significant lesions (>50%) was 44 by CTA. The most commonly involved vessels were proximal, mid or distal segments of the LAD and RCA. The sensitivity and specificity of CTA for detecting significant stenosis on a per patient basis with CIA as reference standard was 95.7% and 90.5%, respectively, while the PPV and NPV value was 91.7% and 95%, respectively.

Conclusions: MDCT has reasonably high accuracy for detecting significant obstructive CAD when assessed at artery level. CTA using scanners with at least 64 slices should be recommended as a test to rule out obstructive coronary stenosis in order to avoid inappropriate invasive coronary angiography in patients with an intermediate pre-test probability of CAD.

INDIALIVE 2018 Coronary interventions

Comparison of new-generation everolimus-eluting stents and new-generation sirolimus-eluting stents in chronic renal failure patients with 3-year outcome

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Aims: To compare the safety and efficacy outcome between new-generation everolimus-eluting stents and sirolimus-eluting stents in patients undergoing PCI.

Methods and results: We retrospectively analysed 150 patients who underwent PCI in our centres between August 2014 and August 2017. Patients were divided into two groups: new EES (n=105) and new SES (n=45). Primary endpoints were, at 1 year, 2 years and 3 years, the composite of all-cause death, MI, CVA, and TVR; MACE and stent thrombosis were also evaluated. Femoral access was used in 30% and radial access was used in 70% of patients. The rate of dual antiplatelet therapy use at 1 year was 96% in EES and 90% in SES. The primary endpoints occurred in 7% of EES patients and in 25% of SES patients. Significant differences were found with respect to the rate of 3-year all-cause mortality (3% vs. 18%), MI (1% vs. 15%), CVA (0.5% vs. 5%), ST (1.5% vs. 15%), TVR (2% vs. 18%), and MACE (1% vs. 14%), and 2 cases of major bleeding were observed in SES patients but not in EES.

Conclusions: New EES stents showed very positive and encouraging results in CKD patients compared with new SES stents. This 3-year study may be extended to evaluate very late events.

INDIALIVE 2018 Coronary interventions

Global longitudinal strain and angiographic correlation in NSTEMI

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Aims: To investigate the role of 2D speckle tracking echocardiography as a non-invasive predictor of significant coronary artery occlusion in patients with non-ST-segment elevation myocardial infarction.

Methods and results: Sixty patients with a first attack of non-ST-segment elevation myocardial infarction were included in the study. The patients were divided into two groups: group 1 with significant (>70%) CAD, and group 2 with non-significant CAD (<70%) based on coronary angiogram results. Images were obtained in the apical long-axis, four-chamber, and two-chamber views. Regional longitudinal systolic strain was measured in 17 myocardial segments and averaged to provide global longitudinal strain (LVGLS). There was a significant decrease in LVGLS in group 1 compared to group 2 ($p<0.05$). The optimal cut-off value of LVGLS for prediction of significant CAD was –15.57 (AUC 0.797, p-value 0.009). The sensitivity, specificity and PPV of LVGLS for detecting significant CAD were 91%, 90%, and 93.3%, respectively. An area of 4 or more adjacent dysfunctional segments had the best ability to identify patients with significant coronary occlusion (AUC 0.945, p-value <0.001, sensitivity 90%, specificity 80% and PPV 90%).

Conclusions: Both global and regional longitudinal systolic strain can offer accurate, feasible, and non-invasive prediction of acute coronary artery occlusion in patients with non-ST-elevation myocardial infarction who may benefit from urgent revascularisation.

INDIALIVE 2018 Coronary interventions

Dilemma in percutaneous coronary interventions in retroviral positive patients with chronic total occlusion (CTO): to treat or not to treat?

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Aims: The objective of our study was to analyse the procedural success and complication rates in performing PCI in CTO in retroviral positive patients.

Methods and results: This was a prospective and observational study. A total of 7 consecutive patients who were reported as being retroviral positive with CTO between August 2012 and June 2017 were evaluated. Detailed clinical presentation and coronary angiography of all patients were evaluated. A procedural success rate of 100% was achieved and the in-hospital course was uneventful. The mean age of patients was 42.66 years, mean duration of HIV was 3.43 years. The mean duration of angina was 7.83 months, 4 patients had 100% LAD occlusion, and 3 patients had 100% RCA occlusion. Out of 7 patients, 2 patients had PCI to the LAD, 3 patients had PCI to the RCA, and one patient each had PCI to LMCA to the LAD, LCX and LMCA to the LAD. The average size of the stent was 3×32 mm. The average fluoroscopy time was three hours.

Conclusions: PCI is an adequate and safe treatment strategy for coronary revascularisation in HIV positive patients with coronary chronic total occlusion.

INDIALIVE 2018 Coronary interventions

Retroviral positive (HIV) patients presenting with STEMI – dilemma for coronary interventions: to do or not to do?

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Aims: To study the clinical profile of HIV infected patients presenting with acute coronary syndrome and their in-hospital outcome and therapeutic challenges with respect to revascularisation.

Methods and results: We studied 109 consecutive patients infected with HIV and presenting with acute coronary syndrome to our acute coronary care unit between 2013 and September 2017. The baseline clinical characteristics, response to fibrinolytic therapy, angiographic findings, and results of PCI and in-hospital outcome were studied. The mean age of patients was 46 years, which is lower than HIV uninfected patients. Most patients presented with acute anterior wall ST-elevation myocardial infarction (n=98, 89%). Most patients presented with lower Killip class (Class I: 84.4%, Class II: 11.9%, Class III: 3.7%). Ninety-six (96) patients (88.1%) received thrombolytic therapy with streptokinase. Thombolysis was successful in 96 (78.33%) and failed in 13 (21.67%) patients. Four patients underwent rescue angioplasty and primary PCI was performed in 3 patients. Coronary angiography was carried out in all the patients and revealed significant residual stenosis in 51 patients. Three-vessel coronary artery disease was seen in only 4 patients (3.7%). Two-vessel coronary artery disease was seen in 16 patients (14.7%). Sixty-nine (69) patients (81.6%) had a significant single-vessel lesion. All patients with significant residual lesions (n=51) underwent PCI with drug-eluting stents. Only 1 patient died due to cardiogenic shock. All 108 patients were followed up for 3 years and they are receiving adjuvant HAART.

Conclusions: HIV infected patients hospitalised for an ACS are relatively young. The presentation and outcomes of ACS in this population are similar to those of uninfected patients. Anterior wall MI is the most common presentation, hence the LAD is the most common culprit vessel. HIV status and HAART therapy did not interfere with the revascularisation approach or clinical outcome.

INDIALIVE 2018 Coronary interventions

Left main treatment with the latest generation sirolimus-eluting stent: preliminary data after one follow-up of an average of 6 months

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Aims: To evaluate the clinical performance of the Abluminus DES+ in LM critical lesions. The peculiarity lies in the coating technology which takes place after the stent is crimped.

Methods and results: Patients undergoing LM angioplasty with the Abluminus DES+ were clinically evaluated at regular intervals in order to evaluate any new symptoms. The target lesion was the LM, either in the LM ostium or the LAD-CFX bifurcation. Primary endpoints were MACE and definite or probable stent thrombosis. The study population was 70.8% male, average age 65.5 years, 8% STEMI for LM occlusion. In relation to DAPT, 58.4% were treated with clopidogrel 75 mg, 41.6% with ticagrelor 90 mg bid, none with prasugrel. There was 83.3% RCA dominance, 65% with RCA critical stenosis and 23% with RCA total occlusion. In LM lesions, average length was 13 mm, TIMI flow 3 was 100% at baseline. Predilatation: 83%, SC balloon 2.67 mm mean calibre (median 2.75), mean length 14.24 mm (median 15). Abluminus DES+: mean diameter of 3.77 mm (median 4.00), mean length of 16.5 mm (median 16). Post-dilatation: 95.8% with mean and median balloon size of 4.00, mean length 9.9, median length 11. IVUS: 50%, confirmed the already well-defined angiographic result. Procedural success: 100% of patients, no signs and/or symptoms in the 24 hours post procedure that could be attributed to myocardial infarction. Six-month follow-up: no symptoms 100% patients. One-year follow-up: 54.6% achieved 12-month follow-up without adverse events.

Conclusions: Due to its peculiarities in coating technology, the Abluminus DES+ is a good treatment strategy even for the most complex coronary lesions, including LM treatment.

INDIALIVE 2018 Coronary interventions

Techniques and outcomes of bioresorbable vascular scaffolds in the treatment of coronary bifurcation lesions: one-scaffold strategy vs. two-scaffold strategy

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Aims: Our objectives were to study the technical aspects and outcomes of treating coronary bifurcation lesions with A-BRS by comparing a "one-scaffold strategy" (OSS) with a "two-scaffold strategy" (TSS).

Methods and results: Patients who underwent coronary bifurcation stenting, either OSS or TSS, with A-BRS over a period of 3 years were prospectively included. The lesion bed was predilated with a non-compliant balloon and a scaffold was deployed gradually at nominal pressure. The side branch was recrossed with a wire and then the scaffold was post-dilated at high pressure. Finally, snuggle balloon dilatation was performed. Patients were followed up periodically with stress testing and CT coronary angiography. Out of 122 bifurcation lesions in 117 patients, 87 lesions were treated with OSS while 35 lesions were treated with TSS. The mean number of A-BRS implanted per lesion was 1.3±0.6 (OSS group: 1.3±0.6, and TSS group: 1.2±0.5). In the TSS group, bail-out stenting of the side branch was performed in 5 (14.3%) lesions with elective stenting in 30 (85.7%) lesions; "T", "TAP" and "V" stenting techniques were performed in 14 (40%), 16 (45.7%) and 5 (14.3%) lesions, respectively; hybrid stenting with A-BRS and metallic stent was performed in 5 (14.3%) lesions. In the OSS group, the side branch was protected, predilated and recrossed in 87 (63.9%), 21 (57.7%) and 24 (49.5%) lesions, respectively. Final snuggle balloon dilatation was performed in 23 (26.4%) and 35 (100%) lesions in the OSS and TSS groups, respectively ($p<0.0001$). The mean duration of follow-up was 26.4±7.9 months with 98.3% follow-up. There was no scaffold thrombosis (0%). One patient in both the OSS group and the TSS group developed restenosis and underwent bypass surgery subsequently (TLR rate: 1.2% vs. 2.9%, $p=0.49$; overall 1.6%). The rest were doing fine without any major adverse clinical events.

Conclusions: Coronary bifurcation stenting with the A-BRS, both the one-scaffold strategy and the two-scaffold strategy, is technically feasible producing excellent results at short-term and long-term follow-up.

INDIALIVE 2018 Coronary interventions

Everolimus-eluting bioresorbable vascular scaffolds for the treatment of diffuse coronary artery disease: technical challenges and long-term outcomes

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Aims: To study the technical challenges and long-term outcomes of using Absorb bioresorbable vascular scaffolds (A-BRS) for the treatment of diffuse coronary artery disease (CAD) requiring a continuous segment of A-BRS measuring more than 40 mm.

Methods and results: Patients who underwent PCI with the A-BRS in diffuse CAD were included in this study from January 2013 to July 2016. After adequate preparation of the lesion, A-BRS was deployed gradually at nominal pressure and post-dilated at high pressure. Minimal overlap of scaffolds was performed in these diffuse lesions. All patients were followed up regularly after the procedure. Sixty-one (61) patients with one diffuse lesion each were included in this study (in total 61 diffuse CAD lesions). The number of A-BRS used per diffuse CAD lesion was 2.3±0.6. All lesions were routinely predilated and post-dilated. The diameter and total length of A-BRS used were 3.01±0.3 mm and 57.5±17.7 mm, respectively. The strategy for deployment of A-BRS was either proximal-to-distal vessel deployment (16 lesions) or distal-to-proximal vessel deployment (45 lesions). Two techniques of overlapping scaffolds were utilised - marker-to-marker overlap and edge-to-edge placement of markers. All patients received dual antiplatelet therapy for at least 12 months. Ticagrelor or prasugrel was preferably used for the initial 3 months and then switched to clopidogrel. A GP IIb/IIIa inhibitor was used as and when required. The median duration of follow-up was 1,026 days (interquartile range: 713-1,305 days). On follow-up, 4 cases underwent target lesion revascularisation but no (0%) definite scaffold thrombosis was reported in any of the study patients.

Conclusions: Treatment of diffuse CAD with a continuous segment of minimally overlapping multiple A-BRS is technically possible with a trend towards favourable outcomes on long-term follow-up, provided optimal implantation techniques and a meticulous antiplatelet regimen are followed.

INDIALIVE 2018 Coronary interventions

Comparison of clinical outcomes in patients treated with indigenous (Indian) versus foreign drug-eluting stents (DES)

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Aims: To compare clinical outcomes in patients treated with indigenous (Indian) versus FDA approved/CE-marked drug-eluting stents (DES).

Methods and results: This study was a single-centre, prospective, observational study in which clinical follow-up data were collected at 9 months in patients undergoing DES implantation in *de novo* native vessel coronary artery disease. Patients were divided into 4 groups: group 1 (n=132) received biodegradable polymer indigenous SES (Metafor), group 2 (n=69) received the biodegradable polymer CE-marked SES (Orsiro), group 3 (n=75) received durable polymer FDA/CE-marked ZES (Resolute Integrity), and group 4 (n=132) received durable polymer FDA/CE-marked EES (XIENCE Xpedition). At 9-month follow-up, stent thrombosis occurred in 1 (0.8%), 0 (0%), 1 (1.3%), and 1 (0.8%) (p-value-0.830) in groups 1, 2, 3 and 4, respectively. TLR occurred in 6 (4.5%), 2 (2.9%), 2 (2.7%) and 2 (1.5%) (p-value-0.542) in groups 1, 2, 3 and 4, respectively, and MACE occurred in 10 (7.6%), 2 (2.9%), 4 (5.3%) and 5 (3.8%) (p-value-0.421) in groups 1, 2, 3 and 4, respectively.

Conclusions: In the present study, we demonstrated that a biodegradable polymer indigenous SES is non-inferior to biodegradable polymer CE-marked SES and two leading permanent polymer-based second-generation DES for hard clinical endpoints. The lower cost of the indigenous stent makes it an attractive option for treating patients with coronary artery disease in developing countries (such as India) without compromising on efficacy.

INDIALIVE 2018 Coronary interventions

Coronary angioplasty in spontaneous coronary artery dissection: strategy and outcomes

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Aims: PCI in spontaneous coronary artery dissection (SCAD) is associated with high rates of technical failure. Studies examining the procedural characteristics and hardware used during PCI in SCAD are limited to anecdotal case reports.

Methods and results: This was a retrospective single-centre study which analysed the clinical, angiographic and procedural characteristics of patients with angiographically confirmed type 1 SCAD undergoing PCI over a period of 4 years (2013-2017). There was a total of 42 patients with type 1 SCAD during the study period, of whom 16 (38.1%) underwent PCI; 14 out of the 16 patients (87.5%) who underwent PCI had technical success. In all patients, the lesion was attempted to be crossed initially with a floppy wire and, if this was unsuccessful, it was escalated to a hydrophilic wire and finally to a stiff wire. The SCAD lesion was crossed with a floppy wire in 71.4% of patients, with a hydrophilic wire in 14.2% and with a stiff wire in 7.1% of patients. Wire escalation was required in 5 patients (31.3%) and in 60% of cases there was technical success after wire escalation. Presence of diabetes mellitus, hypertension, smoking, coexisting atherosclerosis, diffuse nature of the lesion, and baseline TIMI flow ≤2 did not predict procedural failure during PCI.

Conclusions: PCI in SCAD was associated with a fair rate of technical success in our population. Choosing a floppy wire initially and then escalating to a hydrophilic wire followed by a stiff wire is an optimal revascularisation strategy.

INDIALIVE 2018 Coronary interventions

Percutaneous coronary intervention of an anomalous left circumflex coronary artery

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Aims: We report our experience of percutaneous coronary intervention in patients with an anomalous origin of the left circumflex artery.

Methods and results: We report a case series of 14 cases (12 male, 2 female) of mean age 54.14±14.75 years, who have undergone successful coronary angioplasty and stenting of an anomalous left circumflex artery. Eight (57%) cases had a transfemoral approach, while the rest (6; 43%) had a transradial approach. The target lesion was type B in 50% and type C in 50% of cases. The site of the lesion was: proximal retro-aortic portion in 5, ostial in 3, distal portion in 5, and major obtuse marginal in 1 case. A Judkins right coronary guide catheter was used in 11 (79%) cases, while an Amplatz Right-1 catheter was used in the remaining 3 (21%) cases. A two-wire strategy was adopted in 64% of cases. In total, 16 stents of mean diameter 2.95±0.33 mm and mean length of 26.93±7.92 mm were deployed. The long-term follow-up was uneventful in all the cases.

Conclusions: Percutaneous intervention of an anomalous left circumflex coronary artery is technically challenging but feasible with a good success rate. An appropriate selection of hardware and technical expertise results in a favourable outcome.

INDIALIVE 2018 Coronary interventions

Comparison of neointimal coverage between ultrathin biodegradable polymer-coated sirolimus-eluting stents and durable polymer-coated everolimus-eluting stents: 6-month optical coherence tomography follow-up from the TAXCO study

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Aims: The TAXCO study was designed to compare the degree of neointimal coverage and the prevalence of malapposition at 6 months subsequent to implantation of ultrathin biodegradable polymer-coated sirolimus-eluting stents (SES) and durable polymer-coated everolimus-eluting stents (EES) using optical coherence tomography (OCT).

Methods and results: The TAXCO study included a total of 37 patients who consented to and underwent OCT examination between August 2017 and September 2017. Among them, 21 patients had been treated with Tetriflex SES (Sahajanand Medical Technologies Pvt. Ltd., Surat, India) and 16 with XIENCE V EES (Abbott Vascular, Santa Clara, CA, USA), 6 (±1) months earlier at our institution. The OCT was performed using a C7 Dragonfly™ imaging catheter (St. Jude Medical, St. Paul, MN, USA). All OCT images were analysed at an independent core laboratory (Cardiovascular Research Center, São Paulo, Brazil) by analysts who were blinded to patient and procedural information. A total of 763 cross-sections (6,908 struts) were analysed in the XIENCE V EES group, and 1,134 cross-sections (9,992 struts) in the Tetriflex SES group. At 6 months, on a per-lesion basis, no significant differences were observed between the XIENCE V EES group and the Tetriflex SES group in mean percentage of uncovered struts (1.87±3.86 vs. 2.42±3.45, p=0.137) and malapposed struts (0.05±0.20 vs. 0.21±0.69, p=0.302). Strut-level neointimal thickness also did not differ between the XIENCE V EES group and the Tetriflex SES group (0.18±0.12 vs. 0.14±0.07, p=0.370).

Conclusions: This OCT study found no significant difference in strut coverage and neointimal thickness at 6 months after implantation of the biodegradable polymer-coated Tetriflex SES, when compared with the durable polymer-coated XIENCE V EES.

INDIALIVE 2018 Coronary interventions

Seven-year clinical outcomes in patients undergoing percutaneous coronary intervention with biodegradable polymer-coated sirolimus-eluting stent: results from a single-centre real-world experience

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Aims: Sirolimus-eluting stents have been used in clinical practice due to their demonstrated ability to reduce restenosis. However, reports of late and very late stent thrombosis have raised questions about long-term outcome in patients treated with these stents. The aim of the present study was to assess the seven-year clinical outcomes of a biodegradable polymer-coated sirolimus-eluting stent (Supralimus; Sahajanand Medical Technologies Pvt. Ltd., Surat, India) in real-world patients with coronary artery disease.

Methods and results: This observational, retrospective study was carried out in all 346 consecutive enrolled patients who underwent percutaneous coronary intervention (PCI) with the Supralimus sirolimus-eluting stent (SES), between April 2008 and December 2009, at a single centre. We analysed major adverse cardiac events (MACE), a composite of cardiac death, myocardial infarction (MI), target lesion revascularisation (TLR) and target vessel revascularisation (TVR) as the primary outcomes at seven-year follow-up. Out of 346 patients, seven-year follow-up was obtained in 327 (94.5%) patients and hence results were analysed for 327 patients. At seven-year follow-up, MACE occurred in 41 (12.5%) patients, consisting of 23 (7.0%) cardiac deaths, 14 (4.3%) TLR, and 4 (1.2%) TVR. Late stent thrombosis was observed in 3 (0.9%) patients. At follow-up of seven years the cumulative event-free survival was found to be 84.7% using the Kaplan-Meier method.

Conclusions: The present study demonstrated satisfactory and sustained seven-year clinical outcomes, as evidenced by the low rates of MACE and ST for the biodegradable polymer-coated Supralimus SES.

INDIALIVE 2018 **Interventions for structural heart disease and heart failure**

Transcatheter device closure of paravalvular leaks

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Aims: To study our experience with transcatheter PVL (TPVL) closure as a less invasive alternative to surgical reintervention to improve clinical outcomes.

Methods and results: Thirty-one (31) patients underwent PVL closure in our institute between May 2015 and November 2017. Inclusion criteria were patients with significant PVL with heart failure, PAH, haemolytic anaemia. Exclusion criteria were presence of active local or systemic infection, prosthetic valve dysfunction, patients with a life expectancy of less than 6 months. All patients underwent preprocedural 3D TEE evaluation. Thirty-one (31) PVL closure procedures were carried out in 27 patients. Age varied from 12 to 67 years; sex ratio 25:6. The target valve was mitral (22), aortic (5) and both (3). Approaches included femoral arterial (7), femoral venous-transseptal (12) and LV apical (12). Devices used were: AVP1 - 1, AVP2 - 18, AVP3 - 4, AVP4 - 4, Muscular VSD devices - 5, ADO1 - 3, Occlutech PLD - 12. Three patients underwent reinterventions for significant residual leaks. One patient had a device embolisation and was taken up for surgery. There was one in-hospital mortality due to a haemothorax-related complication leading to multiorgan failure and two late deaths. There was no residual PVL in 26 patients and mild to moderate in 4 patients at late follow-up.

Conclusions: Percutaneous device closure of PVL is an effective technique with good clinical outcomes and low morbidity.

INDIALIVE 2018 **Interventions for structural heart disease and heart failure**

Atrial septostomy with a novel atrial flow regulator enables reliable and sustained decompression of the left atrium in diastolic heart failure: early results

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Aims: To study the effects of implantation of a novel atrial flow regulator (AFR) (Occlutech, Istanbul, Turkey) in creating a reliable atrial septal fenestration of requisite size to facilitate left atrial decompression in patients with diastolic heart failure.

Methods and results: In patients aged >12 years and satisfying the inclusion criteria for HFpEF, a) Clinical: symptomatic HF in NYHA Class III or above, needing at least one hospitalisation in the preceding year, despite optimal ongoing medical management of at least 6 months duration and optimal medical rate control (<90/min) of arrhythmias, if present; b) Echocardiographic (2DE): left ventricular ejection fraction (LV-EF) ≥40%; c) Cardiac catheterisation (CC): pulmonary capillary wedge pressure (PCWP) ≥15 (rest); ≥25 (exercise) mmHg and greater than the central venous pressure (CVP), AFR was implanted after septal puncture. Four patients (3 male, 1 female) of age range 12-65 years underwent AFR implantation for HFpEF. In 2 patients the mechanical primary efficacy endpoint of a patent device *in situ* and shunting left-right was confirmed by 2DE and CC at the end of 6 months. Secondary efficacy variables included functional class, 6-minute walk distance (6MWD), N-terminal pro brain natriuretic peptide (NT-pro-BNP) levels.

Conclusions: Based on initial results, LA decompression appears to be a suitable strategy to address LV diastolic dysfunction, and AFR implantation seems to provide a reliable, sustained interatrial communication.

INDIALIVE 2018 Interventions for structural heart disease and heart failure

Comparision of outcomes of transcatheter alcohol septal ablation with surgical myomectomy

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Aims: Retrospective analysis of subjective and objective outcomes of those patients who underwent septal reduction therapies – surgical as well as transcatheter.

Methods and results: Forty-one patients (15 males; age 68±10 years) with symptomatic drug-refractory obstructive HCM were studied. Twenty-four patients underwent surgical myomectomy and 15 alcohol septal ablation. All patients underwent clinical evaluation, echocardiography, Holter, cardiac MRI before and after intervention. Fall in peak gradient by both modalities was almost comparable (myectomy: 115±39 to 22±13 mmHg [p<0.000001]; ablation: 100±35 to 22±8.4 mmHg [p<0.000002]; p=0.24 for myomectomy vs. ablation) and led to similar improvements in NYHA class (myomectomy: 2.54±0.6 to 1.5±0.7 [p<0.00001]; ablation: 2.66±0.48 to 2.2±0.56 [p=0.02]; p=0.3 for myomectomy vs. ablation).

Conclusions: Surgical myomectomy and alcohol septal ablation are equally effective in reducing obstruction and subjective exercise limitation in appropriately selected patients. Periprocedural AV conduction abnormalities were higher in transcatheter therapy; however, these were transient.

INDIALIVE 2018 Interventions for structural heart disease and heart failure

Transcatheter closure of sinus venosus atrial septal defect: how to select patients - institutional experience from 14 patients

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Aims: We present here a total of 14 patients with SVASD and anomalous drainage of RUPV in RSVC in whom we closed the defect along with rerouting of RUPV to the left atrium (LA) using a covered stent in 5 patients; 7 patients were referred for surgery after failed balloon occlusion testing of the defect, and 2 patients in whom our attempts resulted in stent embolisation were referred for surgery.

Methods and results: Among 14 patients, females were predominant, with a 9:5 ratio (F:M). Mean age was 29.14±8.55 (7-41) years. All patients presented with complaints of shortness of breath on exertion (functional class 1). On cardiac examination, there was ESM murmur and wide fixed split S2 sound in all. Chest X-ray showed mild cardiomegaly and electrocardiography (ECG) showed sinus rhythm and incomplete right bundle branch block pattern. Predominantly patients underwent 2-D TTE as well as TEE to diagnose SVASD with left to right shunt and anomalous drainage of RUPV in RSVC. Right-sided cardiac chambers were dilated and pulmonary artery pressure was normal. All patients underwent balloon occlusion testing to delineate the defect and the anatomy of the anomalous pulmonary vein. Procedure: the procedure was carried out under controlled sedation without GA and transoesophageal echocardiography (TEE) guidance. Two femoral venous access routes were used. Anomalous drainage of RUPV into RSVC and the lower end of the sinus venosus ASD was demonstrated with a hand angiogram in AP and steep LAO view. Based upon the size of SVC and drainage site of RUPV into SVC, the desired balloon was selected with a suitable diameter and length, and balloon occlusion of SVC with hand injection in RUPV was carried out to study the relationship and flow pattern of RUPV. Hand injection was carried out in RUPV while blocking the SVC with a balloon to demonstrate free flow of contrast into the LA in 7 patients. Simultaneous TEE was performed during inflation of the balloon in RSVC to check for unobstructed blood flow from RUPV to LA. Among the 7 patients whom we referred for surgery, 2 patients had elevation of pulmonary venous pressure post balloon occlusion, 3 patients had unsuitable anatomy with RUPV becoming occluded on balloon occlusion, 1 patient had drainage of RUPV in the high end of SVC and 1 patient had accessory RUPV with inability to occlude with a balloon.

Conclusions: An attempt can be made to close this type of ASD and reroute the partial anomalous pulmonary vein to LA by transcatheter technique in selected patients. Long-term follow-up data from many more cases are required before comparing the feasibility and safety of this procedure as an alternative to surgery.

INDIALIVE 2018 Interventions for structural heart disease and heart failure

Plasma NT-proBNP: a prognostic and diagnostic marker of diastolic heart failure in hypertensive patients

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Aims: In this study we tried to evaluate the value of plasma NT-proBNP in the diagnosis of diastolic heart failure in hypertensive patients.

Methods and results: The study was carried out for a period of one year where 100 hypertensive patients with diastolic dysfunction on 2D echocardiography and NYHA functional class were selected and classified as: group I - patients with impaired relaxation, group II - patients with pseudonormal, and group III - patients with a restrictive filling pattern within 24 hours after admission or OPD visit and plasma NT-proBNP levels measured simultaneously. The plasma level of NT-proBNP was compared within the study groups. It was observed that mean plasma NT-proBNP was significantly lower for NYHA functional Class I and diastolic function grade I as compared to NYHA Class II and Class III and diastolic function grade II and grade III, respectively. There was significant association of plasma NT-proBNP and NHYA functional Class ($p<0.05$) and diastolic function ($p<0.05$) as per the Student's t-test.

Conclusions: NT-proBNP appears as a strong prognostic index in hypertensive patients with cardiovascular risk profiles, can reliably detect the presence of isolated diastolic dysfunction in symptomatic patients, and is a useful tool to rule out patients with reduced exercise tolerance of non-cardiac origin.

INDIALIVE 2018 Interventions for structural heart disease and heart failure

Intravascular stenting for coarctation of aorta/acquired interruption: Indian experience with early and intermediate follow-up

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Aims: We share our experience of treating coarctation of the aorta and functional acquired interruption with its technical challenges and the effect of stenting on aortic regurgitation associated with the bicuspid valve.

Methods and results: Since 2008, coarctation stenting was attempted in 27 patients with a median age of 21 years (range 9-58 years). The procedure was abandoned in one patient due to profound femoral artery injury. In three patients an interrupted aortic segment was crossed antegradely using a CTO wire. Eleven (11) patients underwent predilatation using a peripheral balloon or serially with a PTCA balloon (in acquired interruption cases). Palmaz/Genesis stents were used in 8 cases, while in the rest CP stents (covered in 6 and uncovered in 12) were used. The median pre-procedure gradient was 70 mmHg (range 30-200 mmHg) which dropped to 10 mmHg (range nil-30 mmHg). Six patients had loss of lower limb pulsations with preserved lower limb circulation. Two patients developed severe radial artery spasm during the procedure and recovered later. On a mean follow-up period of 48 months, four out of 5 patients with significant residual gradient underwent successful balloon coarctoplasty. One of the interesting findings is decrease in severe AR in 5 cases (moderate in 4 and mild in one) after stent placement.

Conclusions: Coarctation of the aorta, including functional interruption cases, is amenable to stenting considering its technical challenges. Interestingly, severe AR associated with the bicuspid valve tends to decrease after successful coarctation stenting.

INDIALIVE 2018 **Interventions for structural heart disease and heart failure**

Combination of ivabradine and eplerenone significantly reduces repeat hospitalisation and mortality in heart failure with reduced ejection fraction (HFrEF)

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Aims: To evaluate the efficiency of an ivabradine and eplerenone combination with current treatment regimes such as ACEI, ARBs, BBs, diuretics, statins, digitalis, etc.

Methods and results: The study was conducted between 2011 and 2017 and included a total of 1,590 heart failure patients: 780 patients were selected for prospective study and 810 with placebo. All patients were selected with history taking, clinical examination, ECG, echo, basic biochemistry and hormone study. Ivabradine 5 mg bid for all patients and eplerenone 25 mg od for 80% of patients, with 20% being titrated to 50 mg od. The patients were followed in terms of complaints, 6MWT, echo and mortality. Significant improvements were found in the ivabradine and eplerenone study compared to placebo. Ejection fraction increased in 80% of patients, 6MWT improved in 92% of patients, repeat hospitalisation reduced in 90% of patients, one wall motion was improved in 90% of patients and two wall motions were improved in 60% of the patients. No hospitalisation was found in the study group.

Conclusions: A combination of I(f) current inhibitor and mineralocorticoid receptor blockers has shown significant positive results with a reduced mortality rate and re-hospitalisation compared to placebo.

INDIALIVE 2018 **Miscellaneous**

Evaluation of the effectiveness and safety of balloon pulmonary angioplasty for inoperable chronic thromboembolic pulmonary hypertension

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Aims: The current established gold standard curative therapy for chronic thromboembolic pulmonary hypertension (CTEPH) is surgical pulmonary thromboendarterectomy (PTE). However, 40% of patients are judged to be inoperable due to associated comorbidities, high-risk status and, predominantly, due to involvement of distal pulmonary arteries. In selected patients who are deemed inoperable, percutaneous balloon pulmonary angioplasty (BPA) is considered as an alternative treatment modality.

Methods and results: CTEPH patients who had 1) distal surgically inaccessible disease, 2) complete occlusion, 3) intravascular webs and filling defects, 4) residual distal pulmonary thrombus following surgical PTE were selected for BPA. Advance Low-Profile PTA Balloon Dilatation Catheters (Cook Medical) of sizes 2×20, 3×20, 4×20 and 5×20 mm were used for dilatation. Thirty-five procedures in 11 consecutive patients (mean age 32.3 years) underwent BPA in Narayana Hrudayalaya Heart Hospital, Bangalore between Jan 2017 and August 2017. Each patient had an average of 3.2 procedures (range 2 to 5) and 12 dilations per procedure (range 10 to 24). After a mean follow-up of seven months, we observed a significant improvement in NYHA Class (from Class IV to II), 6-minute walking distance (from 133 to 390 metres) and mean pulmonary artery pressure (from 70.5 to 43 mmHg). Four patients developed reperfusion pulmonary oedema two of whom required mechanical ventilation. Minimal haemoptysis was observed in two patients which subsided spontaneously. One patient who underwent bail-out BPA after surgical PTE died on the 24th postoperative day.

Conclusions: BPA significantly improves the haemodynamic status and exercise capacity of patients with CTEPH with acceptable complication rates. BPA is a promising and rewarding interventional technique for patients who have inoperable CTEPH.

INDIALIVE 2018 **Miscellaneous**

Association of vitamin D3 with non-specific chest pain

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Aims: To establish the association of vitamin D3 with non-specific chest pain.

Methods and results: A total of 115 patients were included in this study. Of the study population, 75% were female and they were in the age group 31-40 years. According to the study most of the patients were higher middle class. The majority of the patients had non-specific chest pain (86%) and palpitation (79%). Most of the patients (89.6%) had vitamin D deficiency - serum 25 (OH)D concentration less than 30 nmol/l. Ninety-one patients (79.1%) with vitamin D deficiency responded to the proposed treatment and their VAS scores diminished.

Conclusions: This study showed that vitamin D3 deficiency is associated with non-specific chest pain and vitamin D3 supplementation reduces the chest pain significantly.

INDIALIVE 2018 **Miscellaneous**

A study of genetic variation in the metabolism of clopidogrel in patients with stent thrombosis

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Aims: We intended to study the CYP2C19 genetic polymorphism for clopidogrel metabolism in patients with stent thrombosis.

Methods and results: Fifty-one patients were included, 26 cases (angiographically proven stent thrombosis) and 25 controls (post-PCI patients). CYP2C19 genotyping for clopidogrel response was assessed. Allele specific PCR stratified individuals into one of these six categories: CYP2C19*1/*1, CYP2C19*1/*2, CYP2C19*1/*3, CYP2C19*2/*2, CYP2C19*2/*3, CYP2C19*3/*3. Patients were classified as poor metaboliser (2/2, 2/3, 3/3), intermediate metaboliser (1/2, 1/3) and normal metaboliser (1/1) of clopidogrel and correlated between cases and controls. Among stent thrombosis cases, poor metabolisers accounted for 11 cases (42.30%), intermediate metabolisers 13 cases (50%) and normal metabolisers 2 cases (7.69%). In the control group, poor metabolisers accounted for 1 case (4%), intermediate metabolisers 14 cases (56%) and normal metabolisers 10 (40%) cases. Our study showed an increased prevalence of poor metaboliser (CYP2C19 2*2*) genotype in patients with stent thrombosis as compared to controls (p=0.004). Also, there was an increased prevalence of normal metaboliser (CYP2C19 1*1*) genotype in the control group as compared to cases.

Conclusions: Clopidogrel should be avoided in post-PCI patients, who carry the poor metaboliser variants of CYP2C19 gene, to reduce the chances of stent thrombosis.

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