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INTERVENTIONS FOR VALVULAR DISEASE AND HEART FAILURE

ABSTRACTS

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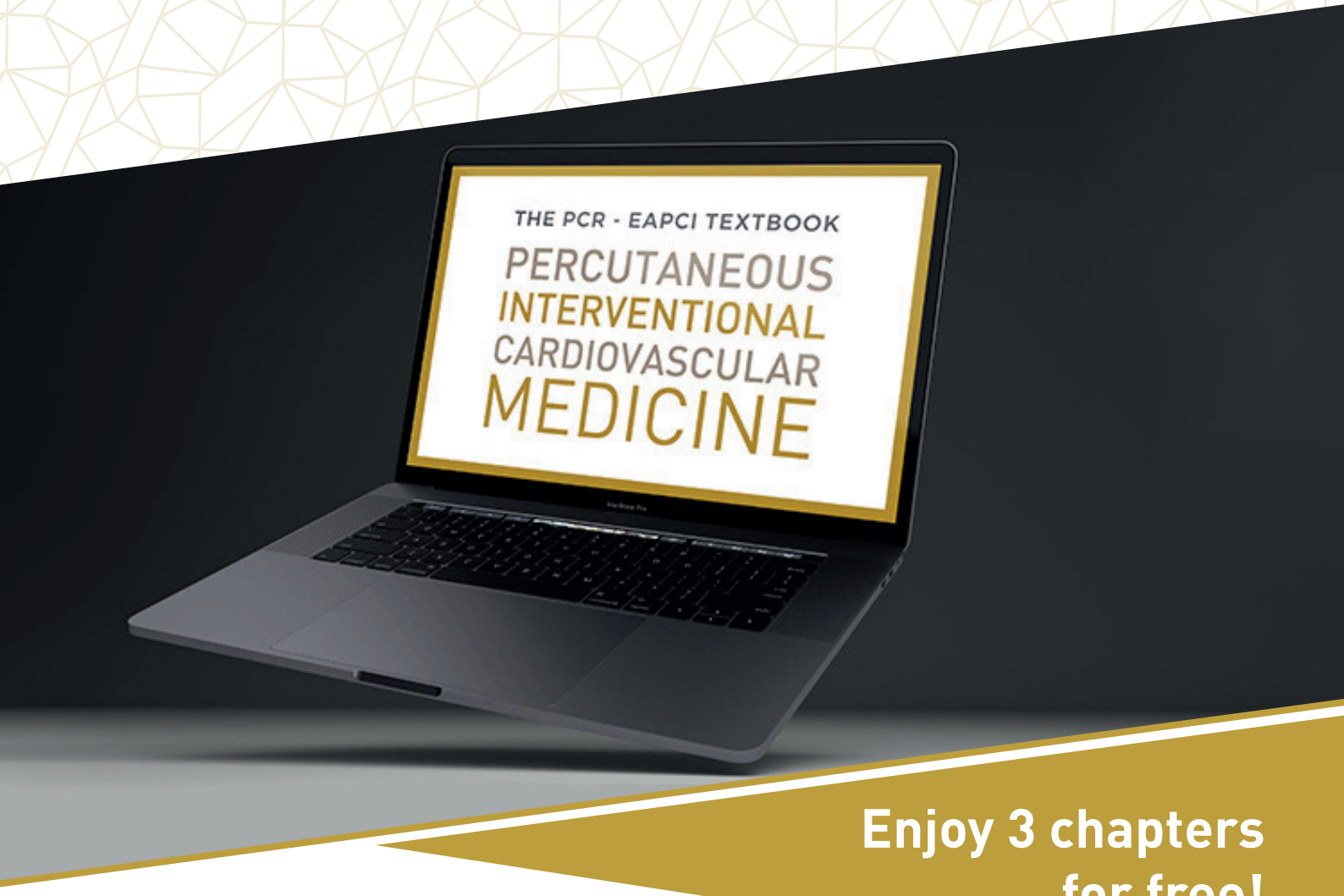

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Interventional cardiology in Asia Pacific: the rise of the young-generation interventional cardiologist

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By the time you all read this, the historic first meeting of AICT-AsiaPCR will be in full progress, representing a landmark partnership between the Asia Pacific Society of Interventional Cardiology and PCR. Having been a part of the development and growth of Interventional Cardiology in Asia Pacific for the last 30 years, I feel proud to witness the astounding contribution of Asia-Pacific interventional cardiology to science, research, techniques and technology, indigenous devices and thought leadership, especially over the last 15 years[1].

I reminisce about the early 1990s, the balloon angioplasty and "cutters and drillers" era, when a few of us from this part of the world started getting together formally at various live courses in Singapore, Australia, India and Japan, to share our knowledge, exchange our experiences and help to improve expertise and patient outcomes. At that time there were perhaps only two or three committed operators from each country, with strong beliefs and convictions to extend the boundaries of interventional cardiology and break down the borders across Asia Pacific to take this specialisation forwards. By the late 1990s, some of us started to travel regularly to other countries, to train and establish angioplasty expertise, and this helped the growth of interventional cardiology in the Philippines, Indonesia, Thailand, Malaysia, Brunei and even China. We also started formal training of fellows from neighbouring countries where interventional cardiology was non-existent. This informal yet powerful friendship and camaraderie amongst the Asia-Pacific countries helped to propagate the massive growth in interventional cardiology that we have seen over the last 15 years.

On a visit to Delhi 20 years ago, Professor Jean Marco made the statement that "it is not just how expert you are, it is how you can pass that expertise to your fellows". Well, the statement is truer today in Asia-Pacific interventional cardiology than ever before. Most Asia-Pacific countries share a common socio-economic fabric ... the rapid growth of interventional cardiology over a short time frame has led to a proliferation of cath labs even in smaller cities, being served by young-generation interventional cardiologists (IC). In some countries they form nearly fifty percent of the workforce performing interventional procedures; they are

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keen, motivated, passionate, and eager to learn more and do better. So the opportunity for seniors to share and teach is greater than ever before. AICT-AsiaPCR is clearly designed for the young-generation interventionalists to satisfy their yearning for learning and sharing. It also provides them with an Asian platform to present their unusual cases, and their scientific and research work, to the world.

But we need to do more. I was impressed by the concept, the belief and the Charter of the "Companions" across the world, unveiled at EuroPCR this year (https://www.pcronline.com/About-PCR/pcr-charter). Our young-generation IC in Asia Pacific are looking for experience, advice and guidance every day as they are sometimes faced with the most difficult cases under demanding circumstances. They need a friend, philosopher and guide. They need MENTORSHIP as never before and we seniors owe this to them.

Information technology now allows "mentoring" through multiple modalities and at short notice, even "real-time advice" on a complex in-lab problem. In India a WhatsApp group of nearly 250 young-generation IC, along with some seniors, share details and cines and images of complex intervention cases, ask for opinions and discuss within the group "how would you do it?", and finally, after a day, how it was done, with expert comments from seniors. Over 24 hours, evidence-based strategies are proposed, IVUS and OCT findings are discussed and, finally, the case is closed. The daily WhatsApp group discussion on 2-3 difficult cases and their solutions is truly an educationally enriching experience. Patient confidentiality is maintained as no names are taken or shown.

As we continue our progress in interventional cardiology in Asia Pacific, let each senior resolve to be a MENTOR on a daily basis to at least 20 young-generation IC who may be practising in smaller centres with no peer support. This is not just for continuing medical education, it is not just a friend in need and it is not just providing comfort or confidence, but it is for improving outcomes on a real-time basis for our patients and community.

Conflict of interest statement

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Reference

1. Gao R. The evolution of percutaneous coronary intervention in Asia: in celebration of the 40th anniversary of percutaneous transluminal coronary angioplasty. *AsiaIntervention.* 2017;3:95-96.

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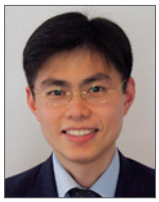
Endovascular recanalisation of chronic aortoiliac occlusions – will this become the initial treatment of choice?



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Chronic distal (infrarenal) aortic occlusion with or without iliac artery occlusion is a relatively uncommon or even rare disease, accounting for only 1-8% of patients presenting with aortoiliac atherosclerotic disease[1,2]. Most patients complain of buttock and/or thigh claudication, with smaller numbers presenting with critical limb ischaemia (rest pain, tissue loss, and non-healing ulcer)[2].

Surgical bypass has been an established treatment modality, either with anatomic bypass (e.g., aorto-bifemoral bypass) or extra-anatomic bypass (e.g., axillo-femoral bypass)[3]. Although aorto-bifemoral bypass has good long-term patency rates of approximately 91% and 87% at five years for patients with claudication and critical limb ischaemia, respectively, the surgical mortality and morbidity are not insignificant (3.3-4.6% and 8.3-13.1%, respectively)[4]. Conversely, extra-anatomic bypass (e.g., axillo-femoral bypass), though less invasive, still carries significant procedural risks and has a poorer patency rate of 71% at five years[5,6].

More recently, with the improvement of technology and technique, percutaneous endovascular treatment (EVT) for recanalising aortic occlusions has been increasingly performed and reported[1,2,7-12]. This is an attractive method of revascularisation as it is less invasive and can be performed with local anaesthesia. As many patients with aortic occlusion also have comorbidities that render them at elevated surgical risk (e.g., concomitant ischaemic heart disease, chronic renal failure, etc.), EVT may therefore impose less procedural risk. Literature on EVT for chronic distal aortic occlusion has been limited; several studies enrolled a mixture of patients with distal aortic or iliac artery stenosis or occlusion, and studies which included only distal aortic occlusions had small patient numbers[1,2,7-12].

In a multicentre registry report published in this issue of AsiaIntervention, Kato et al[13] describe a relatively large cohort of Japanese patients with distal (infrarenal) aortic occlusion (with or without iliac artery occlusion) treated with endovascular therapy. Interestingly, the investigators are all cardiologists who perform both coronary and peripheral artery interventions. A total of 73 patients were initially enrolled; three were excluded from the final analysis as the revascularisation involved only the distal aorta and a single iliac artery (one patient had a previous lower limb amputation, two were patients with ipsilateral foot ulcers), two were excluded because, after successful distal aorta and single

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iliac artery recanalisation, the patients underwent a surgical femorofemoral bypass (hybrid procedure) and one was excluded as treatment was well before the year 2007 (when major restrictions on devices in Japan were in place).

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Although the authors chose not to include these patients in the analysis, it is worthwhile noting that the intended revascularisation procedures were all successful. Furthermore, this practice of selective recanalisation of the distal aorta and a single iliac artery is what many operators would have performed in a "real world" setting so that patients are treated according to clinical indications. Attempting to perform complete distal aortic and bilateral iliac artery recanalisation in all patients may be unnecessary and even harmful in this group of high-risk patients.

Of the remaining 67 patients, 63 had successful revascularisation via EVT. This high procedural success (94%) is in line with previous reports[1,2,7,8]. The high rate of technical success was achieved despite the majority of patients having complex lesions (nearly 85% involved occlusions of the distal aorta and iliac arteries, and half of the lesions showed moderate-severe vessel calcification). In this author's humble experience, this subset of patients is amongst the most challenging in the field of peripheral vascular intervention due to the technical difficulty (multiple access sites [bifemoral and brachial] required, use of multiple [0.014-, 0.018- and even 0.035-inch] wires, use of support catheters/microcatheters, and use of snares and wire exteriorisation) and the severe complications that can occur. This is even more remarkable considering that each centre performed an average of only four to five such cases throughout the long study duration (less than one case per year which is consistent with the rarity of the disease). Modern-day guidewire technology (in particular dedicated 0.018-inch and 0.014-inch stiff wires) and, arguably, experience and techniques with coronary chronic total occlusion interventions, would likely have contributed to this.

Clinical outcomes were also excellent with only one 30-day mortality (1.4%), that was not procedure-related, and one stroke (1.4%). There were two other complications (2.9%): one distal embolisation that improved with thomboaspiration and one access-site haematoma that required blood transfusion. These outcomes are consistent with previous reports of EVT in distal aortic occlusion[1,2,7-12] that showed a very low mortality rate (0-2%), and compares favourably with surgical bypass[4,6].

The four unsuccessful procedures were all due to failure of guidewire passage as a result of significant vascular calcification, in keeping with the experience of previous reports[1,8]. Of note, in this series, there was no vessel dissection or perforation, perhaps due to the fact that the majority of procedures were performed using intraluminal wiring with 0.014- or 0.018-inch guidewires. A high rate of intravascular ultrasound usage (80%), which differs from previous reports[1,2,7,8], may also have contributed to the safe outcomes.

The major limitation of the present study is its short follow-up with only one-year primary and secondary patency rates available. Most studies have reported patency rates of three to five years as the frequency of restenosis and re-occlusion increases with longer follow-up[1,2,7-9]. Reassuringly, the one-year primary and secondary patency rates (90% and 97%, respectively) reported in this study are consistent with the aforementioned publications, and longer-term patency would be expected to be similar. The authors of the current study should be encouraged to continue follow-up of this group of patients to add to data on the long-term (five- and even 10-year) primary and secondary patency rates after successful EVT of distal aortic occlusions.

It is accepted that the mid- to long-term (three to five years) primary patency of EVT is generally inferior to aorto-bifemoral bypass (66-80% vs 85-95%, respectively), whereas secondary patency rates of EVT (83-98%) appear comparable[1,2,4,7,14]. This is a pertinent point because secondary intervention for EVT restenosis is considered to be technically easier and a less risky undertaking.

Another limitation of this study is its retrospective nature with all the caveats that accompany such a study design. For instance, centres/operators with unsuccessful procedures may have declined to join the registry. It is also uncertain if the good results reported in this study can be reproduced by centres/operators with less extensive peripheral vascular intervention experience. Nonetheless, the authors must be congratulated for publishing the largest cohort of (Asian) patients undergoing EVT for a relatively rare but important clinical condition. One other important unanswered question is whether the use of covered stents, as compared to bare metal stents (used in the present study), in distal aortic occlusions would produce better outcomes, as suggested by some studies[3,15,16].

In summary, the current study adds to our understanding of EVT for distal (infrarenal) aortic occlusions with or without iliac artery occlusions. As the body of evidence grows, and as technology, techniques and outcomes continue to improve, it is conceivable that EVT for distal aortic occlusion may become the initial therapy of choice for all patients and not just limited to those at increased surgical risk[3]. This would be particularly relevant for experienced centres/operators as the technical success rate of EVT is high and procedural risk and complication rates appear to be low. Further high-quality and long-term data would be required for such a paradigm shift to occur.

Conflict of interest statement

The author has no conflicts of interest to declare.

References

1. Kim TH, Ko YG, Kim U, Kim JS, Choi D, Hong MK, Jang Y, Shim WH. Outcomes of endovascular treatment of chronic total occlusion of the infrarenal aorta. *J Vasc Surg*. 2011;53:1542-9.

2. Soga Y, Iida O, Kawasaki D, Yamauchi Y, Suzuki K, Hirano K, Koshida R, Kamoi D, Tazaki J, Higashitani M, Shintani Y, Yamaoka T, Okazaki S, Suematsu N, Tsuchiya T, Miyashita Y, Shinozaki N, Takahashi H; REAL-AI investigators. Contemporary outcomes after endovascular treatment for aorto-iliac artery disease. *Circ J*. 2012;76:2697-704.

3. Aboyans V, Ricco JB, Bartelink MEL, Bjorck M, Brodmann M, Cohnert T, Collet JP, Czerny M, De Carlo M, Debus S, Espinola-Klein C, Kahan T, Kownator S, Mazzolai L, Naylor AR, Roffi M, Rother J, Sprynger M, Tendera M, Tepe G, Venermo M, Vlachopoulos C, Desormais I; ESC Scientific Document Group. 2017 ESC Guidelines on the Diagnosis and Treatment of Peripheral Arterial Diseases, in collaboration with the European Society for Vascular Surgery (ESVS): Document covering atherosclerotic disease of extracranial carotid and vertebral, mesenteric, renal, upper and lower extremity arteriesEndorsed by: the European Stroke Organization (ESO)The Task Force for the Diagnosis and Treatment of Peripheral Arterial Diseases of the European Society of Cardiology (ESC) and of the European Society for Vascular Surgery (ESVS). *Eur Heart J.* 2018;39:763-816.

4. de Vries SO, Hunink MG. Results of aortic bifurcation grafts for aortoiliac occlusive disease: a meta-analysis. *J Vasc Surg*. 1997; 26:558-69.

5. Norgren L, Hiatt WR, Dormandy JA, Nehler MR, Harris KA, Fowkes FG; TASC II Working Group. Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II). *J Vasc Surg*. 2007;45 Suppl S:S5-67.

6. Liedenbaum MH, Verdam FJ, Spelt D, de Groot HG, van der Waal J, van der Laan L. The outcome of the axillofemoral bypass: a retrospective analysis of 45 patients. *World J Surg.* 2009;33: 2490-6.

7. Moise MA, Alvarez-Tostado JA, Clair DG, Greenberg RK, Lyden SP, Srivastava SD, Eagleton M, Sarac TS, Kashyap VS. Endovascular management of chronic infrarenal aortic occlusion. *J Endovasc Ther.* 2009;16:84-92.

8. Dohi T, Iida O, Okamoto S, Nanto K, Nanto S, Uematsu M. Mid-term clinical outcome following endovascular therapy in patients with chronic aortic occlusion. *Cardiovasc Interv Ther.* 2013;28:327-32.

9. Martinez R, Rodriguez-Lopez J, Diethrich EB. Stenting for abdominal aortic occlusive disease. Long-term results. *Tex Heart Inst J.* 1997;24:15-22.

10. Rosset E, Malikov S, Magnan PE, Poirier M, Valerio N, Ede B, Branchereau A. Endovascular treatment of occlusive lesions in the distal aorta: mid-term results in a series of 31 consecutive patients. *Ann Vasc Surg.* 2001;15:140-7.

11. Lagana D, Carrafiello G, Mangini M, Lumia D, Caronno R, Castelli P, Cuffari S, Fugazzola C. Endovascular treatment of stenoocclusions of the infrarenal abdominal aorta. *Radiol Med.* 2006;111:949-58.

12. Klonaris C, Katsargyris A, Tsekouras N, Alexandrou A, Giannopoulos A, Bastounis E. Primary stenting for aortic lesions: from single stenoses to total aortoiliac occlusions. *J Vasc Surg*. 2008;47:310-7.

13. Kato T, Zen K, Kawarada O, Hozawa K, Anzai H, Nakamura H, Funatsu A, Kawasaki D, Tsubakimoto Y, Higashimori A, Kozuki A, Matoba S. Clinical outcomes of endovascular treatment for chronic aortic occlusion: a retrospective multicentre registry. *AsiaIntervention.* 2019;5:121-7.

14. Ye W, Liu CW, Ricco JB, Mani K, Zeng R, Jiang J. Early and late outcomes of percutaneous treatment of TransAtlantic Inter-Society Consensus class C and D aorto-iliac lesions. *J Vasc Surg*. 2011;53:1728-37.

15. Sabri SS, Choudhri A, Orgera G, Arslan B, Turba UC, Harthun NL, Hagspiel KD, Matsumoto AH, Angle JF. Outcomes of covered kissing stent placement compared with bare metal stent placement in the treatment of atherosclerotic occlusive disease at the aortic bifurcation. *J Vasc Interv Radiol.* 2010;21:995-1003.

16. Mwipatayi BP, Thomas S, Wong J, Temple SE, Vijayan V, Jackson M, Burrows SA; Covered Versus Balloon Expandable Stent Trial (COBEST) Co-investigators. A comparison of covered vs bare expandable stents for the treatment of aortoiliac occlusive disease. *J Vasc Surg*. 2011;54:1561-70.

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Left ventricular dysfunction before transcatheter aortic valve implantation

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Transcatheter aortic valve implantation (TAVI) has already been established as a viable treatment option for most patients with aortic stenosis. However, left ventricular (LV) systolic dysfunction still remains one of the risk factors for procedural difficulty and poor clinical outcomes.

In this issue of AsiaIntervention, Soon et al report the improvement of LV function after TAVI in 662 patients and identify more severe LV systolic dysfunction as an independent predictor of LV recovery. Among patients with severe LV dysfunction (left ventricular ejection fraction [LVEF] <30%), frailty and male gender were identified as independent predictors of LV recovery.

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Although these findings are in line with those from the PARTNER trial[1], as the authors describe, poor baseline LV function may be associated with worse survival after TAVI. The conclusions from this analysis may suggest that severe LV dysfunction is associated with poor outcomes but also with improvement of LV recovery. One of the most important messages from this study is that the majority of patients with severe LV dysfunction showed LV improvement after TAVI; therefore, TAVI should not be avoided because of the presence of LV dysfunction. Indeed, recent studies have demonstrated excellent midterm clinical outcome after TAVI. The OCEAN-TAVI Japanese multicenter registry demonstrated overall 30-day mortality and cumulative 1-year mortality to be 1.7% and 11.3%, respectively[2]; most of the patients had non-cardiac death during follow-up. These data suggest that most patients had sufficient clinical benefit after TAVI even with concomitant LV dysfunction. The reason for this finding is unclear; however, the less invasive nature of this procedure could maximise survival benefit by minimising periprocedural complications and death. It was also interesting to see that improvement of LV did not have an impact on late mortality by Kaplain-Meier survival analysis in this study. The lack of a sufficient number of events could be the reason for this finding. Further studies comparing TAVI and surgical aortic valve replacement (SAVR) could be of great interest. The authors also demonstrated that female gender was identified as a predictor of good LV recovery. Female gender is known to lead to better survival after TAVI[3]; better LV recovery could be one of the reasons for this.

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Concomitant aortic stenosis and mitral regurgitation is also a challenging situation. The current ESC/EACTS guidelines identified that mitral disease is one of the favourable factors for choosing a surgical procedure over TAVI[4]. However, improvement of mitral regurgitation after TAVI is sometimes found, especially in case of functional mitral regurgitation with the mechanism of tethering[5]. If we could predict LV recovery accurately, this would have an impact on an appropriate selection strategy for patients with aortic stenosis and concomitant mitral regurgitation.

In line with the rapid progress and improvement of TAVI, clinical data after this procedure are improving year by year. This study provides an encouraging message to treat patients with poor LV function. Further studies are needed to clarify this important issue.

Conflict of interest statement

K. Hayashida is a clinical proctor for Edwards Lifesciences.

References

1. Soon KH, Kooistra NHM, Voskuil M, Kraaijeveld AO, Stella PR. LV systolic dysfunction stands to gain the most post transcatheter aortic valve implantation (TAVI). *AsiaIntervention.* 2019;5:142-8.

2. Elmariah S, Palacios IF, McAndrew T, Hueter I, Inglessis I, Baker JN, Kodali S, Leon MB, Svensson L, Pibarot P, Douglas PS, Fearon WF, Kirtane AJ, Maniar HS, Passeri JJ; PARTNER Investigators. Outcomes of transcatheter and surgical aortic valve replacement in high-risk patients with aortic stenosis and left ventricular dysfunction: results from the Placement of Aortic Transcatheter Valves (PARTNER) trial (cohort A). *Circ Cardiovasc Interv.* 2013;6:604-14.

3. Yamamoto M, Watanabe Y, Tada N, Naganuma T, Araki M, Yamanaka F, Mizutani K, Tabata M, Ueno H, Takagi K, Higashimori A, Shirai S, Hayashida K; OCEAN-TAVI investigators. Transcatheter aortic valve replacement outcomes in Japan: Optimized CathEter vAlvular iNtervention (OCEAN) Japanese multicenter registry. *Cardiovasc Revasc Med.* 2018 Dec 4. [Epub ahead of print].

4. Hayashida K, Morice MC, Chevalier B, Hovasse T, Romano M, Garot P, Farge A, Donzeau-Gouge P, Bouvier E, Cormier B, Lefèvre T. Sex-related differences in clinical presentation and outcome of transcatheter aortic valve implantation for severe aortic stenosis. *J Am Coll Cardiol.* 2012;59:566-71.

5. Baumgartner H, Falk V, Bax JJ, De Bonis M, Hamm C, Holm PJ, Iung B, Lancellotti P, Lansac E, Rodriguez Muñoz D, Rosenhek R, Sjögren J, Tornos Mas P, Vahanian A, Walther T, Wendler O, Windecker S, Zamorano JL; ESC Scientific Document Group. 2017 ESC/EACTS Guidelines for the management of valvular heart disease. *Eur Heart J.* 2017;38:2739-86.

6. Bedogni F, Latib A, De Marco F, Agnifili M, Oreglia J, Pizzocri S, Latini RA, Lanotte S, Petronio AS, De Carlo M, Ettori F, Fiorina C, Poli A, Cirri S, De Servi S, Ramondo A, Tarantini G, Marzocchi A, Fiorilli R, Klugmann S, Ussia GP, Tamburino C, Maisano F, Brambilla N, Colombo A, Testa L. Interplay between mitral regurgitation and transcatheter aortic valve replacement with the CoreValve Revalving System: a multicenter registry. *Circulation.* 2013;128:2145-53.

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How has Asia contributed to global interventional cardiology?

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The 21st century is commonly dubbed the "Asian Century" because of the robust economic performance and projected demographic growth in this region, with the population expected to increase from the present day four billion to five billion people by 2050. The major driver is productivity growth as living standards rise. The same parallel can be observed in the field of endovascular therapy in the last three decades, with expected phenomenal growth in interventional volume, coupled with research and innovation and widespread upskilling and training of cardiologists in the region.

I entered the field of interventional cardiology and completed my fellowship training in the mid 1990s. I have had the opportunity to witness the development of interventional therapy in the region. There is no question about the explosive growth in the number of coronary intervention cases in Asia driven by double digit growth in China and India. From a mere 12,000 cases in 2000, China performed more than 915,000 in 2018. India has also witnessed rapid growth from 67,000 in 2010 to more than an estimated 550,000 cases performed last year **(Figure 1)**. Considering that both of these (Asia's two largest countries) have populations that are three times larger than the USA, it is not difficult to imagine that they will exceed the estimated annual 950,000 cases performed in the USA in no time. There have also been many governmental policies formulated in recent years to fund the therapy such as the heavy subsidies for primary percutaneous coronary intervention (PPCI) in Indonesia and Vietnam. It is no wonder that all the major companies in the industry are relooking their marketing and investment strategies in the East.

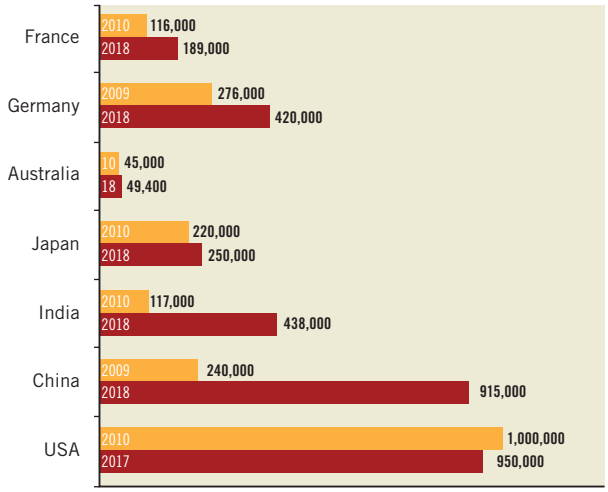

Figure 1. *Number of PCI procedures performed around the world.*

One has to acknowledge that the Western world has clearly taken the lead in pioneering the technique of coronary angioplasty, from the landmark work performed by Dr Andreas Gruntzig in 1997, to the development of the Palmaz-Schatz coronary stent by Drs Julio Palmaz and Richard Schatz, to the first-in-man transcatheter aortic valve implantation in 2002 by Dr Alain Cribier. These achievements have set the stage for future generations of interventionists to build on, many of whom hail from the Asian region.

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Following Dr Ferdinand Kiemeneij's first introduction of transradial access to angioplasty and stent procedure in 1992, there was an almost immediate adoption of this technique in Asia because of the advantage of reducing periprocedural bleeds.

Dr Shigeru Saito started the Yokohama Transradial Intervention Course in Japan; Dr Tejas Patel has written a book on the techniques which has benefited generations of interventionists. In terms of pushing forward new boundaries and techniques, Dr Seung-Jung Park from Korea has shown that PCI of treacherous left main territory disease was feasible and safe, Dr Shao-Liang Chen from China developed the superior technique of double-kissing crush (DK crush) for the treatment of distal left main bifurcation lesions and Dr Osamu Katoh from Japan pioneered the now-common techniques of controlled antegrade and retrograde tracking (CART) and reverse CART for retrograde recanalisation of chronic total occlusion of coronary arteries. In terms of innovation, we remember that it was the late Dr Hideo Tamai from Japan who developed the first bioresorbable scaffold called the Igaki-Tamai stent in 2001, with its interesting self-expanding design using the poly-L-lactic acid polymer. Multivessel complex PCI in high-risk patients, now termed CHIP (complex high-risk indicated patients), with sophisticated and often ingenious techniques are commonplace in Asian countries. This is perhaps a result of the cultural reluctance to undergo open chest surgery among East Asians, with a resultant PCI to coronary artery bypass surgery (CABG) ratio varying from 3 to 100:1. In addition, CABG is not routinely available in most hospitals in Asia and PCI has become the only coronary revascularisation modality available.

While the level of technical expertise has improved considerably over the years, there is still room for improvement in terms of the adoption of an evidence-based approach to PCI. This would include appropriate use criteria, guideline-directed approaches, more use of imaging and physiology-guided therapies, as well as adjuvant pharmacologic therapies. There should also be the systematic training of young fellows, from acquiring core curriculum knowledge, the use of simulator-based technical training, to apprentice-based clinical training with more personal and interactive learning with mentors. There is also a place for better design of clinical trials that are relevant to our practice in Asia. These are areas where I think the Asia Pacific Society of Interventional Cardiology (APSIC) can play a part.

I have been fortunate to be the President of APSIC for an unprecedented two terms of six years' duration. I have had the opportunity to contribute to the growth and development of endovascular therapy in this vast region. APSIC was officially formed during the 3rd live demonstration course held in Singapore in July 1993. Founded initially by 11 eminent cardiologists who were convinced that the 21st century of growth in interventional cardiology would be in Asia, the group had the vision then to provide a forum in which Asia-Pacific experts could share knowledge and expertise in the field of catheter-based therapies, and to develop joint academic research and education programmes **(Figure 2)**.

Figure 2. *Founding members of APSIC in Sydney 1993.*

Membership enrolment for APSIC was to be conducted through the national cardiac societies. It would be under the umbrella of the Asian-Pacific Society of Cardiology (APSC) and the President would be a member of the APSC Council. Drs Richard Ng and Arthur Tan were elected to be the first President and Secretary General of APSIC, respectively. An APSIC newsletter was first published on 29 September 1993 to feature regular updates of scientific development and to share interesting cases and literature reviews among the interventional cardiology fraternity.

In the ensuing 20 years, APSIC has gone through ups and downs but has recently taken on a new momentum. It now boasts membership from 20 Asian-Pacific countries, with 273 fully fledged fellows, including members from Australia and New Zealand, and the Gulf States such as Saudi Arabia and Kuwait. It has a permanent secretariat based in Hong Kong.

Under the current APSIC Board, the Society endeavours to embark on two broad initiatives. The first is to promote the standard of catheter-based therapies in the region through scientific and training activities, and to connect with the rest of the world through collaborative educational opportunities. The Society has its own official scientific meeting called Asian Interventional Cardiovascular Therapeutics (AICT), which is held annually in different AP countries. From 2019 onwards, APSIC will join with the larger PCR family to form the AICT-AsiaPCR meeting. This meeting will incorporate Asian technical expertise with the innovative and educational strengths of PCR to become a true Asian flagship educational meeting. The inaugural meeting will be held in Singapore from 4 to 6 July 2019 and has already generated tremendous support and enthusiasm throughout the entire region, with the expected participation of more than 250 local and international faculties, 2,500 delegates, 300 abstract and case presenters, six Asian national societies and many industry partners. There will be live transmission cases from the National University Heart Centre, Singapore (NUHCS), National Taiwan University Hospital, Taipei, and Clinique Pasteur in Toulouse, France. The meeting will be rotated around selected AP countries every other year, with Singapore selected as its base site.

Given the increasing flurry of research publications and trials originating from Asia, particularly from Korea, China and India, the second initiative of APSIC is to promote collaborative research activities among member countries, and to synergise the strengths, resources and know-how of the Asia Pacific region as a common entity. The APSIC Research Committee, ably led by Dr Michael Lee from Queen Elizabeth Hospital, Hong Kong, has started the first initiative of the Asia Pacific Transcatheter Aortic Valve Implantation (APTAVI) Registry, which is supported by 10 centres from eight countries. The framework of collaboration is developed based on criteria such as the analyses of outcomes, cost-effectiveness, and quality of care, with transparency in data analyses and equity among collaborators to facilitate access and publication of relevant analyses. It is hoped that this APTAVI registry will set the template for more future collaboration in the region. Another project is the SYNERGY 3 Year Registry initiated by NUHCS, which will include nine centres from four Asian countries. It aims to examine the long-term safety and efficacy of everolimus-eluting platinum-chromium SYNERGY™ (Boston Scientific Corporation, Marlborough, MA, USA) stents over a three-year period.

Other important education activities include the designation of AsiaIntervention (https://www.asiaintervention.org) as the official journal of APSIC. First published in 2015, the journal hopes to boost clinical research and scientific communication within Asia and enhance the global visibility of research in this region. The journal is published twice a year and hopes to be PubMed listed soon. The revamp of the APSIC website (http://www.aspic.net) is another significant milestone. In this elegantly designed website, members will have the opportunity to access the latest up-to-date medical information as well as learn best practices from Asian experts for complex procedures.

On a personal note, I am happy to see the results of the training programme at NUHCS which I have set out to provide for the region. Of the more than 50 overseas interventional cardiology fellows trained since 2000 from AP, European and South American countries, many have emerged as prominent opinion leaders in their own countries and have grown to become experts of international repute **(Figure 3, Figure 4)**. The PCI simulator course started in my centre for young aspiring fellows in 2006 has seen more than 300 participants go through simulator-based training; many are now established and competent interventionists.

As I approach the end of my APSIC Presidency, I reflect with gratitude and view with great optimism and excitement the growth of endovascular therapy in the Asia-Pacific region. I deem myself fortunate to have experienced and contributed a small part to this growth journey. I continue to look forward to its future, one which is exceedingly promising and bright.

Conflict of interest statement

The author has no conflicts of interest to declare.

Figure 3. *Chinese NUH Alumni at Beijing CIT meeting 2019.*

Figure 4. *Filipino NUH Alumni at Manila PSCCI meeting 2019.*

AsiaIntervention 2019;5:115-117

Highlights of the 24th Cardiovascular Summit – TCTAP 2019

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The 24th Cardiovascular Summit – TCTAP 2019 (international conference on cardiovascular intervention) – sponsored by the CardioVascular Research Foundation (CVRF) and Asan Medical Center's Heart Institute (Seoul, South Korea), was held at Seoul Coex Convention Centre for four days from 27 April to 30 April 2019 **(Figure 1)**. Since its inauguration in 1995, the conference has been one of the key representative international academic meetings in the Asia Pacific region. This year, more than 3,000 cardiologists from 51 countries attended and shared the latest knowledge and cutting-edge experience in the field of cardiovascular intervention.

Figure 1. *Welcoming remarks at TCTAP 2019.*

The conference was composed of four major specialty symposia comprising a coronary symposium, an endovascular symposium, a structural heart disease symposium, and a master the chronic total occlusion (CTO) symposium **(Figure 2)**. In these symposia, various clinical and research topics were presented and discussed, from basic knowledge to the latest research trends in depth, including left main (LM) and multivessel percutaneous coronary intervention (PCI), interventions for valvular disease (i.e., transcatheter aortic valve replacement [TAVR] and mitral or tricuspid valve intervention), cardiovascular imaging and physiology, complex PCI and patients (complex, high-risk indicated procedures [CHIP] or high bleeding risk [HBR] patients), drug-eluting stents or balloons, antithrombotics, renal denervation, left atrial appendage (LAA) closure, CTO-PCI, and endovascular interventions. This year, many researchers and masters who are in charge of each field of research were invited, and in-depth discussion sessions on research and the latest findings from clinical trials, and sessions on special clinical studies going on all over the world, were held.

Through real-time satellite relay, the centres with a distinguished reputation in cardiology such as Columbia University Hospital in the USA, St. Paul's Hospital in Canada, Asan Medical

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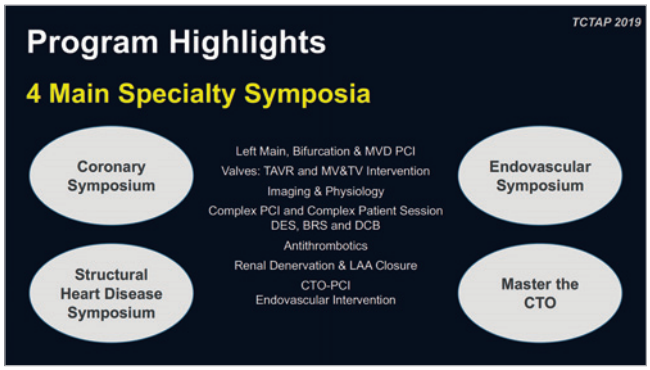

Figure 2. *Programme highlights of TCTAP 2019.*

Center and Yonsei University Severance Hospital in Seoul, participated in the live procedures to provide diverse practical techniques and to improve understanding of procedural tactics. Many complex PCIs including challenging left main, bifurcation, and CTO lesions and valvular interventions (TAVR or valve-in-valve with fracturing) were transmitted from world-renowned medical centres and interactive discussion with panels and audience took place.

Participants experienced a lively educational opportunity that was linked to theory and practice in the experiential space (based on live procedure relay) and at the newly expanded training centre. This training programme was successfully held over three days through first-come first-served registration for the many participants for each session by theme. In addition, to celebrate the 10th anniversary of the Asan Medical Center's Cardiovascular Intervention Training Program (ACT Program), which started in 2009, alumni gathering sessions and many other events were held on 27 April which attracted the attendees at the conference. In addition, a three-day workshop from 27 to 29 April was held to update the basics of cardiovascular intervention and discuss the latest research results. In addition, a partnership session was held with ten overseas academic societies and associations including from the USA, Japan, China, Taiwan and Hong Kong. In the abstract and case presentation contest sessions, the young presenters, who came from over 30 countries and were selected through rigorous screening, had the opportunity to interact with masters from around the world. There was also an in-depth interview, a so-called "Wrap-up Interview", where professors from all over the world gathered and presented their different opinions subdivided by theme and discussed future prospects.

There was a 9th "Master of the Masters" awards ceremony to honour the contributions of the scholars who have contributed to the development of cardiovascular intervention. The TCTAP Award "Master of the Masters" has been bestowed annually upon the most distinguished cardiologist who has made meritorious contributions and has played a significant leading role in the field of interventional cardiology, as well as in TCTAP over the years. This year, Dr Patrick W. Serruys, Professor of Cardiology in the Cardiovascular Science Division at Imperial College London (UK), was selected as the recipient of the 9th TCTAP Award "Master of the Masters" **(Figure 3)**. Dr John Ormiston received


TCTAP Award

Dr. Patrick W. Serruys Is Presented the 9th TCTAP Award "Master of the Masters"

Dr. Patrick W. Serruys, a professor of Cardiology in the Cardiovascular Science Division at Imperial College in London (UK), has been selected as the recipient of the 9th TCTAP Award "Master of the Masters". The award ceremony was held on Sunday, April 28, 2019.

TCTAP Award "Master of the Masters" has been bestowed annually upon the most distinguished cardiologist who has made meritorious contributions and has been playing a significant leading role in the field of interventional cardiology, as well as in TCTAP over the years.

Dr. Patrick W. Serruys studied medicine at the University of Leuven, Belgium. From the beginning of his career to being an expert in cardiology, he devoted a lot of time at the Thorax Center, Erasmus Medical Centre from 1977 to 2014. He was a Chief of Interventional Cardiology at the Thorax Center from 1997 to 2012, and a professor of Medicine until April 1st, 2014, at Erasmus Medical Centre, Netherlands. He once mentioned that if he writes an autobiography, the title would be "Thorax Center".

There are many intellectual achievements of Dr. Patrick W. Serruys. In 1986, he introduced stenting in patients in the Netherlands. Then, he conducted the first randomized trial with stenting that led to the approval of the technique by the Food and Drug Administration in the USA. He regards this as the most important achievement of him. In 1999, he developed drug-eluting stents, which drastically reduced restenosis after procedures, with Dr. Eduardo Sousa. In 2006, he devised a fully biodegradable drug-eluting scaffold. It was a huge discovery since a permanent metallic stent would not need to be implanted in patients.

In addition to his numerous researches, he has brought notable professional results as well. He had (co-) authored more than 3375 ISI-recognized publications and also was an editor of 45 books and textbooks. Through all these outstanding work and contribution, he won the Gold Medal Award of the European Society of Cardiology in 2012, as well as the TCT Career Achievement Award in 1996.

As a great teacher and a mentor, Dr. Patrick W. Serruys has trained more than 250 interventional cardiologists. He has always emphasized the importance of being curious and opening to the novelty. He said, "If you see somewhere unexplored, you have to go there. That's the place to work. That's the place to discover new thing."

TCTAP Award 2019
"Master of the Masters"
» Sunday, April 28, 11:40 AM - 12:00 PM
» Main Arena, Level 3

Figure 3. *TCTAP Award 2019 "Master of the Masters".*

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this year's outstanding lectureship and lifetime achievement in PCI award. The 7th "TCTAP Best Young Scientist Award" was presented to Dr Jeehoon Kang during the conference. This award selects and encourages young researchers who will lead future studies on cardiovascular disease.

Lastly, this conference is expanding the scope of education through annual maintenance training for nurses and an annual symposium on cardiovascular intervention technical study for radiologists. Special lectures, panel discussions and performances were held covering prevention of heart disease among the general public. Additional detailed information on highlights of this congress can be found on the website of TCTAP 2019 daily news (http://www.summit-tctap.com/2019/review_news.htm). Next year, the 25th Cardiovascular Summit – TCTAP 2020 – will be held from 25 to 27 April 2020, COEX, Seoul, South Korea.

Conflict of interest statement

The authors have no conflicts of interest to declare.

AsiaIntervention 2019;5:118-120

Highlights from China Interventional Therapeutics (CIT) 2019

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China Interventional Therapeutics (CIT) 2019, in partnership with TCT, took place at the National Convention Centre, Beijing, China from 28 March to 1 April 2019, organised by the Chinese Medical Association. Co-organisers were Fuwai Hospital, Chinese Academy of Medical Sciences; the meeting was co-sponsored by the Chinese National Centre for Cardiovascular Diseases, the CIT Board of Directors, the Chinese Society of Cardiology and the Cardiovascular Research Foundation (CRF).

During the three-and-a-half-day scientific programme encompassing 177 sessions, 1,644 didactic lectures were presented, 15 late breaking clinical trials and first report investigations were released, and 45 live cases were performed, broadcasting from eight Heart Centres both in China and internationally.

The congress offered a true academic feast for all!

With an enduring focus on "C-Cooperation, I-Innovation, T-Transition", CIT remains the largest scientific meeting in the field of interventional cardiology in the Asia-Pacific region. CIT 2019 welcomed 8,648 participants – 6,550 from mainland China, 381 from overseas regions or internationally, 1,550 from industry, 102 volunteers from local universities or other institutions and 65 media representatives. This year, interactive smartphone and other mobile device platforms allowed the delegates and audience to benefit more fully from the rich scientific programme. As of today, the total audience reached by CIT 2019 online numbers 209,405!

CIT continues to serve as a dynamic and thoroughly fruitful venue, introducing new knowledge and technologies into China, fostering meaningful academic exchanges and cooperation, and showcasing local innovation and progress in cardiovascular interventions to the rest of the world. In his introductory remarks opening CIT 2019, CIT Chairman Dr Runlin Gao highlighted the continued expansion of the PCI caseload in China, which in 2017 counted 753,142 interventions – a 13% increase over 2016 – not to mention innovations in the various devices used as cited below.

In China today: innovations in cardiovascular interventional devices; advances in interventional cardiovascular research

In the field of bioresorbable scaffolds (BRS), the NeoVas™ bioresorbable sirolimus-eluting scaffold developed by Lepu, Beijing, China, was approved by the CFDA and launched on the market. A first-in-human study of the Firesorb® bioresorbable sirolimus target eluting coronary scaffold, a second-generation BRS with a strut thickness of 100-120 µm developed by MicroPort, Shanghai, China, demonstrated its efficacy, safety and biocompatibility by clinical, angiographic and intravascular images. A novel, innovative iron bioresorbable sirolimus-eluting scaffold (IBS) was independently developed by Lifetech, Shenzhen, China. This device has a strut thickness of 70 µm

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and a scaffold that can be biodegraded in one and a half years. It demonstrated similar mechanical properties to the XIENCE stent (Abbott Vascular, Santa Clara, CA, USA) as well as good biocompatibility in animal experiments. In March 2018, the CFDA granted approval for the IBS to undergo a first-in-human study, which is now ongoing.

In the field of transcatheter aortic valve replacement (TAVR), the Venus A-Valve® (Venus Medtech, Hangzhou, China) and J-Valve™ System (Jiecheng, Suzhou, China) were approved by the CFDA and launched commercially. The Venus A-Valve has been implanted in approximately 2,000 patients with favourable outcomes. The VitaFlow® TAVR system (MicroPort, Shanghai, China) completed its registration trial with favourable outcomes and is currently undergoing regulatory review. The registration trials for the TaurusOne TAVR device (Peijia Medical, Suzhou, China) and Venus A-Plus, a retrieval system with an expandable sheath, have completed patient enrolment. The Venibri I (Colibri Heart Valve, Broomfield, CO, USA, and Venus Medtech), a pre-mounted TAVR system with a dry tissue valve, has now been implanted in 15 cases in Argentina, India and China.

First-in-human studies of the locally developed transcatheter mitral repair devices MitralStitch™ (DeJin Medtech, Hangzhou, China) and ValveClamp (Hanyu Medical, Shanghai, China) are ongoing and were reported.

A novel technique for the detection of haemodynamic abnormalities and quantitative flow ratio (QFR; Pulse Medical Imaging, Shanghai, China) performed well in the FAVOR II China trial and is now ready for assessment in multicentre blinded randomised clinical trials.

The innovative LAmbre™ left atrial appendage closure device (Lifetech, Shenzhen, China) showed promising performance in patients with anatomies unsuitable for WATCHMAN™ device (Boston Scientific, Marlborough, MA, USA) use.

The SyMapCath I™ Catheter and SYMPIONEER S1™ Stimulator/Generator, a novel renal denervation (RDN) system (SyMap Medical, Suzhou, China), have integrated functions for guidance, angiography, stimulation/mapping, temperature-controlled ablation, and manual open-loop irrigation. The Iberis™ RDN system (AngioCare, Shanghai, China) with its spiral ablation catheter is undergoing multicentre, single-blinded, randomised, sham-controlled clinical trials.

Research on cardiovascular interventions continues to increase rapidly in China as reflected by the quality and quantity of articles and presentations. The "Late Breaking Clinical Trials" and "First report Investigations" sessions at CIT 2019 featured 15 studies. The topics included efficacy and safety of bioresorbable coronary scaffolds; randomised comparisons among DES and strategies for treating left main bifurcation lesions; registration studies for new TAVR devices developed in China; the implications of QFR for predicting long-term MACE; a novel intracoronary optical coherence tomography-based fractional flow reserve measurement; comparisons between FFRCT and FFRQCA; a novel plasma biomarker for plaque rupture in patients with STEMI; and the outcomes of carotid artery plaque intervention with the Tongxinluoc capsule (a traditional Chinese medicine).

In-depth discussions exploring the most impactful research presented at the latest ACC and TCT meetings

On 29 March, immediately following the opening ceremony, Drs Gregg Stone, Jeffrey Popma and Runlin Gao chaired a plenary session reviewing the most impactful studies presented at the recent ACC and last year's TCT meetings. Dr Stone's presentation focused on the COAPT trial (transcatheter leaflet approximation in heart failure patients with secondary mitral regurgitation). Dr Martin Leon delivered a presentation on balloon-expandable TAVR vs surgery (PARTNER 3) and Dr Popma spoke about self-expanding TAVR vs surgery in low-risk patients with severe symptomatic aortic stenosis. The in-depth discussions by speakers and panellists on the clinical significance as well as the impact on clinical practice of these findings were considered to be very useful by the enthusiastic audience.

Case-oriented discussion on clinical hot topics

A subsequent case-oriented clinical discussion session chaired by Drs Gary Mintz, Bo Yu and William Fearon focused on coronary physiology and imaging. Dr Jun-Jie Zhang reviewed the results of the ULTIMATE trial (intravascular ultrasound-guided vs angiography-guided DES implantation in all-comer patients) presented at TCT 2018, and a case-based learning programme addressed OCT stent sizing and optimisation. Also, a discussion was held on when and how to use resting and hyperaemic coronary flow indices.

In the plenary session's "New Technology Forum: Angiography-Based FFR", Drs Bo Xu and William Fearon presented the QFR System and the FAVOR trials along with the FFRangio™ System (CathWorks, Kfar-Saba, Israel) and the FAST-FFR trial, respectively. Clinical use of the angiography-based FFR measurement, which can be performed online without using special catheters, appears promising.

The case-oriented clinical discussions II plenary session highlighted complex and high-risk patients (CHIP). Dr Ajay Kirtane delivered a talk, illustrated with appropriate cases, entitled "CHIP Manifesto: Rationale, Workup, Heart Teams, Haemodynamic Support, and Much More…". This presentation was followed by an extensive discussion on PCI in patients with severe coronary calcification, chronic total occlusion and challenging vascular access and management of complications, among other topics.

All presentations and discussions by domestic and international experts in the field were well attended and received.

Joint partnership sessions with international academic organisations and societies

Chaired by Drs Andreas Baumbach and Bo Xu, the PCR at CIT plenary session I took place on 30 March and focused on complex PCIs. The session started with a live case demonstration from

Fuwai Hospital. A case of left main distal bifurcation stenosis was presented and treated by Drs Jean Fajadet and Jingang Cui. After an intensive discussion between operators and panellists, a V-stenting technique was performed with an excellent outcome. Then, Dr Michael Haude presented new data on the impact of PCI on hard events (reduced MI rates) in patients with chronic coronary syndromes. Drs Patrick Serruys and Niels Holm spoke about the role of coronary CT combined with FFR for diagnosis and the impact of QFR on PCI practice.

The PCR at CIT plenary session II, chaired by Drs Bernard Prendergast and Runlin Gao, focused on TAVR in low-/intermediate-risk patients. A live case of severe bicuspid aortic stenosis from Fuwai Hospital was presented and successfully treated by TAVR using a TaurusOne valve; this case was performed by Drs Yongjian Wu and Christoph Naber. Following the live case transmission, Dr Thomas Modine spoke about the current status of indications for TAVR vs SAVR in low-/intermediate-risk patients. Dr Lars Søndergaard addressed the question of how to streamline TAVR in order to render it simpler, less invasive, and reproducible. Finally, Dr Mao Chen presented local perspectives on TAVR, indicating that bicuspid aortic stenosis and more severe calcification are more common in China than in Western populations, a fact which warrants further investigation.

The overall quality of cardiovascular interventions in China has rapidly improved in recent years. One of CIT's major goals is the optimisation of treatment of complex lesions and patients at high risk. To this end, a one-and-a-half-day academic agenda focused heavily on these complex and high-risk indicated patients (CHIP), as did the international partnership sessions (such as CCT, TCT-AP, CRT, NCVH, SCAI, APSIC, CACI and HK STENT, etc.) with many cases being transmitted live to the audience in the auditorium. The programmes on peripheral vascular intervention, left atrial appendage closure and interventions for congenital heart diseases were also well attended. Participants benefitted from an intellectually enriching exchange of both theory and clinical practice and experience during these live case demonstrations, case reports, technical lectures, indication seminars, and panel discussions.

Hands-on training in our learning centre

This year CIT especially strengthened the physician's hands, augmenting their skills with hands-on training. The CIT Learning Centre organised 188 courses in 20 rooms over three-and-a-half days with a total of 2,970 delegates being trained! The attendees actively participated in the hands-on programme using simulators to learn new techniques under the watchful gaze of renowned experts. All the training rooms were full to capacity – and even reservations were required!

The 11th annual clinical research workshop

The 11th annual clinical research workshop was another attractive feature of CIT. Designed and organised by Drs Ajay Kirtane, Bo Xu, and Roxana Mehran, its broad content included coverage spanning good clinical practice (GCP) principles, the design and implementation of a clinical trial project and on to correctly interpreting and publishing its outcomes. Lectures by prominent physicians/scientists clearly benefitted the attendees, in particular young investigators, some of whom participated in the Young Investigator Award competition. This workshop's audience continues to increase year after year.

CIT 2019 in partnership with TCT was very successful, thanks to the outstanding contributions from its international and Chinese faculty, the CIT Working Group as well as all the participants. CIT 2020 in partnership with TCT will be held at the National Convention Centre, Beijing, China, from 2 April to 5 April 2020. We hope to see you there.

Conflict of interest statement

The author has no conflicts of interest to declare.

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Clinical outcomes of endovascular treatment for chronic aortic occlusion: a retrospective multicentre registry

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KEYWORDS

- diffused disease
- iliac disease
- total occlusion

Abstract

Aims: The aim of this study was to evaluate the clinical outcomes of endovascular treatment (EVT) for chronic aortic occlusion (CAO) using multicentre registry data.

Methods and results: From April 2003 to December 2015, data on 73 consecutive patients (55 men and 18 women; aged 70.7±12.2 years) who underwent EVT for CAO were collected retrospectively from 15 centres in Japan. The primary endpoint was the primary patency at 12 months after EVT. Secondary endpoints were procedural success and periprocedural complication rates. We analysed 67 patients who underwent complete endovascular revascularisation after 2007. Initial procedural success was achieved in 63 cases (94.0%). Complications occurred in three patients (4.5%) (stroke, n=1; distal embolism, n=1; access-site haematoma requiring blood transfusion, n=1). In patients after successful EVT (n=63), the primary and secondary patency rates at 12 months were 90.7% and 97.7%, respectively. During a mean follow-up period of 17.8 months, restenosis/re-occlusion was observed in eight patients (12.7%).

Conclusions: EVT for CAO could be performed safely with a high procedural success rate. The short-term clinical outcome was acceptable despite lesion complexity.

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Abbreviations

ABI	ankle-brachial index
CAD	coronary artery disease
CAO	chronic aortic occlusion
CKD	chronic kidney disease
COPD	chronic obstructive pulmonary disease
CTO	chronic total occlusion
CVD	cerebrovascular disease
EVT	endovascular treatment
IVUS	intravascular ultrasound
TASC	Trans-Atlantic Inter-Society Consensus
TLR	target lesion revascularisation

Introduction

Although favourable results of endovascular treatment (EVT) for aortoiliac lesions have been reported[1-3], EVT for complex lesions, especially chronic total occlusion (CTO), still remains challenging[3].

Chronic aortic occlusion (CAO) is defined as CTO of the infrarenal aorta with or without iliac artery occlusion; the specific ischaemic symptoms of CAO are commonly known as Leriche syndrome[4]. Surgical revascularisation has been the treatment of choice for patients with this disease. Only a small number of single-centre studies or single case reports have been published on the outcomes of EVT for CAO[5-9]. The purpose of this study was to evaluate the clinical outcomes of EVT for CAO using multicentre registry data.

Methods

STUDY DESIGN AND PATIENT POPULATION

This was a multicentre, retrospective observational study that included 73 Japanese patients (55 men, 18 women), who had a mean±SD age of 70.7±12.2 years (range, 34-90 years). The study was conducted in accordance with the Declaration of Helsinki and was approved by the ethics committee of each participating hospital. Patients had CTO of the infrarenal aorta, and EVT was attempted between April 2003 and December 2015 at 15 Japanese medical institutions. Anonymised data were collected and analysed.

Treatment indications and strategies were decided at the physician's discretion at each institution. We excluded two patients who underwent hybrid therapy (unilateral revascularisation and femorofemoral bypass) and three patients who underwent unilateral revascularisation. Furthermore, we excluded the first of the remaining 68 patients who underwent complete EVT. The patient had been treated in 2003, and there were major restrictions on the devices and techniques available in Japan at that time. The second and subsequent procedures had been performed annually since 2007, four years after the first case.

EVT PROCEDURE

The cardiologists at each hospital decided on the procedural strategies. Therefore, treatment strategies were not unified in each institution. Here, we describe one of the EVT procedures for CAO **(Figure 1)**[9]. Three sheaths were inserted from the bilateral femoral arteries and the left brachial artery under local anaesthesia.

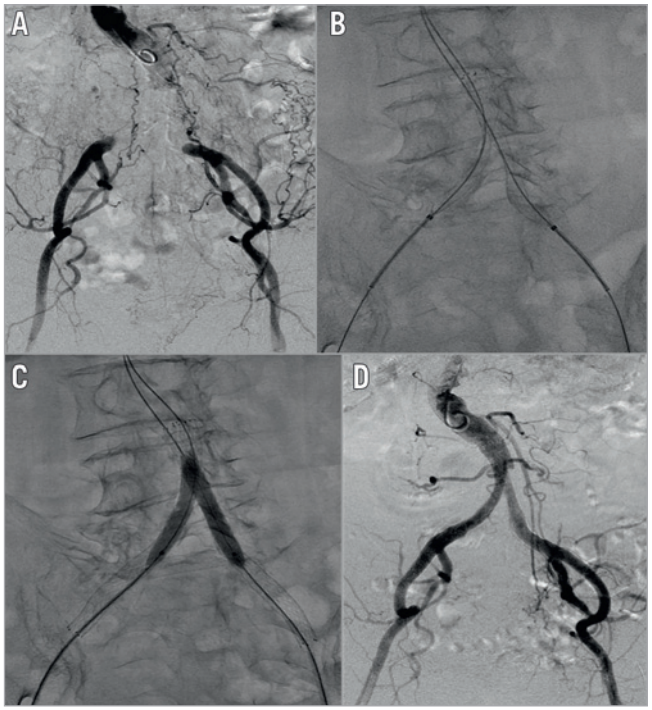

Figure 1. *One of the interventional procedures. A) Preprocedural angiography showed total occlusion of the terminal abdominal aorta and bilateral common iliac artery. B) Kissing stent with self-expanding nitinol stents after guidewire crossing. C) Post balloon dilatation. D) Postoperative angiography showed a favourable flow.*

Guidewire manipulation was performed intraluminally with a 0.014-inch guidewire. After the guidewire had successfully passed through the bilateral occlusive lesions, kissing stenting with two self-expanding nitinol stents followed by post-dilatation was performed.

STUDY OUTCOMES

Study outcomes comprised procedural success, procedural safety, and patency. The primary endpoint was primary patency at 12 months after EVT. Secondary endpoints were procedural success and periprocedural complication rates. Initial success was defined as <30% residual stenosis without any flow limitation noted on the final angiography. A procedural complication was defined as any adverse event caused by endovascular treatment including death, stroke, emergent surgery, blue toe syndrome/distal emboli, vessel rupture, access-site complication with prolongation of the in-hospital stay, blood transfusion, gastrointestinal haemorrhage, worsening renal function (a 50% increase in serum creatinine), and other critical complications.

DEFINITIONS

Primary patency was defined as the treated vessel without restenosis and repeat revascularisation that remained patent. Secondary patency was defined as patency achieved after reintervention for restenosis or re-occlusion of the treated vessel. Restenosis was defined as >2.4 peak systolic velocity ratio on duplex, >50% stenosis on angiography or computed tomography. Coronary artery disease (CAD) was defined as angina with documented CAD, previous myocardial infarction, a history of percutaneous coronary intervention, and history of coronary artery bypass graft surgery. Cerebrovascular disease (CVD) was defined as a history of stroke or transient ischaemic attack, carotid artery stenosis of >80%, history of carotid artery stenting, or history of carotid endarterectomy. Chronic obstructive pulmonary disease (COPD) was defined as patients with a forced expiratory volume in 1 s (FEV1) of <70% or COPD diagnosis requiring medical treatment. Chronic kidney disease (CKD) was defined as an estimated glomerular filtration rate (eGFR) less than 60 mL/min/1.73 m^2.

STATISTICAL ANALYSIS

Results are expressed as the mean±standard deviation or numbers with percentages. Statistical analyses were performed using EZR (Saitama Medical Center, Jichi Medical University, Saitama, Japan), which is a graphical user interface for R (The R Foundation for Statistical Computing, Vienna, Austria)[10].

Results

PATIENTS AND LESION CHARACTERISTICS

The baseline clinical characteristics of the patients are presented in **Table 1**. A total of 30 patients (44.8%) had CAD, 18 (26.9%) had CVD, 8 (11.9%) had COPD, and 25 (37.3%) had CKD. All patients were symptomatic. Fifty patients (74.6%) presented with claudication (Rutherford classification 2 or 3[11]), 9 (13.4%) with rest pain (Rutherford classification 4), and 8 (12.0%) with an ulcer (Rutherford classification 5 or 6). The mean preprocedural ankle-brachial index (ABI) was 0.46±0.20 on the right side, and 0.40±0.25 on the left side.

Table 1. Patient and lower limb characteristics (N=67).

		Mean±SD or N (%)
Age (years)		70.3±12.5
Body mass index (kg/m^2)		21.4±3.2
Male		50 (74.6)
Coronary artery disease		30 (44.8)
Cerebrovascular disease		18 (26.9)
Congestive heart failure		11 (16.4)
Hypertension		55 (82.1)
Dyslipidaemia		38 (56.7)
Diabetes		25 (37.3)
Smoking history		49 (73.1)
Chronic obstructive pulmonary disease		8 (11.9)
Chronic kidney disease (eGFR <60 ml/min/1.73 m^2)		25 (37.3)
Haemodialysis		5 (7.5)
BUN (mg/dL)		17.8±9.9
CRE (mg/dL)		1.38±2.0
Hb (g/dL)		12.8±2.1
Ht (%)		38.6±5.8
LDL (mg/dL)		104±49
HDL (mg/dL)		49.1±16
HbA1c (%)		6.31±1.3
Rutherford classification before treatment	1	0 (0)
	2	6 (9.0)
	3	44 (65.7)
	4	9 (13.4)
	5	6 (9.0)
	6	2 (3.0)
ABI before treatment	Right	0.46±0.20
	Left	0.40±0.25

ABI: ankle-brachial index; BUN: blood urea nitrogen; CRE: creatinine; Hb: haemoglobin; HDL: high-density lipoprotein; Ht: haematocrit; LDL: low-density lipoprotein

Lesion characteristics are summarised in **Table 2**. A total of 56 lesions (83.6%) were associated with occlusion from the aorta to the iliac artery, and 11 (16.4%) were associated with solitary aortic occlusion. The mean lesion length was 121 mm. Thirty-four lesions (50.7%) showed moderate or severe calcification.

INTERVENTIONAL PROCEDURE OF COMPLETE REVASCULARISATION

Interventional procedures and initial outcomes of complete EVT are summarised in **Table 3**. The procedural success rate was 94.0% (63/67). Procedural failures were due to guidewire passage failure in four patients. Complications occurred in three patients

Table 2. Lesion characteristics.

		Mean±SD or N (%)
Occlusion pattern	Aortoiliac occlusion	56 (83.6)
	Isolated aortic occlusion	11 (16.4)
Lesion length (mm)		121±78.0
Calcification	None	13 (19.4)
	Mild	20 (29.9)
	Moderate	16 (23.9)
	Severe	18 (26.9)
Presence of FP lesion		23 (34.3)

FP: femoropopliteal

(4.5%) (stroke, n=1; distal embolism, n=1; access-site haematoma requiring blood transfusion, n=1). One case of distal embolism was improved by thromboaspiration only.

Most of the procedures were performed with a bidirectional approach. An intraluminal approach using 0.014-inch and/or 0.018-inch guidewires was performed in more cases (76.1%) compared with a subintimal approach using a 0.035-inch guidewire. A total of 88.1% of the procedures were performed with intravascular ultrasound (IVUS) guidance. The average number of stents per case was 3.2±1.2, and 90.0% of the stents were self-expanding. The kissing stent technique with bare metal stents was performed in 57 cases (90.5%). Most of the procedures (92.5%) were performed without a distal protection device. Five procedures of distal protection were performed with an occlusion balloon guiding catheter (OPTIMO; Tokai Medical Products, Aichi, Japan).

The ABI and clinical symptoms improved markedly in all patients with successful EVT.

CLINICAL FOLLOW-UP

Clinical follow-up after successful EVT is summarised in **Table 4**. Primary and secondary patency rates at 12 months were 90.7% and 97.7% (n=43), respectively **(Figure 2)**. During the mean follow-up period of 17.8 months, either restenosis or re-occlusion was

Table 3. Initial outcome and interventional procedure (N=67).

	N (%) or Mean±SD
Procedure success	
Success	63 (94.0)
Failure	4 (6.0)
Guidewire crossing failure	4
Periprocedural complication	3 (4.5)
Stroke	1
Distal embolism	1
Access-site complication	1
Before and after successful EVT (N=63)	
Preprocedural ABI	
Right side	0.46±0.20
Left side	0.41±0.24
Post-procedural ABI	
Right side	0.90±0.16
Left side	0.86±0.18
Improvement of the clinical symptoms	63 (100)
Contrast medium (ml)	155±79.6
Fluoro dose (Gy)	1.4±1.3
Wiring strategy	
Intraluminal	51 (76.1)
Subintimal	16 (23.9)
IVUS usage	59 (88.1)
Number of stents (per case)	3.2±1.4
Total number of stents	201
Self-expanding stent	181 (90.0)
Balloon-expandable stent	20 (10.0)
Kissing stent technique	57 (90.5)
Distal protection	5 (7.5)
Occlusion balloon guiding catheter	5

In the intraluminal wiring strategy, a 0.014- or 0.018-inch guidewire was used to cross the occlusive lesion; in the subintimal wiring strategy, a 0.035-inch hydrophilic guidewire was used.

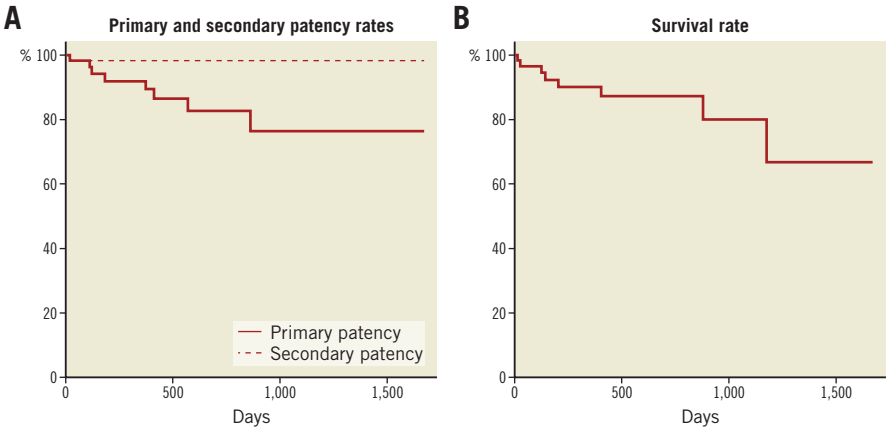

Figure 2. *Kaplan-Meier life-table analysis of primary and secondary patency rates. A) After EVT. B) Survival rate.*

Table 4. Clinical follow-up after EVT (N=63).

	N (%) or Mean±SD
12-month primary patency (N=43)	90.7 (39)
12-month secondary patency (N=43)	97.7 (42)
Follow-up period (months)	17.8±13.9
Restenosis/re-occlusion	8 (12.7)
TLR	7 (11.1)
Balloon angioplasty	2
Stent implantation	4
Fogarty catheter embolectomy	1
Death	8 (12.7)
Malignancy	3
Sudden death	1
Heart failure	1
Sepsis	1
Ischaemic colitis	1
Unknown	1
Amputation	1 (1.8)
Toe amputation	1
Bleeding	3 (4.4)
Intestinal haemorrhage	1
Chronic subdural haematoma	1
Other	1

EVT: endovascular treatment

observed in eight patients. Among them, seven patients underwent reintervention (additional stent implantation, n=4; balloon angioplasty, n=2; Fogarty catheter embolectomy, n=1), five of whom were subsequently relieved of TLR. In one case, intensive medical therapy was maintained, because the patient did not desire reintervention. The incidence of all-cause death was 12.7% (sudden death, n=1; congestive heart failure, n=1; malignancy, n=3; sepsis, n=1; ischaemic colitis, n=1; unknown cause, n=1). There was only one death within 30 days of EVT as a result of sepsis; the patient died 11 days after EVT. The patient presented with severe infectious foot gangrene and was in poor general condition before EVT.

Discussion

Favourable results of EVT for aortoiliac lesions have been reported[1-3]. Furthermore, in aortoiliac lesions, the primary patency after successful stenting does not differ between TASC II lesion categories[3].

Recently, EVT of complex lesions has been increasingly performed, yielding high success and low complication rates[12]. Even CTOs are now treated endovascularly with favourable early and long-term results[13]. Hans et al[14] reported that aortoiliac stenting can be an alternative to aortobifemoral bypass in TASC C and D lesions. However, EVT for extensive aortoiliac occlusive disease is considered for patients unsuitable for surgical treatment in the present circumstances[15,16].

CAO is defined as CTO of the infrarenal aorta with or without iliac artery occlusion. Specific ischaemic symptoms of CAO are commonly known as Leriche syndrome[4]. Surgical revascularisation has been the treatment of choice for patients with this disease[17]. Surgical revascularisation for CAO can be divided roughly into anatomical and extra-anatomical bypass (aortobifemoral and axillobifemoral, respectively). Favourable results of aortobifemoral bypass have been reported[18-22]. However, in older patients, or those at high risk for anatomical bypass, axillofemoral, extra-anatomical bypass is often selected[18]. Although axillofemoral bypass is less invasive, its patency is generally lower than that of aortofemoral bypass[17,18,23,24]. On the other hand, only a small number of single-centre studies have been reported on the outcomes of EVT for CAO[5,6,25]. We evaluated the safety and efficacy of EVT for CAO using multicentre registry data in this study.

In the present study, we collected data on 73 treated cases of CAO. The average age of the patients was over 70, and many patients had some comorbidities.

In this study, three patients underwent unilateral revascularisation. Two of them with a non-ambulatory status had an ulcer on only one leg. The remaining one had already undergone unilateral limb amputation. Another two patients underwent the hybrid procedure, comprising unilateral endovascular treatment and femorofemoral bypass surgery. The occlusive lesions of the two patients showed severe calcification. It is considered to be a valid decision to shorten the procedural time based on the age and status of the patient, as well as the lesion characteristics.

Complete EVT procedures failed in four cases, all of which were due to guidewire passage failure. In all these cases, the guidewire could not be crossed through the occlusive lesion due to marked calcification. A markedly calcified lesion is still one of the greatest challenges of EVT despite progress in techniques and therapeutic devices.

Next, we would like to consider procedural safety. The periprocedural complication rate was low in this study. There was no arterial rupture or procedure-related death. Another serious complication in aortoiliac intervention is distal embolisation. Only one patient developed minor distal embolisation in this study, although most procedures were performed without distal protection. It should be noted that most of the procedures in this study were performed with IVUS guidance (88.2%). IVUS images provide much information – on the vessel size, plaque characteristics, location and degree of plaque calcification, and the location of the guidewire in the CTO lesion. The usefulness of IVUS-guided EVT for improving procedural success and post-procedural patency has already been reported[26,27]. Moreover, IVUS usage might contribute to a safe procedure.

In this study, all of the successful EVT cases were treated with bare metal stents, and most cases were treated with the kissing stent technique. The covered endovascular reconstruction of an aortic bifurcation (CERAB) technique[28] may become one of the useful options.

Even when EVT is successfully and safely completed, a risk of restenosis remains. In this study, one-year primary and secondary patency rates were 90.7% and 97.7%, respectively. This result is comparable to past reports of overall aortoiliac lesions[3] and chronic aortic occlusion[6,25]. In this study, either restenosis or re-occlusion was observed in eight cases (12.7%) during a mean follow-up period of 17.8 months. Among them, seven patients underwent reintervention, five of whom subsequently showed TLR resolution. Soga et al[3] reported that the individual predictors of primary patency in aortoiliac lesions are female sex, diabetes, renal failure, non-use of aspirin, reference vessel diameter <8.0 mm, and an outflow lesion. In this study, various collected parameters did not show significant differences between the restenosis and non-restenosis groups **(Table 5)**. The statistical power may not have been sufficient.

Table 5. Various parameters between the ISR and non-ISR groups.

	ISR (n=8)	non-ISR (n=55)	*p*-value
Female gender (%)	37.5	23.6	0.328
Age (years)	68.1±14.9	69.9±12.1	0.495
Diabetes (%)	25.0	41.8	0.265
CKD (%)	25.0	38.2	0.432
CLI before treatment	12.5	27.3	0.970
Aortoiliac occlusion (%)	87.5	81.8	0.503
Lesion length (mm)	118±74	119±80	0.662
Moderate or severe calcification	50.0	47.3	0.805
FP lesion	25.0	32.7	0.831
IVUS usage rate	100	87.3	0.994

CKD: chronic kidney disease; CLI: critical limb ischaemia; FP: femoropopliteal; ISR: in-stent restenosis; IVUS: intravascular ultrasound

The incidence of all-cause death was 12.7% (sudden death, n=1; congestive heart failure, n=1; malignancy, n=3; sepsis, n=1; ischaemic colitis, n=1; unknown cause, n=1). The life prognosis of patients with peripheral artery disease is generally poor[17], and the indication for revascularisation should be carefully considered.

This is the first report on the clinical outcome of EVT for CAO using multicentre registry data including a relatively large number of patients. More long-term durability of EVT for CAO is expected.

Limitations

There are some limitations of this study that should be noted. Firstly, this study was a non-randomised, retrospective registry, and decisions on the treatment strategy were not unified in each institution. Secondly, the sample size was small, although this study contains the highest number of cases reported to date. Thirdly, the follow-up period was relatively short. Finally, the racial background of all patients was Japanese, and the results may not be representative if the methods are applied to a broader patient population. Despite these limitations, the results of this study provide important information regarding EVT for CAO.

Conclusions

In conclusion, EVT for CAO could be performed safely with a high procedural success rate, and the short-term clinical outcome was acceptable despite lesion complexity. The evolution of techniques and materials may contribute to a further increase in the success of such procedures in the future.

Impact on daily practice

The evidence of clinical outcomes of EVT for CAO is insufficient despite the marked advances in complex EVT over the past few years. This is a first report of multicentre analysis of EVT for CAO, and the clinical outcome was acceptable. Especially in patients who are not candidates for surgery and/or older patients, EVT for CAO can be an alternative choice.

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Conflict of interest statement

The authors have no conflicts of interest to declare.

References

1. Murphy TP, Ariaratnam NS, Carney WI Jr, Slaiby JM, Soares GM, Kim HM. Aortoiliac insufficiency: long-term experience with stent placement for treatment. *Radiology.* 2004; 231:243-9.

2. Jongkind V, Akkersdijk GJ, Yeung KK, Wisselink W. A systematic review of endovascular treatment of extensive aortoiliac occlusive disease. *J Vasc Surg*. 2010;52:1376-83.

3. Soga Y, Iida O, Kawasaki D, Yamauchi Y, Suzuki K, Hirano K, Koshida R, Kamoi D, Tazaki J, Higashitani M, Shintani Y, Yamaoka T, Okazaki S, Suematsu N, Tsuchiya T, Miyashita Y, Shinozaki N, Takahashi H; REAL-AI investigators. Contemporary outcomes after endovascular treatment for aorto-iliac artery disease. *Circ J.* 2012;76:2697-704.

4. Leriche R, Morel A. The Syndrome of Thrombotic Obliteration of the Aortic Bifurcation. *Ann Surg.* 1948;127:193-206.

5. Dohi T, Iida O, Okamoto S, Nanto K, Nanto S, Uematsu M. Mid-term clinical outcome following endovascular therapy in

patients with chronic aortic occlusion. *Cardiovasc Interv Ther.* 2013;28:327-32.

6. Kim TH, Ko YG, Kim U, Kim JS, Choi D, Hong MK, Jang Y, Shim WH. Outcomes of endovascular treatment of chronic total occlusion of the infrarenal aorta. *J Vasc Surg*. 2011;53:1542-9.

7. Alkhouli M, Shafi I, Patil P, Bashir R. Percutaneous treatment of chronic distal aortic occlusion: a viable option. *JACC Cardiovasc Interv.* 2014;7:e185-6.

8. Nadahama T, Kawarada O, Shibata K, Harada K, Noguchi T, Minatoya K, Ogawa H, Yasuda S. Stenting for Juxtarenal Abdominal Aortic Occlusion. *JACC Cardiovasc Interv.* 2016;9:856-8.

9. Kubota H, Kato T, Nomura T, Keira N, Tatsumi T. Successful endovascular treatment with GuideLiner catheter of chronic aortic occlusion with severe calcification. *Cardiovasc Interv Ther.* 2017;32:137-41.

10. Kanda Y. Investigation of the freely available easy-to-use software 'EZR' for medical statistics. *Bone Marrow Transplant.* 2013;48:452-8.

11. Rutherford RB, Baker JD, Ernst C, Johnston KW, Porter JM, Ahn S, Jones DN. Recommended standards for reports dealing with lower extremity ischemia: revised version. *J Vasc Surg*. 1997;26: 517-38.

12. Leville CD, Kashyap VS, Clair DG, Bena JF, Lyden SP, Greenberg RK, O'Hara PJ, Sarac TP, Ouriel K. Endovascular management of iliac artery occlusions: extending treatment to TransAtlantic Inter-Society Consensus class C and D patients. *J Vasc Surg*. 2006;33:32-9.

13. Pulli R, Dorigo W, Fargion A, Innocenti AA, Pratesi G, Marek J, Pratesi C. Early and long-term comparison of endovascular treatment of iliac artery occlusions and stenosis. *J Vasc Surg*. 2011;53:92-8.

14. Hans SS, DeSantis D, Siddiiqui R, Khoury M. Results of endovascular therapy and aortobifemoral grafting for Transatlantic Inter-Society type C and D aortoiliac occlusive disease. *Surgery.* 2008;144:583-9.

15. European Stroke Organisation, Tendera M, Aboyans V, Bartelink ML, Baumgartner I, Clément D, Collet JP, Cremonesi A, De Carlo M, Erbel R, Fowkes FG, Heras M, Kownator S, Minar E, Ostergren J, Poldermans D, Riambau V, Roffi M, Röther J, Sievert H, van Sambeek M, Zeller T; ESC Committee for Practice Guidelines. ESC Guidelines on the diagnosis and treatment of peripheral artery diseases: Document covering atherosclerotic disease of extracranial carotid and vertebral, mesenteric, renal, upper and lower extremity arteries: the Task Force on the Diagnosis and Treatment of Peripheral Artery Diseases of the European Society of Cardiology (ESC). *Eur Heart J.* 2011;32:2851-906.

16. Society for Vascular Surgery lower extremity guidelines writing group, Conte MS, Pomposelli FB, Clair DG, Geraghty PJ, McKinsey JF, Mills JL, Moneta GL, Murad MH, Powell RJ, Reed AB, Schanzer A, Sidawy AN; Society for Vascular Surgery. Society for Vascular Surgery practice guidelines for atherosclerotic occlusive disease of the lower extremities: management of asymptomatic disease and claudication. *J Vasc Surg*. 2015;61: 2S-41S.

17. Norgren L, Hiatt WR, Dormandy JA, Nehler MR, Harris KA, Fowkes FG; TASC II Working Group. Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II). *J Vasc Surg*. 2007;45:S5-67.

18. Hertzer NR, Bena JF, Karafa MT. A personal experience with direct reconstruction and extra-anatomic bypass for aortoiliofemoral occlusive disease. *J Vasc Surg*. 2007;45:527-35.

19. Kashyap VS, Pavkov ML, Bena JF, Sarac TP, O'Hara PJ, Lyden SP, Clair DG. The management of severe aortoiliac occlusive disease: endovascular therapy rivals open reconstruction. *J Vasc Surg*. 2008;48:1451-7.

20. West CA Jr, Johnson LW, Doucet L, Caldito G, Heldman M, Szarvas T, Speirs RD, Carson S. A contemporary experience of open aortic reconstruction in patients with chronic atherosclerotic occlusion of the abdominal aorta. *J Vasc Surg*. 2010;52:1164-72.

21. Ballotta E, Lorenzetti R, Piatto G, Tolin F, Da Giau G, Toniato A. Reconstructive surgery for complex aortoiliac occlusive disease in young adults. *J Vasc Surg*. 2012;56:1606-14.

22. Bredahl K, Jensen LP, Schroeder TV, Sillesen H, Nielsen H, Eiberg JP. Mortality and complications after aortic bifurcated bypass procedures for chronic aortoiliac occlusive disease. *J Vasc Surg*. 2015;62:75-82.

23. Schnelder JR, Golan JF. The role of extraanatomic bypass in the management of bilateral aortoiliac occlusive disease. *Semin Vasc Surg.* 1994;7:35-44.

24. Martin D, Katz SG. Axillofemoral bypass for aortoiliac occlusive disease. *Am J Surg.* 2000;180:100-3.

25. Moise MA, Alvarez-Tostado JA, Clair DG, Greenberg RK, Lyden SP, Srivastava SD, Eagleton M, Sarac TS, Kashyap VS. Endovascular management of chronic infrarenal aortic occlusion. *J Endovasc Ther.* 2009;16:84-92.

26. Kawasaki D, Tsujino T, Fuijii K, Masutani M, Ohyanagi M, Masuyama T. Novel use of ultrasound guidance for recanalization of iliac, femoral, and popliteal arteries. *Catheter Cardiovasc Interv.* 2008;71:727-33.

27. Kumakura H, Kanai H, Araki Y, Hojo Y, Iwasaki T, Ichikawa S. 15-Year Patency and Life Expectancy After Primary Stenting Guided by Intravascular Ultrasound for Iliac Artery Lesions in Peripheral Arterial Disease. *JACC Cardiovasc Interv.* 2015;8:1893-901.

28. Goverde PC, Grimme FA, Verbruggen PJ, Reijnen MM. Covered endovascular reconstruction of aortic bifurcation (CERAB) technique: a new approach in treating extensive aortoiliac occlusive disease. *J Cardiovasc Surg.* 2013;54:383-7.

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Bioresorbable vascular scaffold implantation in a lesion with a coronary artery aneurysm: long-term optical coherence tomography follow-up

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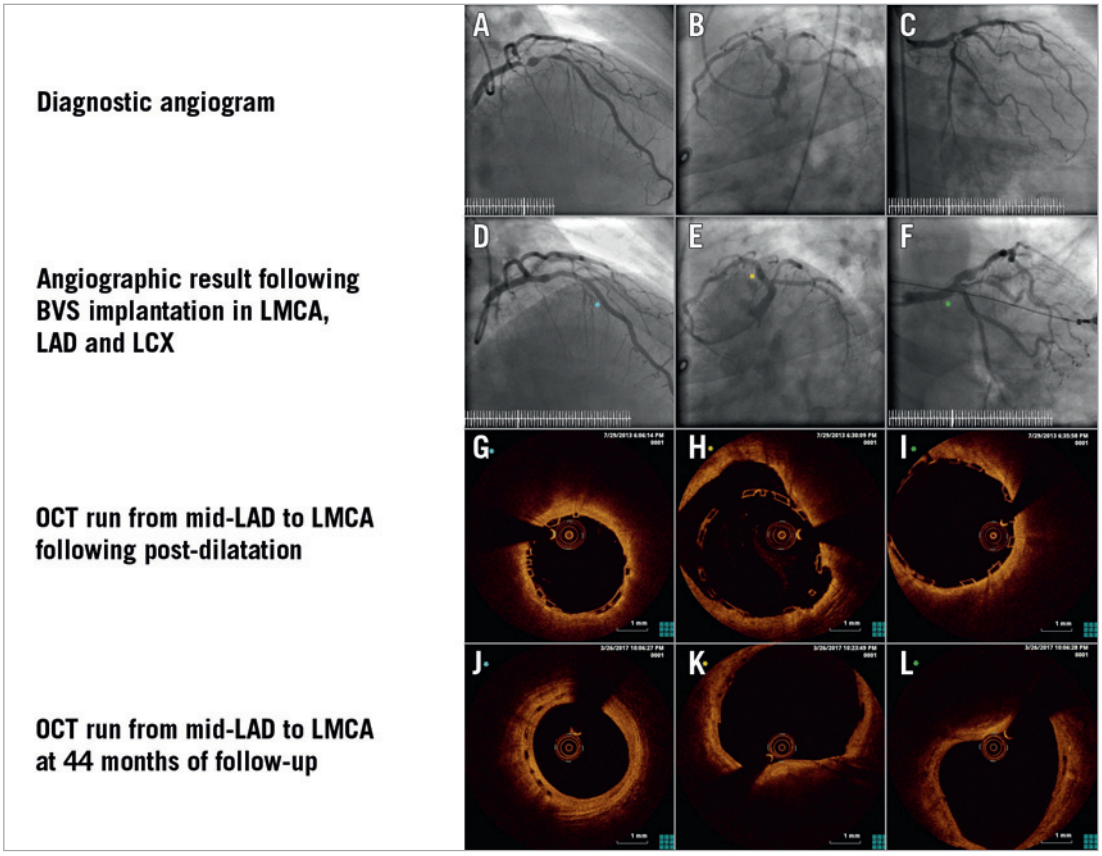

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A 54-year-old male underwent coronary angiography for non-ST-elevation myocardial infarction. This identified significant proximal left anterior descending artery (LAD) disease with an aneurysm **(Panel A)**. In addition, the ostial left circumflex (LCX) and first obtuse marginal (OM1) had significant disease **(Panel B, Panel C)**. The OM1 lesion was treated with a 3.0x26 mm SeQuent® Please (B. Braun, Melsungen, Germany) drug-eluting balloon. A 3.0x18 mm Absorb™ bioresorbable vascular scaffold (BVS) (Abbott Vascular, Santa Clara, CA, USA) was implanted from the ostial LCX. Subsequently, two additional Absorb BVS were implanted from the distal left main coronary artery (LMCA) to the proximal LAD (3.5x28 mm), and the mid-LAD (3.0x18 mm). The final angiographic result is shown in **Panel D-Panel F**. An optical coherence tomography (OCT) study from the mid-LAD to the LMCA showed well expanded struts without scaffold fracture **(Panel G-Panel I, Moving image 1, Moving image 2)**. The scaffold was malapposed in the aneurysmal segment **(Panel H, Moving image 2, Moving image 3)**. The minimal luminal area (MLA) measured 8.13 mm^2 in the LAD and 12.87 mm^2 in the LMCA at the end of the procedure **(Moving image 3)**. The patient was on dual antiplatelet therapy (aspirin and clopidogrel) for 30 months, followed by single antiplatelet therapy with aspirin.

There are concerns following the implantation of BVS, with reports of early as well as late scaffold failure, resulting in adverse cardiac outcomes. As this was a complex lesion subset, we performed a repeat angiogram with OCT at 44 months to ensure that there were no complications related to BVS implantation. The coronary angiogram showed a patent LMCA, LAD, LCX and OM1 **(Moving image 4-Moving image 6)**. An OCT study was performed from the mid-LAD to the LMCA. The majority of the strut remnants showed complete endothelialisation with positive remodelling **(Panel J-Panel L, Moving image 7, Moving image 8)**, including the aneurysmal segment **(Panel K, Moving image 8)**. The MLA measured 12.35 mm^2 in the LAD and 15.79 mm^2 in the LMCA at matched cross-sections **(Moving image 8)**.

Long-term follow-up concerning BVS deployment in lesions with coronary aneurysm is lacking. On the other hand, coronary aneurysm formation is a well described complication following implantation of drug-eluting stents and BVS. In addition, this complication has also been described with novolimus-eluting BVS. Hence, the implantation of a scaffold to an aneurysmal lesion with long-term OCT follow-up demonstrating resorption is unique in this patient.

The risk of scaffold thrombosis in the aneurysmal segment persists until the struts are completely resorbed. There are no protective factors for scaffold thrombosis in the initial period following implantation. At 44-month follow-up, OCT showed completely endothelialised strut remnants in the aneurysmal segment. Therefore, complete resorption in the aneurysmal segment results in the absence of late strut malapposition, and probably a lower risk of very late scaffold thrombosis.

Conflict of interest statement

The authors have no conflicts of interest to declare.

Supplementary data

Moving image 1. OCT run from mid-LAD to proximal LAD during the index procedure.

Moving image 2. OCT run from aneurysmal proximal LAD segment to distal LMCA during the index procedure.

Moving image 3. 3D OCT run across the aneurysmal proximal LAD segment during the index procedure.

Moving images 4, 5 and **6.** Coronary angiogram at 44-month follow-up.

Moving image 7. OCT run from mid-LAD to LMCA at 44-month follow-up.

Moving image 8. 3D OCT run from proximal LAD to LMCA at 44-month follow-up.

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Concertina effect caused by stents: insights from OCT

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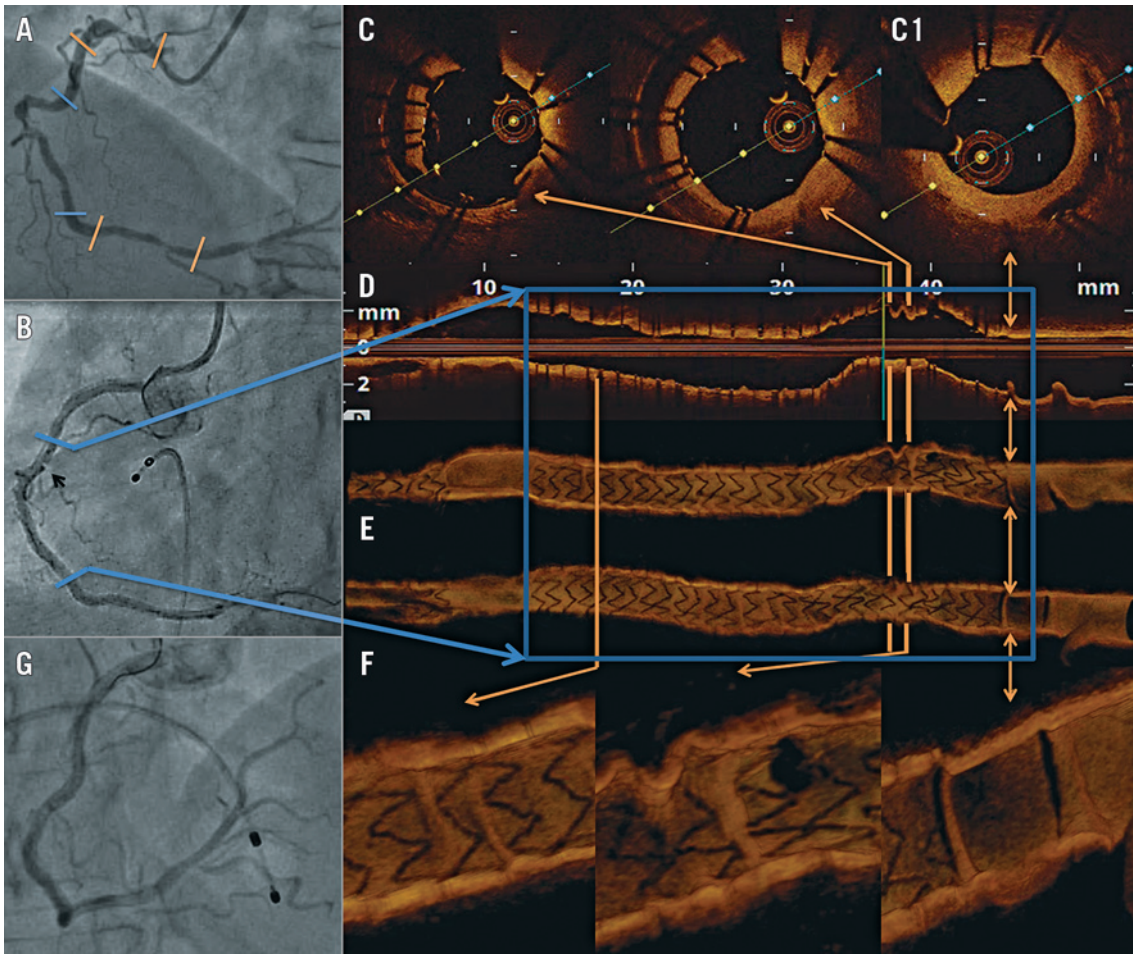

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A 59-year-old male with effort angina was found to have tandem lesions involving the tortuous right coronary artery (RCA) **(Panel A, Moving image 1)**. These were treated with three non-overlapping drug-eluting stents in the distal, mid and ostio-proximal RCA, in that order. After deploying the long second stent across the tortuous mid RCA, an angiogram showed a distinct cut-like intraluminal filling defect within the proximal part of the stented segment, possibly a pseudostenosis due to straightening of the vessel and non-conformability **(Panel B, Moving image 1)**.

Optical coherence tomography (OCT) imaging showed a well apposed stent with an area appearing like a cavity/dissection flap seen on the outer side of the stent struts which was actually infolding of the vessel wall due to the straightening of the tortuous segment by the stent **(Panel C)**. OCT also showed infolding of the vessel proximal to the stent (not obvious on the angiogram) which appeared like a cavity with ruptured plaque **(Panel C1)**. In the longitudinal view these areas were clearly seen as infolding of the vessels **(Panel D)**. Once the wire was removed, there was only a mild irregularity seen within the proximal part of the mid RCA stent **(Panel G, Moving image 1c)**. 3D OCT images revealed newer insights which were diagnostic of a concertina effect showing folds of vessel wall protruding through the stent struts that corresponded to the angiographic haziness and the dissection flaps on the axial OCT **(Panel E, Panel F)**. In addition, there were multiple vessel wall infoldings all along the mid RCA stent that were not obvious on the angiogram, axial and longitudinal OCT. The straightening of tortuous coronary arteries by intracoronary guidewires has been well described as a concertina effect causing angiographic pseudostenosis and has been imaged using OCT. We report an unusual case of a concertina effect within and proximal to the stent caused by stenting of a tortuous vessel. 3D OCT images showed unique findings confirmative of a concertina effect and appear to be more sensitive than axial and longitudinal OCT. New lesions appearing during percutaneous coronary interventions are challenging to the operator and recognition of pseudostenosis is critical to avoid unnecessary stents. The axial OCT dissection-like appearance is due to the oblique cutting of the eccentric infolding by the arc of light. When these axial frames align and merge, it reforms the infolding of the vessel with smooth intima on the *en face* view in the 3D OCT **(Supplementary Figure 1)** A magnified view of the angiogram to show the concertina within the mid RCA stent is presented in **Supplementary Figure 2**.

Conflict of interest statement

The authors have no conflicts of interest to declare.

Supplementary data

Supplementary Figure 1. Illustration of axial OCT having a dissection-like appearance (concertina effect).

Supplementary Figure 2. Magnified view of angiogram to show the pseudostenosis within the mid RCA stent.

Moving image 1. Angiogram and axial OCT run of concertina effect. a. Tortuous RCA with multiple stenoses. b. Haziness and pseudostenosis after mid RCA stent. c. Final angiogram after removing the wire. d. Axial OCT run showing mimicking dissection flaps and ruptured cavities.

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Multiple coronary artery aneurysms seen five years after Absorb implantation during routine angiographic and OCT follow-up

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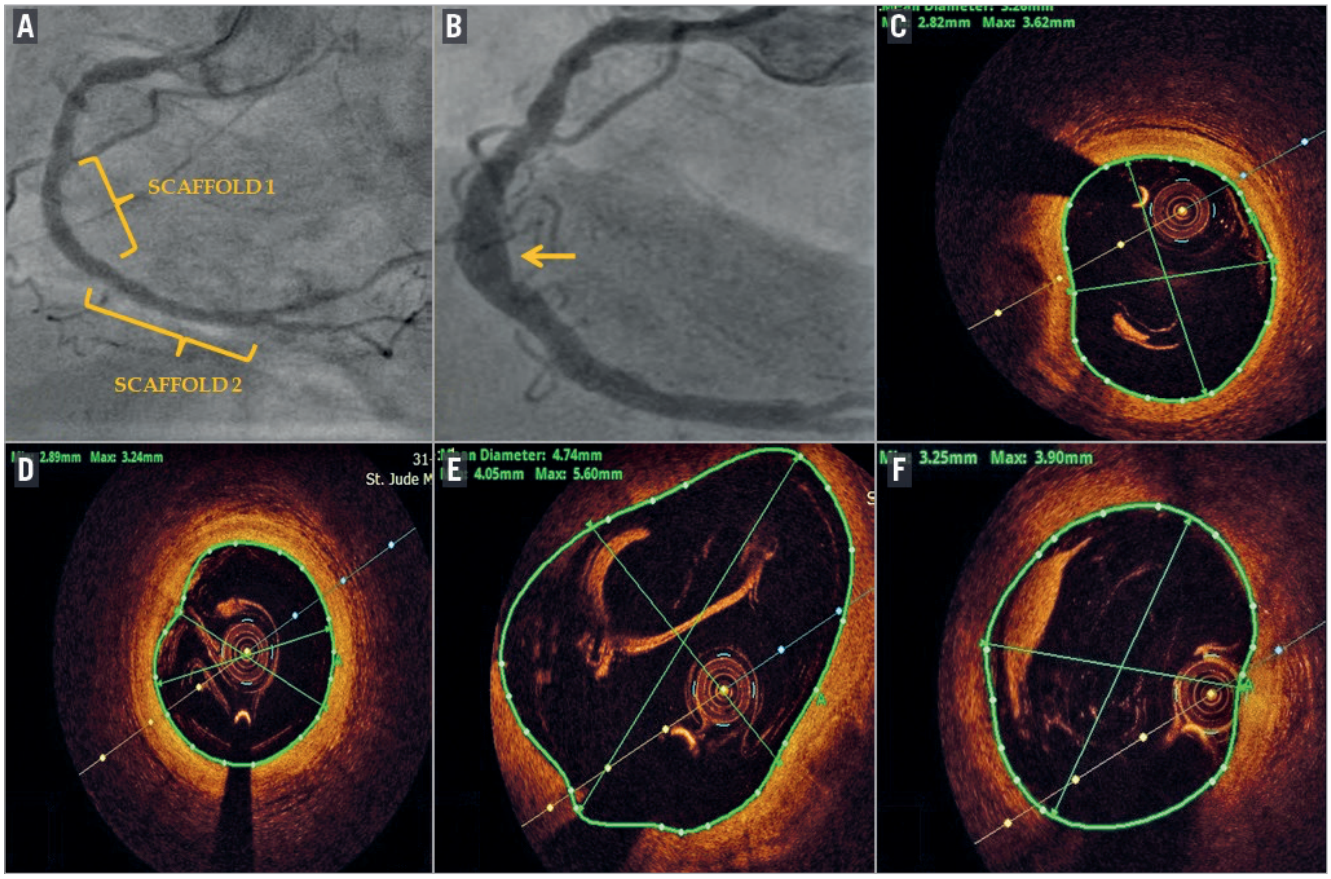

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Coronary artery aneurysm (CAA) is defined as coronary dilatation which exceeds the diameter of normal adjacent segments or the diameter of the patient's largest coronary vessel by 1.5 times[1]. The overall incidence of CAAs ranges from 1.5 to 5%, with a male preponderance and predilection for the right coronary artery[1]. We present a case report of iatrogenic CAAs which developed after Absorb™ bioresorbable vascular scaffold (BVS; Abbott Vascular, Santa Clara, CA, USA) implantation.

In 2013, a 65-year-old gentleman with hypertension, obesity, effort angina and positive stress test, underwent a coronary angiogram which revealed an occluded mid right coronary artery (RCA) and critical stenosis of the proximal left circumflex artery. Two overlapping Absorb BVS were deployed in the RCA **(Panel A)** and a staged PCI of the LCX with deployment of one Absorb BVS followed one month later. A coronary angiogram and OCT of the RCA were carried out five years later, as part of the study. This revealed an aneurysm in the mid RCA (**Panel B**, arrow) and LCX **(Supplementary Figure 1)**. OCT showed complete resorption of the Absorb scaffold, with areas of near normal segments in the proximal RCA, having a maximum lumen diameter of 3.6 mm and lumen area of 8.4 mm² **(Panel C)**. The mid RCA, after the aneurysmal segment, had a lumen diameter of 3.2 mm and area of 7.7 mm² **(Panel D)**. There was a significant aneurysmal dilatation of the mid RCA with a maximum diameter of 5.6 mm (area 16.89 mm²) **(Panel E)**. The distal RCA showed ectatic dilatation with an MLD of 3.9 mm (area 10.2 mm²) **(Panel F)**.

In case reports, the time to aneurysm formation in BVS varies from 6 to 32 months. The reasons are not clear but could be due to aggressive bed preparation with resultant deep dissections. The distinct morphological characteristics of the BVS – thicker struts and slower expandability – require higher pressures for balloon inflation, which could damage the arterial wall[2]. Late development of scaffold strut discontinuity and the resultant outward displacement of struts may result in aneurysm formation. The polymer and the antiproliferative drug could also play a role[3].

Conflict of interest statement

The authors have no conflicts of interest to declare.

References

1. Syed M, Lesch M. Coronary artery aneurysm: a review. *Prog Cardiovasc Dis.* 1997;40:77-84.

2. Varghese S, Lauer B, Ohlow MA. Coronary Artery Aneurysm After Everolimus-Eluting Bioabsorbable Vascular Scaffold Implantation. *JACC Cardiovasc Interv.* 2016;9:e23-5.

3. Abou Sherif S, Ozden Tok O, Taşköylü Ö, Goktekin O, Kilic ID. Coronary Artery Aneurysms: A Review of the Epidemiology, Pathophysiology, Diagnosis, and Treatment. *Front Cardiovasc Med.* 2017;4:24.

Supplementary data

Supplementary Figure 1. Left circumflex artery angiogram at scaffold deployment and at 5-year follow-up.

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Measurement of left ventricular end-diastolic pressure improves the prognostic utility of the Global Registry of Acute Coronary Events score in patients with ST-segment elevation myocardial infarction

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KEYWORDS

- depressed left ventricular function
- risk stratification
- STEMI

Abstract

Aims: This study aimed to evaluate the clinical significance of measuring left ventricular end-diastolic pressure (LVEDP) in patients with ST-segment elevation myocardial infarction (STEMI).

Methods and results: We retrospectively analysed clinical data from 277 patients with STEMI between October 2006 and June 2014. LVEDP and left ventricular ejection fraction (LVEF) were perioperatively measured during percutaneous coronary intervention (PCI). The primary endpoint was a major adverse cardiac event (MACE) such as cardiac death, non-fatal myocardial infarction, or hospitalisation due to heart failure during the observation period. The independent predictors were identified by Cox proportional hazards regression analysis. Continuous net reclassification improvement (cNRI) and integrated discrimination improvement (IDI) were conducted to assess the incremental prognostic value of adding cardiovascular parameters, including LVEDP, to the Global Registry of Acute Coronary Events (GRACE) score. The mean follow-up period was 44±31 months. A MACE occurred in 33 patients (12.0%). In the Cox proportional hazards regression model, after adjusting for confounding factors, LVEDP was an independent predictor of a MACE (hazard ratio [HR] 1.11, 95% confidence interval [CI]: 1.06-1.17, p<0.001). In addition, the predictive value of the GRACE score for a MACE was significantly improved by LVEDP (NRI 0.66, 95% CI: 0.32-1.01, p<0.001; IDI 0.06, 95% CI: 0.02-0.11, p=0.001), but not by LVEF (NRI 0.14, 95% CI: -0.22-0.50, p=0.44; IDI 0.01, 95% CI: 0.00-0.03, p=0.11).

Conclusions: The results of this study demonstrated that evaluating LVEDP provides an additive prognostic value over conventional risks estimated by the GRACE score among STEMI patients.

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Abbreviations

GRACE	Global Registry of Acute Coronary Events
IABP	intra-aortic balloon pump
IDI	integrated discrimination improvement
LVEDP	left ventricular end-diastolic pressure
LVEDV	left ventricular end-diastolic volume
LVEF	left ventricular ejection fraction
MACE	major adverse cardiac event
NRI	net reclassification improvement
PCI	percutaneous coronary intervention
STEMI	ST-segment elevation myocardial infarction
TIMI	Thrombolysis In Myocardial Infarction

Introduction

The incidence of ST-segment elevation myocardial infarction (STEMI) remains a leading cause of morbidity and mortality in patients with atherosclerotic risk factors. Myocardial ischaemia (MI) after STEMI initiates both systolic and diastolic myocardial dysfunction with subsequent advanced left ventricular (LV) remodelling[1,2]. Therefore, the development of more physiologically integrative methods for predicting global LV function during the acute phase of STEMI may be required for a better prognosis. LV end-diastolic pressure (LVEDP) is easily obtained from catheterisation during the follow-up of patients with STEMI. Currently, there are accumulating data on LVEDP in predicting outcomes in patients with MI[3-5].

Risk stratification using clinical markers or parameters such as the Global Registry of Acute Coronary Events (GRACE) score has been widely used to predict clinical outcomes after STEMI[6,7]. However, the GRACE score lacks haemodynamic information defining LV systolic and diastolic function. Therefore, this study investigated the additive prognostic value of LVEDP over the GRACE score in patients with STEMI undergoing successful percutaneous coronary intervention (PCI).

Methods

STUDY POPULATION

This retrospective study analysed data from 277 consecutive patients who underwent PCI for STEMI at Toho University Omori Medical Center (Tokyo, Japan) between October 2006 and June 2014. Patients were included if they had STEMI with characteristic chest pain within 12 hours before hospital admission. All patients underwent successful PCI with subsequent left ventriculography (LVG) to measure LVEDP and LV ejection fraction (LVEF). STEMI was diagnosed by electrocardiography as (i) an ST elevation of ≥2 mm either in two contiguous anterior-lateral leads or in inferior leads, or (ii) a new left bundle branch block with concordant ST elevation of 1 mm[8]. Patients who lacked LVG data and had a Thrombolysis In Myocardial Infarction (TIMI) flow grade of <3 after PCI were excluded. This study was conducted according to the guidelines of the Declaration of Helsinki and was approved by the relevant ethics committee at Toho University Faculty of Medicine (No. M16259). Baseline clinical information was obtained from medical records. Cardiovascular risk factors including diabetes, dyslipidaemia, hypertension, and current smoking were defined in accordance with the accepted criteria[9-11]. Baseline laboratory data and information on blood pressure and heart rate were collected at admission. Troponin I and creatinine kinase myocardial band (CK-MB) were measured at least twice a day, until peak values were recorded. For each patient, the GRACE risk score was calculated using eight specific variables collected upon admission as reported (http://www.gracescore.org/website/webversion.aspx).

The primary endpoint was a major adverse cardiac event (MACE), including cardiac death, non-fatal myocardial infarction, and heart failure requiring hospitalisation, during the observation period.

INVASIVE CORONARY ANGIOGRAPHY PROTOCOL

Primary PCI was performed according to standard methods[8]. Patients who received a diagnosis of STEMI were treated with 100 mg aspirin and either 150 mg clopidogrel or 200 mg ticlopidine before catheterisation. There was no case of thrombolysis during PCI. Procedural success was defined as a successful guidewire and balloon crossing with residual stenosis >50% and TIMI flow grade ≥3 after coronary stenting. Measurements of LVEDP and LVEF during LVG were performed as described[12].

STATISTICAL ANALYSIS

Data were analysed with the Statistical Package for EZR for Windows, Version 1.35 (Saitama Medical Center, Japan)[13]. Continuous variables are expressed as the mean±standard deviation. The Kolmogorov-Smirnov test was applied to test for normal distribution. Continuous variables were compared using the Student's t-test. Demographics, traditional risk factors, and clinical outcomes were compared using Pearson's chi-square test or Fisher's exact test, as appropriate, for categorical data, and were expressed as percentages. A Kaplan-Meier analysis was performed to calculate the unadjusted MACE rate according to the median value of LVEDP. Cox proportional hazards regression analysis was used to identify independent predictors of MACE during the observation period. The multivariate model was built by backward stepwise variable selection, with entry and exit criteria set at $p<0.05$. We used the area under the curve (AUC) by receiver operating characteristic for the prediction of MACE to assess the added value of LVEDP or LVEF over assessment of the GRACE score. Continuous net reclassification improvement (cNRI) and integrated discrimination improvement (IDI) were also used to investigate whether LVEDP or LVEF reclassified patients with respect to MACE risk relative to their GRACE score.

Results

PATIENT CHARACTERISTICS AND INCIDENCE OF MACE

We evaluated 277 patients hospitalised due to confirmed STEMI. During the mean follow-up period of 44±31 months, 33 patients (12.0%) developed a MACE **(Table 1)**. Patients with a MACE were older than those without a MACE. The GRACE score was

Table 1. Baseline characteristics of patients with and without a MACE.

		With a MACE (n=33)	Without a MACE (n=244)	*p*-value
Demographics				
Age, years		70.6±12.1	63.5±12.0	0.001
Male (%)		24 (72.7)	198 (81.1)	0.07
Body mass index		23.8±6.5	23.6±5.3	0.86
Diabetes (%)		12 (36.4)	74 (30.3)	0.54
Hypertension (%)		20 (60.6)	140 (57.4)	0.85
Dyslipidaemia (%)		10/33 (30.3)	97/244 (39.8)	0.34
Current smoking habit (%)		20 (60.6)	151 (62.1)	0.86
Previous MI (%)		3 (9.1)	10 (4.1)	0.19
Previous PCI (%)		4 (12.1)	11 (4.1)	0.08
Previous CABG (%)		0 (0)	1 (0.4)	0.99
Onset-to-balloon time, hours		4.4±2.5	4.2±2.7	0.71
Heart rate, bpm		74.3±27.3	74.7±19.7	0.90
Systolic blood pressure, mmHg		133.9±36.6	139.5±31.5	0.34
Killip class	I (%)	28 (84.9)	217 (88.9)	0.19
	II (%)	0 (0.0)	11 (4.5)	
	III (%)	4 (12.1)	9 (3.7)	
	IV (%)	1 (3.0)	7 (2.9)	
Laboratory data				
Peak troponin I, U/L		118.7±124.3	90.5±95.5	0.12
Peak CK-MB, U/L		323.2±299.1	259.5±242.5	0.17
Haemoglobin level, g/L		14.1±1.8	14.0±2.0	0.75
Creatinine, mg/dl		0.8±0.2	0.8±0.2	0.78
BNP, pg/mL		133.0±236.0	94.0±123.9	0.14
GRACE score		161.3±35.3	144.7±32.4	<0.001
Use of IABP		4 (12.1)	7 (2.9)	0.03
Medications before PCI				
Aspirin (%)		2 (6.1)	24 (9.8)	0.75
ARB (%)		3 (9.1)	32 (13.1)	0.78
ACE inhibitors (%)		1 (3)	6 (2.5)	0.59
Beta-blockers (%)		0 (0)	6 (2.5)	0.99
Statins (%)		1 (3)	19 (7.8)	0.48
Medications after PCI				
Aspirin (%)		33 (100)	244 (100)	0.99
ARB (%)		13 (39.4)	79 (32.4)	0.50
ACE inhibitors (%)		17 (51.5)	137 (56.1)	0.71
Beta-blockers (%)		26 (78.8)	177 (72.5)	0.53
Statins (%)		23 (69.7)	175 (72.0)	0.83

ACE inhibitor: angiotensin-converting enzyme inhibitor; ARB: angiotensin II receptor blocker; BNP: brain natriuretic peptide; CABG: coronary artery bypass grafting; CK-MB: creatinine kinase-myocardial band; GRACE: Global Registry of Acute Coronary Events; IABP: intra-aortic balloon pump; MACE: major adverse cardiac event; MI: myocardial infarction; PCI: percutaneous coronary intervention

significantly higher and the use of an intra-aortic balloon pump (IABP) was more frequent in patients with a MACE relative to those who did not experience such an event. There was a tendency towards statistical significance in gender and prior PCI rates between the two groups. There was no significant difference in prescribed medications including angiotensin-converting enzyme inhibitors/angiotensin receptor blockers, beta-blockers, and statins after STEMI between the two groups. **Table 2** shows the angiographic and haemodynamic data during catheterisation. There was no significant difference in the number of diseased vessels and the location of culprit lesions found with coronary angiography between the two groups. In contrast, LVEDP was significantly higher and LVEF was significantly lower in patients with a MACE. Among the MACE components, there were 13 cardiac deaths (5.0%), 10 incidents of non-fatal myocardial infarction (3.6%), and 10 hospitalisations due to heart failure (3.6%).

Table 2. Catheterisation analysis of patients with and without a MACE.

		With a MACE	Without a MACE	*p*-value
Angiographic data				
Number of diseased vessels	1 (%)	20 (60.6)	147 (60.2)	0.99
	2 (%)	12 (36.4)	71 (29.1)	
	3 (%)	1 (3.0)	26 (10.7)	
Culprit lesions	RCA (%)	10 (30.3)	90 (36.9)	0.42
	LAD (%)	21 (63.6)	125 (51.2)	
	LCX (%)	2 (6.1)	29 (11.9)	
TIMI flow=0 or 1 before PCI (%)		23 (69.7)	178 (73.0)	0.81
Haemodynamic data				
LVEDP, mmHg		26.6±6.9	21.2±6.9	<0.001
LVEF, %		51.4±14.7	55.6±11.2	<0.05

LAD: left anterior descending artery; LCX: left circumflex artery; LVEDP: left ventricular end-diastolic pressure; LVEF: left ventricular ejection fraction; MACE: major adverse cardiac event; PCI: percutaneous coronary intervention; RCA: right coronary artery; TIMI: Thrombolysis In Myocardial Infarction

ASSOCIATION BETWEEN HIGHER LVEDP AND THE INCIDENCE OF MACE

Patients were divided into two groups according to the median value of LVEDP (21 mmHg). As shown in **Table 3**, patients with LVEDP ≥21 mmHg had higher incidences of cardiac death, non-fatal myocardial infarction and MACE, as compared with patients with LVEDP <21 mmHg. Also, on Kaplan-Meier analysis, patients with LVEDP ≥21 mmHg showed higher rates of MACE incidence **(Figure 1)**.

INDEPENDENT PREDICTORS OF MACE

Age, use of IABP, LVEDP, LVEF, and GRACE score were applied to the Cox proportional hazards regression model to identify independent predictors of a MACE. In **Table 4**, after adjustment by

Table 3. Incidence of MACE components according to the median value of LVEDP (21 mmHg).

	LVEDP ≥21 mmHg	LVEDP <21 mmHg	*p*-value
MACE, n (%)	27 (18.5)	6 (4.6)	<0.001
Cardiac death, n (%)	11 (7.5)	2 (1.5)	0.02
Non-fatal MI, n (%)	9 (6.2)	1 (0.8)	0.02
Hospitalisation due to heart failure, n (%)	7 (4.8)	3 (2.3)	0.34

LVEDP: left ventricular end-diastolic pressure; MACE: major adverse cardiac event; MI: myocardial infarction

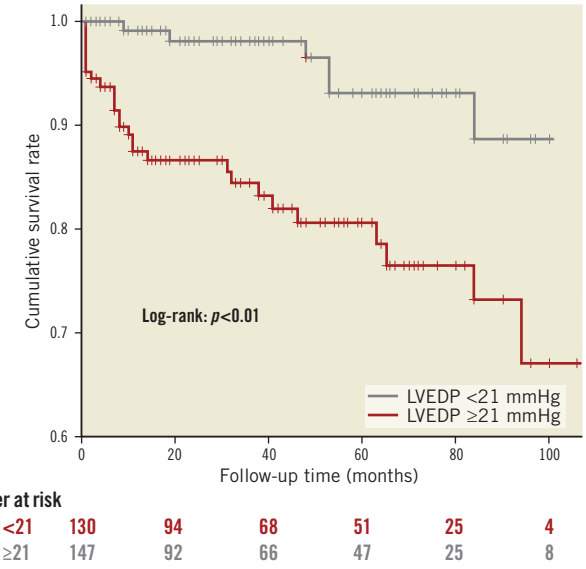

Figure 1. *Kaplan-Meier curves for MACE according to the median value of LVEDP (21 mmHg).*

these variables without LVEDP, age, use of IABP and LVEDP were associated with the incidence of a MACE (model 1). In the full adjusted model, LVEDP, age, and the use of IABP were found to be associated with the incidence of a MACE.

INCREMENTAL PROGNOSTIC VALUE OF LVEDP OVER THE GRACE SCORE

For the incidence of MACE, the incremental predictive value of LVEDP and LVEF over the GRACE score was evaluated. As shown in **Figure 2A** and **Figure 2B**, including the LVEF data with the GRACE score did not improve the area under the curve (AUC) for the GRACE score alone (p=0.54), but there was a tendency towards statistical significance for the LVEDP to increase the AUC over the GRACE score alone (p=0.06). In addition, we assessed the additive predictive value of the LVEDP or LVEF in combination with the GRACE score by cNRI and IDI. As shown in **Table 5**, the addition of LVEDP successfully recategorised patients based on the GRACE score alone, but the addition of LVEF did not.

Discussion

We evaluated the possibility of using LVEDP for the early risk stratification of patients with STEMI who were successfully treated by PCI. LVEDP was significantly higher in patients who developed a MACE. In addition, LVEDP provided an incremental prognostic value over the GRACE risk score according to reclassification analyses, but LVEF did not.

This study demonstrated that the LVEDP was superior to other common clinical factors such as infarct size and LVEF in predicting long-term outcomes after STEMI. Our negative impact of LVEF at admission was consistent with the data by Dutcher et al[7]. Of note, as was shown in the previous study, we also found that LVEF is an independent predictor of a MACE in multivariate

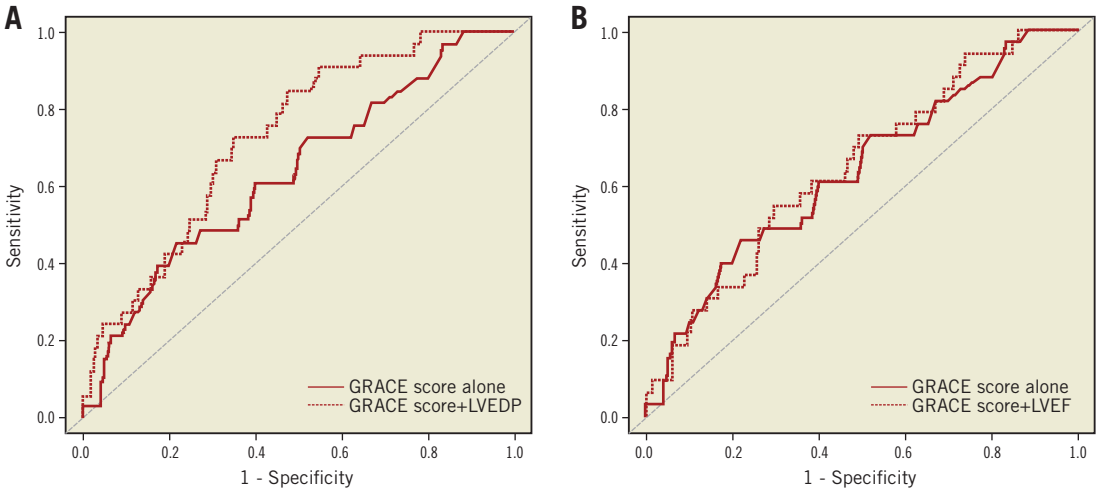

Figure 2. *The predictive value of LVEDP and LVEF by ROC curve analysis for MACE incidence. A) Comparison of the AUC to predict MACE between GRACE score and GRACE score + LVEDP. B) Comparison of the AUC to predict MACE between GRACE score and GRACE score + LVEF.*

Table 4. Cox proportional hazards regression model to predict a MACE.

	Univariate analysis		Multivariate analysis model 1		Multivariate analysis model 2	
	HR (95% CI)	*p*-value	HR (95% CI)	*p*-value	HR (95% CI)	*p*-value
Age	1.05 (1.02-1.08)	<0.001	1.05 (1.02-1.09)	<0.001	1.07 (1.02-1.11)	<0.001
Male	0.71 (0.31-1.58)	0.4	–	–	–	–
Diabetes	1.28 (0.63-2.62)	0.48	–	–	–	–
Current smoking habits	0.91 (0.46-1.73)	0.79	–	–	–	–
Previous PCI	2.41 (0.84-6.88)	0.1	–	–	–	–
Killip class II or more	1.40 (0.92-2.13)	0.1	–	–	–	–
Baseline TIMI flow 0 or 1	1.08 (0.75-1.57)	0.65	–	–	–	–
Creatinine level	1.05 (0.20-5.32)	0.94	–	–	–	–
Haemoglobin level	1.00 (0.84-1.20)	0.93	–	–	–	–
BNP level	1.00 (0.00-1.00)	0.13	–	–	–	–
Peak CK-MB level	1.00 (0.99-1.00)	0.19	–	–	–	–
Use of IABP	4.33 (1.50-12.4)	<0.01	7.90 (2.60-24.0)	<0.001	4.28 (1.35-13.57)	0.01
Onset-to-balloon time	1.02 (0.90-1.15)	0.72	–	–	–	–
LAD culprit	1.79 (0.88-3.66)	0.1	–	–	–	–
LVEDP	1.11 (1.06-1.17)	<0.001	–	–	1.13 (1.06-1.20)	<0.001
LVEF	0.96 (0.93-0.99)	0.02	0.96 (0.94-0.99)	0.02	0.99 (0.96-1.02)	0.74
GRACE score	1.01 (1.00-1.02)	0.003	1.00 (0.99-1.01)	0.64	1.00 (0.98-1.01)	0.79

BNP: brain natriuretic peptide; CI: confidence interval; CK-MB: creatinine kinase-myocardial band; GRACE: Global Registry of Acute Coronary Events; HR: hazard ratio; IABP: intra-aortic balloon pump; LAD: left anterior descending artery; LVEDP: left ventricular end-diastolic pressure; LVEF: left ventricular ejection fraction; MACE: major adverse cardiac event; PCI: percutaneous coronary intervention; TIMI: Thrombolysis In Myocardial Infarction

Table 5. Reclassification analysis of patients based on the GRACE score alone and the GRACE score with the LVEDP or LVEF.

	AUC	*p*-value	cNRI	*p*-value	IDI	*p*-value
GRACE	0.63	–	–	–	–	–
LVEDP	0.71	–	–	–	–	–
LVEF	0.57	–	–	–	–	–
GRACE + LVEDP	0.72	0.06	0.66 (0.32-1.01)	<0.001	0.06 (0.02-0.11)	0.001
GRACE + LVEF	0.65	0.54	0.14 (–0.22-0.50)	0.44	0.01 (0.00-0.03)	0.11

AUC: area under the curve; cNRI: continuous net reclassification improvement; GRACE: Global Registry of Acute Coronary Events; IDI: integrated discrimination improvement; LVEDP: left ventricular end-diastolic pressure; LVEF: left ventricular ejection fraction

analysis[14]. However, this impact was eliminated when adjusted by LVEDP. These interesting findings may be due to the relationship between an increase in LVEDP and subsequent LV remodelling. As described in the Frank-Starling law, compensatory increases in LV end-diastolic volume (LVEDV) and LVEDP maintain stroke volume during severe LV dysfunction after STEMI[15]. In those cases, the renin-angiotensin system and sympathetic nervous system are highly activated with inducible monotype hypertrophy and compensatory LV dilation in the long term[16-18]. According to a study by Garber et al[19], LVEDV at baseline is an independent predictor of LV remodelling after STEMI. The ventricular dilation and wall thinning that result from infarct zone expansion reportedly increase LVEDV during the early phase of MI. Interestingly, we previously reported that increasing LVEDP is associated with LV dilation during the acute phase after STEMI, showing that both LV end-systolic volume index (LVESVI) and LV end-diastolic volume index are significantly higher in patients with higher LVEDP[5]. In addition, we also found that there is a relationship between higher LVEDP and subsequent progression of LV remodelling after STEMI, showing that LVESVI after PCI remains higher during long-term follow-up in patients with higher LVEDP, irrespective of baseline LVEF. Through these processes, the higher LVEDP may influence LV function and long-term clinical outcomes after STEMI. Therefore, this invasive but simple method to assess global LV function and systemic haemodynamics may affect current early risk stratification after STEMI. We found that the GRACE score was not a significant factor in our multivariate analysis, suggesting that it is basically more suitable for assessing the short-term outcome after STEMI, whereas limited studies have demonstrated that it is also a preferred scoring system for risk stratification in the long term[20,21]. Of importance, the GRACE score does not provide haemodynamic information (i.e., LVEDP or LVEF); very little has been investigated about the additive impact of LVEDP to risk stratification using prognostic factors over clinical risk scores including the GRACE score. This study demonstrated that its inclusion resulted in a tendency to increase

the AUC relative to that with the GRACE score alone to predict MACE incidence. In addition, by adding the LVEDP information to the GRACE score, 66% of patients were successfully recategorised. Interestingly, these effects were not observed by inclusion of LVEF. Our results are similar to those in a study by Abu-Assi et al, which showed that the addition of LVEF did not provide incremental prognostic information to the GRACE score in patients with acute coronary syndrome[22]. The authors found that there was high collinearity between the GRACE score and LVEF, suggesting that the GRACE score predicts prognosis effectively irrespective of LVEF. These results were consistent with a previous study in which a higher LVEDP was found to have comparable prognostic value with risk scores including the GRACE risk score[3]. In the light of these data, it is worth emphasising the periprocedural assessment of LVEDP during PCI in patients with STEMI.

Limitations

This study had the following limitations. This was a single-centre, observational cohort study of a relatively small population. In this retrospective setting, a variability of follow-up duration according to the different enrolment timing might have affected the results. In fact, most of the patients during 2011 and 2014 were followed for less than the mean follow-up period of 44 months (97 out of 110). In addition, because we possibly excluded those with very low LVEF due to intolerability to undergo LVG, the subsequent prognostic impact of LVEF might be underestimated. Thus, a prospective large-scale multicentre clinical setting is needed for further confirmation. Of importance, as was shown in our previous reports[5], the combined assessment of LVEDP and LVEF at admission was a useful prognostic parameter after STEMI. Therefore, the pathophysiological mechanism of LV remodelling after STEMI may be clarified by serial haemodynamic assessment including LVEDP and LVEF in the larger sample size. In addition, lower LVEF and larger infarct size were not associated with worse outcome in the current study, because patients with cardiac shock and higher peak troponin I levels were excluded from this study due to the lack of data on LVG. In addition, the optimal timing of LVEDP measurements remains unclear. LVEDP measurements at different time points may be more informative for treatment strategy and predicting prognosis. Finally, the relationship between increasing LVEDP and LV remodelling needs further assessment. For example, imaging modalities such as cardiac magnetic resonance may be less invasive and more useful for assessing the progression of LV remodelling.

Conclusions

Including LVEDP measurements provides additional information to the GRACE risk score for assessing the risk of a MACE in patients with STEMI. Further prospective approaches should be investigated to determine if LVEDP reduction guides care after MI.

Impact on daily practice

The assessment of LVEDP guides care after STEMI.

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Conflict of interest statement

The authors have no conflicts of interest to declare.

References

1. De Luca L, Sardella G, Davidson CJ, De Persio G, Beraldi M, Tommasone T, Mancone M, Nguyen BL, Agati L, Gheorghiade M, Fedele F. Impact of intracoronary aspiration thrombectomy during primary angioplasty on left ventricular remodelling in patients with anterior ST elevation myocardial infarction. *Heart.* 2006;92:951-7.

2. Carrick D, Haig C, Rauhalammi S, Ahmed N, Mordi I, McEntegart M, Petrie MC, Eteiba H, Lindsay M, Watkins S, Hood S, Davie A, Mahrous A, Sattar N, Welsh P, Tzemos N, Radjenovic A, Ford I, Oldroyd KG, Berry C. Pathophysiology of LV Remodeling in Survivors of STEMI: Inflammation, Remote Myocardium, and Prognosis. *JACC Cardiovasc Imaging.* 2015;8:779-89.

3. Planer D, Mehran R, Witzenbichler B, Guagliumi G, Peruga JZ, Brodie BR, Dudek D, Mockel M, Reyes SL, Stone GW. Prognostic utility of left ventricular end-diastolic pressure in patients with ST-segment elevation myocardial infarction undergoing primary percutaneous coronary intervention. *Am J Cardiol.* 2011;108:1068-74.

4. Bagai A, Armstrong PW, Stebbins A, Mahaffey KW, Hochman JS, Weaver WD, Patel MR, Granger CB, Lopes RD. Prognostic implications of left ventricular end-diastolic pressure during primary percutaneous coronary intervention for ST-segment elevation myocardial infarction: Findings from the Assessment of Pexelizumab in Acute Myocardial Infarction study. *Am Heart J.* 2013;166:913-9.

5. Saito D, Nakanishi R, Watanabe I, Yabe T, Okubo R, Amano H, Toda M, Ikeda T. Combined assessment of left ventricular end-diastolic pressure and ejection fraction by left ventriculography predicts long-term outcomes of patients with ST-segment elevation myocardial infarction. *Heart Vessels.* 2018;33:453-61.

6. Parenica J, Kala P, Pavkova MG, Tomandl J, Spinar J, Littnerova S, Jarkovsky J, Mebazaa A, Tomandlova M, Dastych M, Gottwaldova J, Gayat E. Natriuretic peptides, nitrite/nitrate and superoxide dismutase have additional value on top of the GRACE score in prediction of one-year mortality and rehospitalisation for heart failure in STEMI patients - Multiple biomarkers prospective cohort study. *Int J Cardiol.* 2016;211:96-104.

7. Dutcher JR, Kahn J, Grines C, Franklin B. Comparison of left ventricular ejection fraction and exercise capacity as predictors of two- and five-year mortality following acute myocardial infarction. *Am J Cardiol.* 2007;99:436-41.

8. Task Force on the management of ST-segment elevation acute myocardial infarction of the European Society of Cardiology (ESC),

Steg PG, James SK, Atar D, Badano LP, Blomstrom-Lundqvist C, Borger MA, Di Mario C, Dickstein K, Ducrocq G, Fernandez-Aviles F, Gershlick AH, Giannuzzi P, Halvorsen S, Huber K, Juni P, Kastrati A, Knuuti J, Lenzen MJ, Mahaffey KW, Valgimigli M, van 't Hof A, Widimsky P, Zahger D. ESC Guidelines for the management of acute myocardial infarction in patients presenting with ST-segment elevation. *Eur Heart J.* 2012;33:2569-619.

9. Ohman EM, Bhatt DL, Steg PG, Goto S, Hirsch AT, Liau CS, Mas JL, Richard AJ, Röther J, Wilson PW; REACH Registry Investigators. The REduction of Atherothrombosis for Continued Health (REACH) Registry: an international, prospective, observational investigation in subjects at risk for atherothrombotic events-study design. *Am Heart J.* 2006;151:786.

10. National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III). Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III) final report. *Circulation.* 2002;106:3143-421.

11. Parikh NI, Gona P, Larson MG, Fox CS, Benjamin EJ, Murabito JM, O'Donnell CJ, Vasan RS, Levy D. Long-term trends in myocardial infarction incidence and case fatality in the National Heart, Lung, and Blood Institute's Framingham Heart study. *Circulation.* 2009;119:1203-10.

12. Levine GN, Bates ER, Blankenship JC, Bailey SR, Bittl JA, Cercek B, Chambers CE, Ellis SG, Guyton RA, Hollenberg SM, Khot UN, Lange RA, Mauri L, Mehran R, Moussa ID, Mukherjee D, Ting HH, O'Gara PT, Kushner FG, Ascheim DD, Brindis RG, Casey DE Jr, Chung MK, de Lemos JA, Diercks DB, Fang JC, Franklin BA, Granger CB, Krumholz HM, Linderbaum JA, Morrow DA, Newby LK, Ornato JP, Ou N, Radford MJ, Tamis-Holland JE, Tommaso CL, Tracy CM, Woo YJ, Zhao DX. 2015 ACC/AHA/SCAI Focused Update on Primary Percutaneous Coronary Intervention for Patients With ST-Elevation Myocardial Infarction: An Update of the 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention and the 2013 ACCF/AHA Guideline for the Management of ST-Elevation Myocardial Infarction: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Society for Cardiovascular Angiography and Interventions. *Circulation.* 2016;133:1135-47.

13. Kanda Y. Investigation of the freely available easy-to-use software 'EZR' for medical statistics. *Bone Marrow Transplant.* 2013;48:452-8.

14. Daneault B, Généreux P, Kirtane AJ, Witzenbichler B, Guagliumi G, Paradis JM, Fahy MP, Mehran R, Stone GW. Comparison of Three-year outcomes after primary percutaneous coronary intervention in patients with left ventricular ejection fraction <40% versus ≥40% (from the HORIZONS-AMI trial). *Am J Cardiol.* 2013;111:12-20.

15. Lew WY, Ban-Hayashi E. Mechanisms of improving regional and global ventricular function by preload alterations during acute ischemia in the canine left ventricle. *Circulation.* 1985;72:1125-34.

16. Parashar A, Agarwal S, Krishnaswamy A, Garg A, Poddar KL, Sud K, Ellis S, Tuzcu EM, Kapadia SR. Renin-Angiotensin System Antagonists in Patients Without Left Ventricular Dysfunction After Percutaneous Intervention for ST-Segment Elevation Myocardial Infarction. *Am J Cardiol.* 2015;116:508-14.

17. Park H, Kim HK, Jeong MH, Cho JY, Lee KH, Sim DS, Yoon NS, Yoon HJ, Hong YJ, Kim KH, Park HW, Kim JH, Ahn Y, Cho JG, Park JC, Kim YJ, Cho MC, Kim CJ; Korea Acute Myocardial Infarction Registry Investigators. Clinical impacts of inhibition of renin-angiotensin system in patients with acute ST-segment elevation myocardial infarction who underwent successful late percutaneous coronary intervention. *J Cardiol.* 2017;69:216-21.

18. Kasama S, Toyama T, Sumino H, Kumakura H, Takayama Y, Minami K, Ichikawa S, Matsumoto N, Sato Y, Kurabayashi M. Effects of spironolactone on cardiac sympathetic nerve activity and left ventricular remodelling after reperfusion therapy in patients with first ST-segment elevation myocardial infarction. *Heart.* 2011;97:817-22.

19. Garber L, McAndrew TC, Chung ES, Stancak B, Svendsen JH, Monteiro J, Fischer TM, Kueffer F, Ryan T, Bax J, Leon AR, Stone GW. Predictors of Left Ventricular Remodeling After Myocardial Infarction in Patients With a Patent Infarct Related Coronary Artery After Percutaneous Coronary Intervention (from the Post-Myocardial Infarction Remodeling Prevention Therapy [PRomPT] Trial). *Am J Cardiol.* 2018;121:1293-8.

20. Littnerova S, Kala P, Jarkovsky J, Kubkova L, Prymusova K, Kubena P, Tesak M, Toman O, Poloczek M, Spinar J, Dusek L, Parenica J. GRACE Score among Six Risk Scoring Systems (CADILLAC, PAMI, TIMI, Dynamic TIMI, Zwolle) Demonstrated the Best Predictive Value for Prediction of Long-Term Mortality in Patients with ST-Elevation Myocardial Infarction. *PloS One.* 2015;10:e0123215.

21. Kozieradzka A, Kaminski KA, Maciorkowska D, Olszewska M, Dobrzycki S, Nowak K, Kralisz P, Prokopczuk P, Musial WJ. GRACE, TIMI, Zwolle and CADILLAC risk scores--do they predict 5-year outcomes after ST-elevation myocardial infarction treated invasively? *Int J Cardiol.* 2011;148:70-5.

22. Abu-Assi E, Ferreira-Gonzalez I, Ribera A, Marsal JR, Cascant P, Heras M, Bueno H, Sanchez PL, Aros F, Marrugat J, Garcia-Dorado D, Pena-Gil C, Gonzalez-Juanatey JR, Permanyer-Miralda G. "Do GRACE (Global Registry of Acute Coronary events) risk scores still maintain their performance for predicting mortality in the era of contemporary management of acute coronary syndromes?". *Am Heart J.* 2010;160:826-34.

23. Sola M, Venkatesh K, Caughey M, Rayson R, Dai X, Stouffer GA, Yeung M. Ratio of systolic blood pressure to left ventricular end-diastolic pressure at the time of primary percutaneous coronary intervention predicts in-hospital mortality in patients with ST-elevation myocardial infarction. *Catheter Cardiovasc Interv.* 2017;90:389-95.

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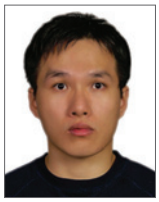
Drug-coated balloon treatment of late scaffold thrombosis and proliferated neointima and atherosclerotic plaque



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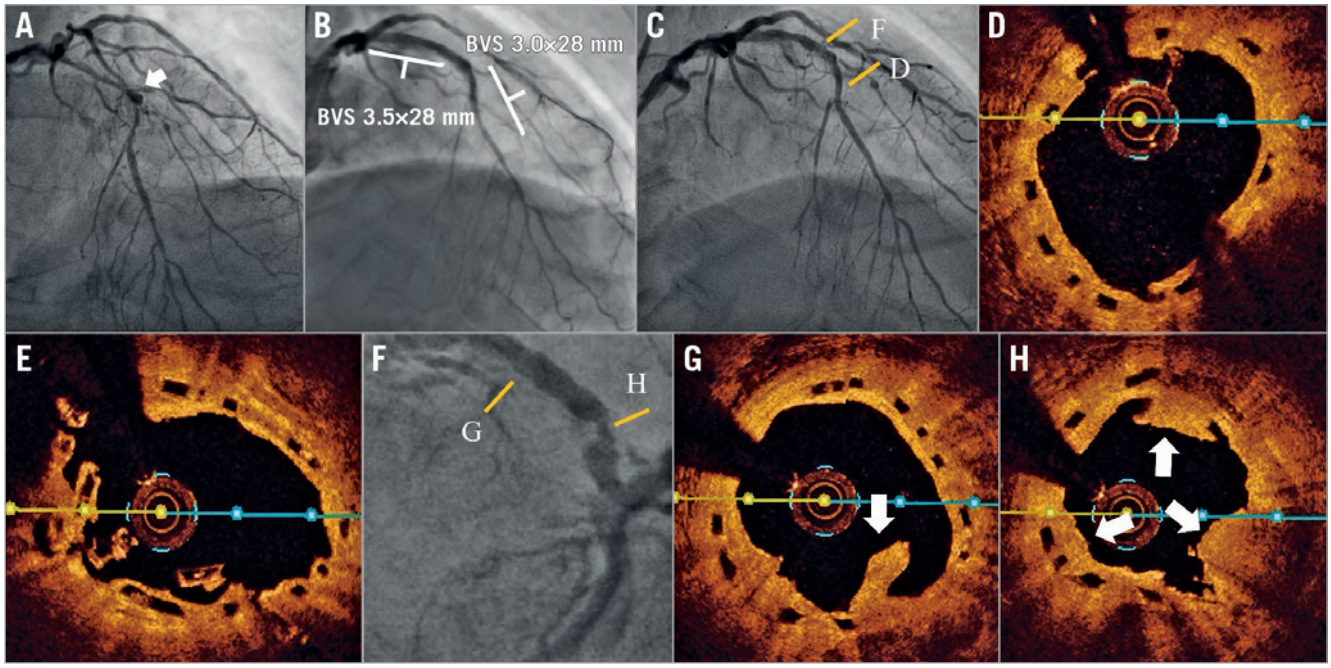

A 68-year-old man experienced unstable angina, and had type 2 diabetes mellitus and hyperlipidaemia. The left anterior descending artery (LAD) showed long stenotic lesions with calcification, and one aneurysm at the mid segment **(Panel A)**. After intravascular ultrasound for pre-sizing, predilatation was performed with a high-pressure balloon. One 3.0×28 mm bioresorbable vascular scaffold (BVS; Abbott Vascular, Santa Clara, CA, USA) was deployed at the mid LAD at 16 atm, and another 3.5×28 mm BVS was deployed at the proximal LAD at 16 atm **(Panel B)**. After adequate post-dilatation, optical coherence tomography (OCT) showed a good apposition. One year later, the patient experienced typical angina symptoms; follow-up angiography and OCT imaging showed no stenosis at the mid LAD **(Panel C, Panel D)**. OCT imaging did however show poor absorption at the overlapping site **(Panel E)**, one severe in-stent restenosis (ISR) with haziness at the proximal LAD **(Panel F)**, and proliferated neointima with atherosclerotic plaque rupture and some thrombi in the previous BVS of the proximal LAD **(Panel G, Panel H)**. One 3.5×30 mm SeQuent Please® drug-coated balloon (DCB; B. Braun Melsungen AG, Melsungen, Germany) was inserted and inflated. Dual antiplatelet therapy was prolonged for two years and the patient did not present with any angina symptoms. A thallium perfusion scan showed a negative ischaemic finding. The BVS has been proved to be feasible for complex and calcified lesions. However, BVS absorption and endothelial growth may differ in different individuals. The use of a DCB for BVS thrombosis with proliferated neointima and atherosclerotic plaque has not been reported previously. We have reported here a case using DCB treatment for in-scaffold neointima proliferation.

Conflict of interest statement

The authors have no conflicts of interest to declare.

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LV systolic dysfunction stands to gain the most post transcatheter aortic valve implantation (TAVI)

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KEYWORDS

- aortic stenosis
- TAVI
- LV recovery

Abstract

Aims: We aimed to evaluate the extent of left ventricular (LV) recovery post transcatheter aortic valve implantation (TAVI) and its clinical predictors.

Methods and results: This was a retrospective study on patients treated with TAVI from August 2008 to September 2017. Patients were sub-classified according to their baseline LV function as normal, mildly impaired, moderately impaired or severely impaired. Echo pre TAVI and early post TAVI were compared to assess LV function change. Predictors of LV function change were sought from univariate and multivariate ordinal logistic regression analyses. There were 662 patients included in this study. Nearly half of them, 323 patients (49%), had abnormal LV systolic dysfunction of various degrees. Of these, 193 (60%) showed LV function improvement post TAVI. Based on their pre-TAVI LV function, 55% of the mild LV dysfunction cohort, 62% of the moderate LV dysfunction cohort and 74% of the severe LV dysfunction cohort had LV function improvement post TAVI. Multivariate logistic regression analysis revealed baseline LV dysfunction as the only significant predictor of LV function improvement post TAVI.

Conclusions: The majority of patients with baseline LV dysfunction had LV improvement post TAVI, more so those patients with severe LV dysfunction.

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Abbreviations

AS aortic stenosis
EF ejection fraction
LV left ventricular
LVF left ventricular failure
LVFn left ventricular function
NYHA New York Heart Association
SAVR surgical aortic valve replacement
TAVI transcatheter aortic valve implantation

Introduction

Transcatheter aortic valve implantation (TAVI) is becoming the treatment of choice for intermediate- and high-risk patients with severe aortic stenosis (AS). TAVI is non-inferior to surgical aortic valve replacement (SAVR) in terms of perioperative mortality and stroke rate; it is associated with a lower incidence of acute kidney injury, atrial fibrillation and shorter recovery time, albeit at the expense of increased pacemaker implantation rate and vascular complications[1,2]. Among patients with severe AS undergoing TAVI, about one third of them have left ventricular systolic failure (LVF) with ejection fraction (EF) lower than 50%[3]. The prognosis of patients with reduced left ventricular (LV) function is worse than that of those with preserved LV function, whether they are treated with TAVI or SAVR[4-6]. Concerns about its prognosis and uncertainty about the possibility of LV recovery may lead to reluctance of TAVI operators to accept severe AS patients with poor LV function for TAVI. Our study aimed to assess the extent and time course of LV function recovery post TAVI. We also aimed to identify factors that might predict the reversibility of LVF dysfunction in the setting of severe AS after TAVI.

Methods

This was a retrospective study carried out at a tertiary cardiac centre with an established structural heart intervention programme. All cases of TAVI performed between August 2008 and September 2017 were included in the study. The inclusion criterion was TAVI in the defined period. Exclusion criteria were absence of echo pre TAVI or within a week post TAVI, and cases that were lost to follow-up.

Patient demographics, cardiovascular risk factors, comorbidities, and the findings of pre-TAVI and post-TAVI echo within a week were used for analysis and comparison. LVF was defined as mild if the EF was 45-54% (grade II), moderate if the EF was 30-44% (grade III) and severe if the EF was <30% (grade IV). The outcome of interest was improvement of LV function by at least one grade. Clinical variables and imaging findings were summarised in mean and standard deviation for continuous variables and count and proportion for categorical variables for the whole cohort and subgroups of LV function **(Table 1)**. The differences in these clinical

Table 1. Patients' clinical, echo and CT variables versus their baseline LV function (LVFn).

Variables	Total (n=662)	LVFn-I (n=339)	LVFn-II (n=170)	LVFn-III (n=104)	LVFn-IV (n=49)	*p*-value
Age, mean (SD), years	80.34 (7.31)	80.79 (7.33)	80.12 (6.81)	79.89 (8.27)	78.88 (6.57)	0.283
Gender, M/F	295/367 (45%/55%)	127/212 (37%/63%)	84/86 (49%/51%)	56/48 (54%/46%)	28/21 (57%/43%)	0.002
Mean body mass index, kg/m² (SD)	26.28 (4.62)	26.44 (4.60)	26.59 (4.90)	25.30 (4.39)	26.22 (4.01)	0.121
AMI (yes/no)	126/536 (19%/81%)	37/302 (11%/89%)	41/129 (24%/76%)	28/76 (27%/73%)	20/29 (41%/59%)	<0.001
COPD (yes/no)	143/519 (22%/78%)	77/262 (23%/77%)	34/136 (20%/80%)	26/78 (25%/75%)	6/43 (12%/88%)	0.29
TIA (yes/no)	102/560	60/279	22/148	14/90	6/43	0.417
Stroke (ischaemic/ bleeding/no)	78/7/577 (12%/11%/87%)	44/5/290 (13%/1%/86%)	16/0/154 (9%/0%/91%)	14/2/88 (13%/2%/85%)	4/0/45 (8%/0%/92%)	N/A*
Diabetes (yes/no)	202/460 (31%/69%)	100/239 (29%/71%)	48/122 (28%/72%)	30/74 (29%/71%)	24/25 (49%/51%)	0.035
Hypertension (yes/no)	409/253 (62%/38%)	221/118 (65%/35%)	98/72 (57%/43%)	65/39 (63%/37%)	25/24 (51%/49%)	0.149
Smoking (current/ex/no/ missing)	182/58/421/1 (27%/9%/64%/0%)	95/26/218/0 (28%/8%/64%/0%)	52/17/101/0 (31%/10%/59%/0%)	23/12/68/1 (22%/12%/65%/1%)	12/3/34/0 (24%/6%/69%/0%)	0.575
Atrial fibrillation (paroxysmal/chronic/no)	145/70/447 (22%/11%/67%)	65/34/240 (19%/10%/71%)	42/19/109 (25%/11%/64%)	28/9/67 (27%/9%/64%)	10/8/31 (21%/16%/63%)	0.405
Mean GFR, ml/min (SD)	57.48 (21.92)	59.88 (21.84)	57.49 (22.02)	55.42 (20.18)	45.27 (21.79)	<0.001
Dialysis (No/HD/PD)	645/14/3 (97%/2%/1%)	334/4/1 (99%/1%/0%)	163/6/1 (96%/3%/1%)	101/3/0 (97%/3%/0%)	47/1/1 (96%/2%/2%)	N/A*
NYHA (I/II/III/IV/missing)	95/191/326/32/18 (14%/29%/49%/5%/3%)	53/110/155/10/11 (16%/32%/46%/3%/3%)	30/47/81/9/3 (18%/27%/48%/5%/2%)	7/21/63/10/3 (7%/20%/61%/9%/3%)	5/13/27/3/1 (10%/27%/55%/6%/2%)	0.024
Frailty (yes/no)	267/395 (40%/60%)	132/207 (39%/61%)	77/93 (45%/55%)	37/67 (36%/64%)	21/28 (43%/57%)	0.373
Mean logistic EuroSCORE (SD)	15.67 (10.03)	13.48 (8.56)	15.16 (10.58)	20.13 (10.80)	23.15 (9.49)	<0.001
Mean pre-TAVI echo AV gradient, mmHg (SD)	40.76 (18.62)	43.73 (18.70)	40.14 (18.61)	34.31 (12.87)	35.76 (23.16)	<0.001
Mean pre-TAVI CT AV annular area (mm²)	554.60 (187.96)	533.5 (193.7)	570.4 (180.3)	560.1 (157.8)	634.0 (209.6)	0.002

LVFn indicates LV function on echo. P-values were obtained from ANOVA one-way analysis for continuous variables and Pearson's chi-square correlation for discrete variables. N/A* – there were subcategories with cell number <1; chi-square approximation would be invalid. AMI: acute myocardial infarction; AV: aortic valve; GFR: glomerular filtration rate; HD: haemodialysis; NYHA: New York Heart Association; PD: peritoneal dialysis; SD: standard deviation; TIA: transient ischaemic attack

variables among the subgroups of LV function were analysed using one-way analysis of variance (one-way ANOVA) for continuous variables and the chi-square test for discrete variables **(Table 1)**. To identify predictors of LV function change post TAVI, univariate ordinal logistic regression analysis was performed first by setting the order of outcomes as "LV improvement", "no change" and "LV deterioration". Variables with a p-value <0.05 were grouped together for subsequent multivariate ordinal logistic regression analysis to identify independent predictors of LV function change.

In the subgroup analysis of patients with severe LVF (grade IV), descriptive analysis was performed in the same manner as described above. Univariate binary logistic regression analysis was performed first to identify predictors of LV improvement in this subgroup. Only those variables with a p-value <0.05 from the univariate analysis were subsequently used in multivariate analysis to identify independent predictors of LV function improvement in this subgroup. All the statistics performed in this study were conducted using the statistics software Minitab® 18 (Minitab LLC, State College, PA, USA).

The patients were followed up by clinic visit at intervals of one month, six months, twelve months and yearly at our centre or at the referring hospital. The study complied with the Declaration of Helsinki and ethics committee approval from our institution was waived given the non-experimental design of the study. All data collected were anonymised before analysis.

Results

In total, 678 consecutive patients were treated with TAVI in the predefined period. Of these, 662 patients with complete data were included in the current analysis **(Table 1)**. Among those not included in the analysis were 11 in-hospital deaths due to complications of bleeding (n=6), tamponade (n=2), stroke (n=2), and pneumonia (n=1); four of these patients had normal grade-I LV function (LVFn) pre TAVI, three patients had grade-II LVFn, three patients had grade-III LVFn and one patient had grade-IV LVFn. Hence, all the in-patient deaths were not statistically skewed towards the cohort with severe LV dysfunction.

The characteristics of the 662 patients are summarised in **Table 1** according to their baseline LVFn. Overall, those patients with poorer LVFn were more likely to be male, diabetic, renally impaired, symptomatic with higher NYHA class, and with a smaller aortic valve gradient due to reduced LV contractility **(Table 1)**.

LV FUNCTION CHANGE POST TAVI

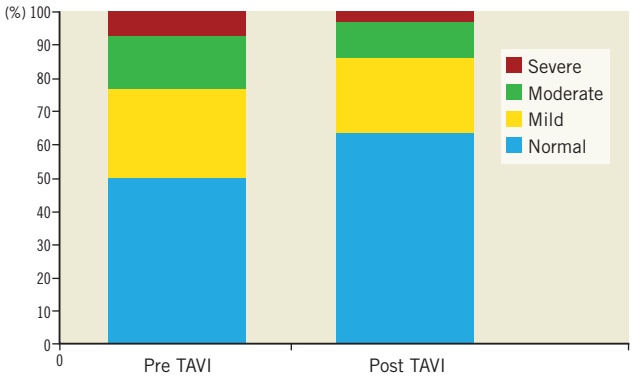
Of the 662 patients included in the analysis, 339 patients (51%) had normal baseline LVFn whereas 323 patients (49%) had abnormal LVFn of various degrees **(Table 2)**. Among 323 patients with abnormal LVFn at baseline, 193 patients (60%) had LVFn improvement post TAVI. Of patients with mild LV dysfunction (grade-II) at baseline, 55% (93/170) had LVFn improvement post TAVI. Of those with moderate LV dysfunction (grade-III), 61% (64/104) had LVFn improvement post TAVI: 42% (44/104) improved by one grade and 19% (20/104) improved by two grades. Of those with severe LV dysfunction (grade-IV), 73% (36/49) improved in their LVFn post TAVI: 55% (27/49) had LV improvement by one grade, 10% (5/49) had LVFn improvement by two grades and 8% (4/49) had improvement by three grades. Interestingly, of those with normal LVFn at baseline, 11% had deteriorated LVFn **(Table 2)**.

Table 2. Baseline LV function versus change of LV function post TAVI; chi-square p<0.001.

	Worse	Same	Improved	Total
Baseline normal LVFn	38 (11.2%)	301 (88.8%)	0 (0%)	339
Baseline mild LVF (LVFn-II)	10 (5.9%)	67 (39.4%)	93 (54.7%)	170
Baseline moderate LVF (LVFn-III)	5 (4.8%)	35 (33.7%)	64 (61.5%)	104
Baseline severe LVF (LVFn-IV)	0 (0%)	13 (26.5%)	36 (73.5%)	49

LVFn: LV function on echo

For the whole study cohort (662 patients), 193 patients (29%) had an improved LVFn early post TAVI; 416 patients (63%) had no change in their LVFn while 53 patients (8%) had a deteriorated LVFn **(Figure 1)**.



LV dysfunction	Normal	Mild	Moderate	Severe
Pre TAVI	51%	26%	16%	7%
Post TAVI	63%	23%	11%	3%

Figure 1. *Distribution of LV function pre and post TAVI.*

The improvement of LVFn occurred shortly after valve implantation and appeared to be persistent with time as the fraction of LVFn in each LVFn subgroup at baseline remained similar up to 12 months after the procedure **(Figure 2)**.

PREDICTORS FOR LV FUNCTION CHANGE IN THE WHOLE COHORT

Based on the univariate ordinal logistic regression analysis, only logistic EuroSCORE, pre-TAVI mitral regurgitation (graded), pre-TAVI right ventricular systolic pressure (continuous variable) and LV dysfunction (graded) and post-TAVI pacemaker implantation were identified as significant predictors of LVFn change. Further multivariate analysis of these predictors resulted

in identification of LV dysfunction as the only independent clinical predictor of LV change **(Table 3)**.

SEVERE LV DYSFUNCTION SUBGROUP

In the subgroup analysis of patients with severe LV dysfunction pre TAVI, only gender and frailty were identified as significant predictors of LV change based on univariate binary logistic regression analysis **(Table 4)**; female gender was a favourable variable for LV improvement whereas increased frailty was less likely to be associated with improved LVFn post TAVI **(Table 4)**. Both variables remained significant predictors despite correcting for each other on further multivariate analysis **(Table 4)**.

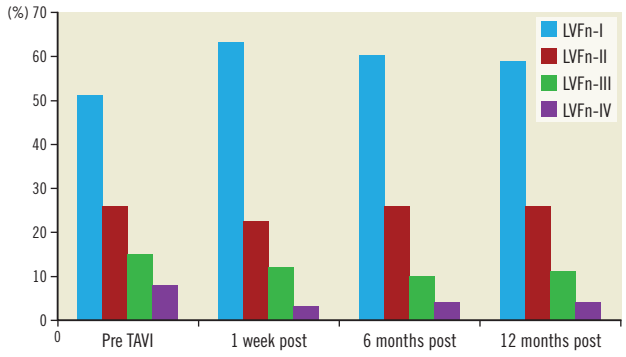
FOLLOW-UP

Patients were followed up over a median period of 962 days. Kaplan-Meier survival plots based on pre-TAVI echo LVFn are

Table 3. Univariate and multivariate ordinal logistic regression analysis for LV improvement, no change or deterioration post TAVI.

Predictor	Coeff.	SE coeff.	z	*p*-value	Odds ratio	95% CI (lower)	95% CI (upper)
Univariate analysis							
Age	0.011	0.011	1.02	0.308	1.01	0.99	1.03
Sex (F)	0.115	0.159	0.72	0.47	1.12	0.82	1.53
BMI	–0.007	0.017	–0.04	0.968	1.00	0.97	1.03
Pre-CAD-1	–0.127	0.211	–0.6	0.547	0.88	0.58	1.33
Pre-CAD-2	0.141	0.222	0.64	0.525	1.15	0.75	1.78
Pre-CAD-3	–0.271	0.250	–1.08	0.279	0.76	0.47	1.25
Previous MI	0.229	0.199	1.15	0.251	1.26	0.85	1.86
Hypertension	–0.095	0.162	–0.59	0.558	0.91	0.66	1.25
Diabetes mellitus	0.038	0.171	0.22	0.824	1.04	0.74	1.45
Smoking, past	–0.197	0.181	–1.09	0.277	0.82	0.58	1.17
Smoking, current	–0.090	0.285	–0.32	0.751	0.91	0.52	1.60
AF, paroxysmal	0.266	0.193	1.38	0.167	1.31	0.89	1.90
AF, chronic	0.127	0.261	0.49	0.626	1.14	0.68	1.89
Frailty	0.102	0.161	0.63	0.527	1.11	0.81	1.52
Logistic EuroSCORE	0.038	0.008	4.66	<0.001	1.04	1.02	1.05
GFR	–0.006	0.004	–1.71	0.087	0.99	0.99	1.00
Pre-AV annular area	<0.001	<0.001	0.03	0.975	1.00	1.00	1.00
Pre-AV mean gradient	–0.007	0.004	–1.56	0.118	0.99	0.98	1.00
Pre-TAPSE	–0.086	0.0567	–1.52	0.128	0.92	0.82	1.03
Pre-MR	0.524	0.223	2.35	0.019	1.69	1.09	2.62
Pre-RVSP	0.027	0.010	2.84	0.005	1.03	1.01	1.05
Pre-LVFn-II	3.315	0.307	10.81	<0.001	27.52	15.09	50.20
Pre-LVFn-III	3.624	0.333	10.88	<0.001	37.50	19.52	72.04
Pre-LVFn-IV	4.250	0.420	10.12	<0.001	70.10	30.77	159.69
Post-PPM	0.534	0.265	2.02	0.004	1.71	1.02	2.87
Post-PVR	0.163	0.143	1.14	0.254	1.18	0.89	1.56
Multivariate analysis							
Const (1)	–3.591	0.653	–5.50	<0.001	–	–	–
Const (2)	0.959	0.570	1.68	0.093	–	–	–
Logistic EuroSCORE	–0.009	0.014	–0.65	0.515	0.99	0.97	1.02
Pre-MR	–0.094	0.398	–0.24	0.813	0.91	0.42	1.99
Pre-RVSP	0.021	0.011	1.85	0.064	1.02	1.00	1.04
Pre-LVFn-II	2.972	0.421	7.06	<0.001	19.54	8.56	44.61
Pre-LVFn-III	3.299	0.451	7.31	<0.001	27.08	11.18	65.59
Pre-LVFn-IV	4.199	0.600	7.0	<0.001	66.62	20.55	216.05
Post-PPM	0.187	0.423	0.44	0.659	1.21	0.53	2.76

AF: atrial fibrillation; BMI: body mass index; GFR: glomerular filtration rate; MI: myocardial infarction; n: number of vessels with disease; Post-PPM: post-TAVI permanent pacemaker implantation; Post-PVR: post-TAVI paravalvular leak (graded); Pre-AV: pre-TAVI aortic valve; Pre-CAD-n: pre-TAVI coronary artery disease; Pre-LVFn: pre-TAVI LV function grade; Pre-MR: pre-TAVI mitral regurgitation; Pre-TAPSE: pre-TAVI tricuspid annular plane systolic excursion; Pre-RVSP: pre-TAVI right ventricular systolic pressure



	Pre TAVI	1 week post	6 months post	12 months post
LVFn-I	339	418	327	283
LVFn-II	170	148	139	126
LVFn-III	102	77	56	53
LVFn-IV	51	19	20	20
Total N	662	662	542	482

Figure 2. *Fractions of LV function class (percentage) pre-TAVI, within a week, six months and twelve months post TAVI remain the same.*

shown in **Figure 3**. Kaplan-Meier survival plots for subsets of severe LV dysfunction (with or without LV improvement) are shown in **Figure 4**. Statistics of the survival plots indicate that the differences among the subgroups of pre-TAVI LVFn were not significant (log-rank p-value=0.053 and Wilcoxon test p-value=0.223). Nonetheless, there was a trend showing that in the long term the separation among the curves became wider; those with a better baseline LVFn might have a better survival probability. Similarly, in the cohort of severe LV failure (LVFn class IV), there was no significant difference in survival probability between those with LV improvement versus those without LV improvement post TAVI (log-rank test p-value=0.414 and Wilcoxon test p-value=0.509).

Discussion

In our large cohort of patients undergoing TAVI, almost half of them had LV systolic dysfunction of various degrees. Our study showed that more than half of these patients with LV dysfunction had a prompt improvement in their LV systolic function post TAVI. Interestingly, a larger proportion of patients with severe LV systolic dysfunction showed an improvement in LVFn after TAVI in comparison with the subgroups of patients with milder LV systolic dysfunction at baseline. Our findings concur with the findings of a study by Elhmidi et al in which, of patients with severe LV dysfunction, 15% improved to normal EF and 66% improved to mild-moderate dysfunction post TAVI[7].

The LV improvement present at one week after TAVI appeared to be sustained during subsequent follow-up. Sustained LVFn improvement is potentially associated with a better survival rate in comparison to those with no LVFn improvement. In a study using LV global longitudinal strain (GLS) as a marker of LVFn

Table 4. Univariate and multivariate binary logistic regression analysis for LV improvement post TAVI in severe LV dysfunction subgroup.

Predictor	Coeff.	SE coeff.	Chi-square	*p*-value	Odds ratio	95% CI (lower)	95% CI (upper)
Univariate analysis							
Age	–0.038	0.053	0.55	0.459	0.96	0.87	1.07
Sex (F)	1.816	0.838	5.97	0.015	6.15	1.19	31.77
BMI	–0.048	0.079	0.36	0.549	0.95	0.82	1.11
Pre-CAD, yes vs no	0.416	0.656	0.40	0.527	1.52	0.42	5.48
Previous MI	–0.298	0.653	0.21	0.649	0.74	0.21	2.67
Hypertension	–0.058	0.661	0.79	0.374	0.56	0.15	2.04
Diabetes mellitus	–0.693	0.661	1.12	0.289	0.50	0.14	1.83
Smoking, ex or current	–0.010	0.701	0.00	0.989	0.99	0.25	3.91
AF, PAF/CAF	0.868	0.740	1.49	0.222	2.38	0.56	10.15
Frailty	–2.025	0.751	8.56	0.003	0.132	0.03	0.58
Log. EuroSCORE	0.055	0.039	2.21	0.137	1.06	0.98	1.14
GFR	0.004	0.015	0.08	0.775	1.00	0.97	1.04
Pre-mean gradient	–0.002	0.0138	0.03	0.864	0.998	0.971	1.025
Pre-TAPSE	–0.304	0.319	2.84	0.092	0.74	0.39	1.38
Pre-RVSP	0.054	0.042	1.99	0.159	1.05	0.97	1.14
Post-PPM	0.095	0.889	0.01	0.914	1.100	0.193	6.286
Post-PVR	0.034	0.523	0.00	0.948	1.035	0.371	2.884
Multivariate analysis							
Sex (F)	1.962	0.907	35.82	0.016	7.114	1.202	42.108
Frailty	-2.145	0.806	8.42	0.004	0.117	0.024	0.569

AF: atrial fibrillation - paroxysmal (PAF) or chronic (CAF); BMI: body mass index; GFR: glomerular filtration rate; Log. EuroSCORE: logistic EuroSCORE; MI: myocardial infarction; Post-PPM: post-TAVI permanent pacemaker implantation; Post-PVR: post-TAVI paravalvular leak (graded); Pre-mean gradient: pre-TAVI mean aortic valve gradient on echo; Pre-TAPSE: pre-TAVI tricuspid annular plane systolic excursion; Pre-RVSP: pre-TAVI right ventricular systolic pressure

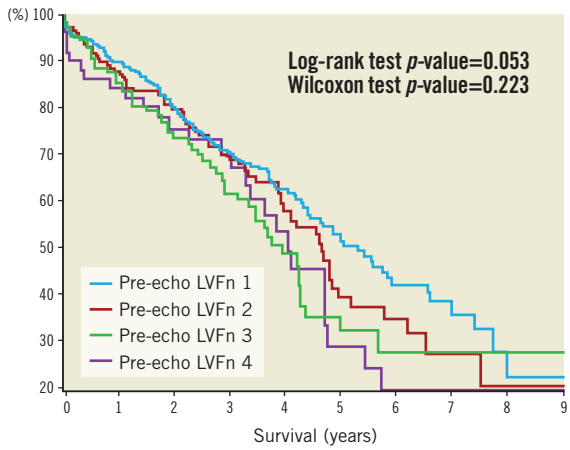


Figure 3. *Kaplan-Meier survival plot as per baseline LV function.*

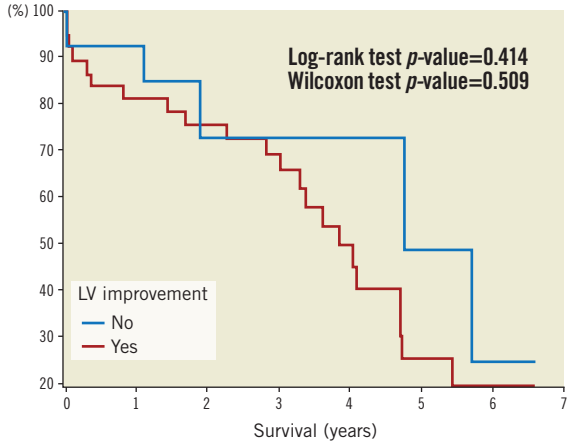


Figure 4. *Kaplan-Meier survival plot in the cohort of severe LV failure.*

improvement, Sato et al demonstrated that such an improvement of LV was sustained even during follow-up over five years. Patients with improved GLS were less likely to die in comparison with those who failed to demonstrate improvement in GLS post TAVI[8]. Similarly, in the PARTNER-1 trial, the mortality rate of patients with no LVFn recovery after 30 days was twice as high as the mortality rate of those with LV recovery during two-year follow-up[3].

Identifying those likely to have LV improvement post TAVI among the patients with baseline LV systolic dysfunction would be an important stratification process, particularly when the resources for TAVI are limited. In our attempt to do so, we could only identify baseline LV systolic dysfunction as the only independent predictor. Elhmidi et al also found that baseline LV systolic dysfunction was the strongest predictor of LV recovery post TAVI[7]. Contrary to the findings of Freixa et al, our study did not show that coronary artery disease and previous myocardial infarction were significant predictors of failure of LV improvement[9].

In the subgroup of patients with severe baseline LV systolic dysfunction, only female gender was identified as a significant predictor of LV function improvement post TAVI, whereas the presence of frailty predicted a low likelihood of LV recovery. Interestingly, in a study comparing TAVR versus SAVR in terms of LV recovery post procedure, Clavel et al also reported that one of the independent predictors of LV recovery was female gender[10]. The reason for this finding remains to be elucidated.

Limitations

A major limitation of our study is the lack of dobutamine stress echo data. Several studies have shown that dobutamine stress echo can predict LV recovery post aortic valve replacement[5,6]. SAVR patients with no contractile reserve appear to have a much higher operative mortality rate in comparison to patients with contractile reserve, 32% vs. 6%, respectively. In a small study looking at 49 patients with a low gradient type of severe AS, Hayek et al reported a higher mortality in the cohort with no contractile reserve versus those with contractile reserve during in-hospital stay, at 30 days, one year and two years post TAVI[11]. On the other hand, in the recently published TOPAS-TAVI registry, absence of contractile reserve on dobutamine stress echo did not negate the possibility of LV function improvement post TAVI in those with low-flow low-gradient type of severe aortic stenosis (LFLG-AS); it also failed to predict the mortality outcome of the LFLG-AS patients post TAVI. Hence, the value of pre-TAVI dobutamine stress echo is still questionable[12].

As this was a retrospective observational study it has other limitations including missing data, observer and patient selection bias. Not all patients with poor LV systolic function were included in this study due to significant comorbidities and frailty. A randomised controlled study on patients with severe LV dysfunction would help to address these issues.

Conclusions

In our large cohort of patients with severe AS and LV systolic dysfunction, nearly two thirds of the patients had improvement in LV function post TAVI. LV function improvement occurred in a greater proportion of patients with more severe LV dysfunction. Patients should not be excluded from TAVI treatment based on the extent of pre-TAVI LV dysfunction alone.

Impact on daily practice

Patients with severe aortic stenosis and severe LV systolic dysfunction potentially benefit the most from TAVI. They should not be discriminated from receiving TAVI treatment based on their baseline LV dysfunction.

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Conflict of interest statement

The authors have no conflicts of interest to declare.

References

1. Reardon MJ, Van Mieghem NM, Popma JJ, Kleiman NS, Sondergaard L, Mumtaz M, Adams DH, Deeb GM, Maini B, Gada H, Chetcuti S, Gleason T, Heiser J, Lange R, Merhi W, Oh JK, Olsen PS, Piazza N, Williams M, Windecker S, Yakubov SJ, Grube E, Makkar R, Lee JS, Conte J, Vang E, Nguyen H, Chang Y, Mugglin AS, Serruys PW, Kappetein AP; SURTAVI Investigators. Surgical or Transcatheter Aortic-Valve Replacement in Intermediate-Risk Patients. *N Engl J Med.* 2017;376:1321-31.

2. Leon MB, Smith CR, Mack MJ, Makkar RR, Svensson LG, Kodali SK, Thourani VH, Tuzcu EM, Miller DC, Herrmann HC, Doshi D, Cohen DJ, Pichard AD, Kapadia S, Dewey T, Babaliaros V, Szeto WY, Williams MR, Kereiakes D, Zajarias A, Greason KL, Whisenant BK, Hodson RW, Moses JW, Trento A, Brown DL, Fearon WF, Pibarot P, Hahn RT, Jaber WA, Anderson WN, Alu MC, Webb JG; PARTNER 2 Investigators. Transcatheter or Surgical Aortic-Valve Replacement in Intermediate-Risk Patients. *N Engl J Med.* 2016;374:1609-20.

3. Elmariah S, Palacios IF, McAndrew T, Hueter I, Inglessis I, Baker JN, Kodali S, Leon MB, Svensson L, Pibarot P, Douglas PS, Fearon WF, Kirtane AJ, Maniar HS, Passeri JJ; PARTNER Investigators. Outcomes of transcatheter and surgical aortic valve replacement in high-risk patients with aortic stenosis and left ventricular dysfunction: results from the Placement of Aortic Transcatheter Valves (PARTNER) trial (cohort A). *Circ Cardiovasc Interv.* 2013;6:604-14.

4. Sannino A, Gargiulo G, Schiattarella GG, Brevetti L, Perrino C, Stabile E, Losi MA, Toscano E, Giugliano G, Scudiero F, Chiacchio E, Trimarco B, Esposito G. Increased mortality after transcatheter aortic valve implantation (TAVI) in patients with severe aortic stenosis and low ejection fraction: a meta-analysis of 6898 patients. *Int J Cardiol.* 2014;176:32-9.

5. Monin JL, Quéré JP, Monchi M, Petit H, Baleynaud S, Chauvel C, Pop C, Ohlmann P, Lelguen C, Dehant P, Tribouilloy C, Guéret P. Low-gradient aortic stenosis: operative risk stratification and predictors for long-term outcome: a multicenter study using dobutamine stress hemodynamics. *Circulation.* 2003;108:319-24.

6. Quere JP, Monin JL, Levy F, Petit H, Baleynaud S, Chauvel C, Pop C, Ohlmann P, Lelguen C, Dehant P, Gueret P, Tribouilloy C. Influence of preoperative left ventricular contractile reserve on postoperative ejection fraction in low-gradient aortic stenosis. *Circulation.* 2006;113:1738-44.

7. Elhmidi Y, Bleiziffer S, Deutsch MA, Krane M, Mazzitelli D, Lange R, Piazza N. Transcatheter aortic valve implantation in patients with LV dysfunction: impact on mortality and predictors of LV function recovery. *J Invasive Cardiol.* 2014;26:132-8.

8. Sato K, Kumar A, Jones BM, Mick SL, Krishnaswamy A, Grimm RA, Desai MY, Griffin BP, Rodriguez LL, Kapadia SR, Obuchowski NA, Popovic ZB. Reversibility of Cardiac Function Predicts Outcome After Transcatheter Aortic Valve Replacement in Patients With Severe Aortic Stenosis. *J Am Heart Assoc.* 2017 Jul 11;6(7).

9. Freixa X, Chan J, Bonan R, Ibrahim R, Lamarche Y, Demers P, Basmadjian A, Ibrahim R, Cartier R, Asgar AW. Impact of coronary artery disease on left ventricular ejection fraction recovery following transcatheter aortic valve implantation. *Catheter Cardiovasc Interv.* 2015;85:450-8.

10. Clavel MA, Webb JG, Rodés-Cabau J, Masson JB, Dumont E, De Larochellière R, Doyle D, Bergeron S, Baumgartner H, Burwash IG, Dumesnil JG, Mundigler G, Moss R, Kempny A, Bagur R, Bergler-Klein J, Gurvitch R, Mathieu P, Pibarot P. Comparison between transcatheter and surgical prosthetic valve implantation in patients with severe aortic stenosis and reduced left ventricular ejection fraction. *Circulation.* 2010;122:1928-36.

11. Hayek S, Pibarot P, Harzand A, Cheng JW, Gay H, Chrysohoou C, Ribeiro H, Rodes-Cabau J, Babaliaros V, Lerakis S. Dobutamine stress echocardiography for risk stratification of patients with low-gradient severe aortic stenosis undergoing TAVR. *JACC Cardiovasc Imaging.* 2015;8:380-2.

12. Ribeiro HB, Lerakis S, Gilard M, Cavalcante JL, Makkar R, Herrmann HC, Windecker S, Enriquez-Sarano M, Cheema AN, Nombela-Franco L, Amat-Santos I, Munoz-Garcia AJ, Garcia Del Blanco B, Zajarias A, Lisko JC, Hayek S, Babaliaros V, Le Ven F, Gleason TG, Chakravarty T, Szeto WY, Clavel MA, de Agustin A, Serra V, Schindler JT, Dahou A, Puri R, Pelletier-Beaumont E, Côté M, Pibarot P, Rodés-Cabau J. Transcatheter Aortic Valve Replacement in Patients With Low-Flow, Low-Gradient Aortic Stenosis: The TOPAS-TAVI Registry. *J Am Coll Cardiol.* 2018;71:1297-308.

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TAVR facilitated by high-pressure balloon post-dilatation to fracture the ring of the small dysfunctional aortic Mosaic bioprosthesis

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KEYWORDS

- aortic stenosis
- balloon valvuloplasty
- femoral
- TAVI
- valve-in-valve

Abstract

Treatment of a failing aortic bioprosthesis by transcatheter valve-in-valve (ViV) therapy has become an alternative to redo surgery. However, the ViV technique may be less effective in small surgical valves because of patient/prosthesis mismatch (PPM). Here we will discuss the bioprosthetic valve fracture/remodelling (BVF) procedure and the most important issues regarding this promising new technique.

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Abbreviations

AVA	aortic valve area
AV-Vmax	aortic valve peak velocity
BPV	bioprosthetic valve
BVF	bioprosthetic valve fracture
CABG	coronary artery bypass grafting
CAF	chronic atrial fibrillation
COPD	chronic obstructive pulmonary disease
GA	general anaesthesia
HOR	hybrid operating room
ICU	intensive care unit
ID	inner diameter
MDSCT	multidetector spiral computed tomography
MG	mean gradient
MR	mitral regurgitation
LAD	left anterior descending artery
LVEF	left ventricular ejection fraction
OD	outer diameter
OM	obtuse marginal
PG	peak gradient
PPM	patient/prosthesis mismatch
sAVR	surgical aortic valve replacement
SOV	sinus of Valsalva
sPAP	systolic pulmonary artery pressure
TAVR	transcatheter aortic valve replacement
TEE	transoesophageal echocardiography
TF	transfemoral
ViV	valve-in-valve

Introduction

Treatment of a failing bioprosthesis by transcatheter valve-in-valve (ViV) therapy has become an alternative to redo surgery. However, ViV treatment is problematic with small (≤21 mm in diameter) surgical bioprostheses because of a further reduction in the effective valve orifice[1]. One way to overcome this challenge may be to fracture the ring of the surgical valve by high-pressure balloon dilatation after implanting a transcatheter aortic valve[2].

Methods

An 84-year-old Caucasian male was referred to our Heart Team due to severe symptomatic bioprosthetic aortic valve deterioration. Symptoms included shortness of breath and fatigue, and the patient was in New York Heart Association (NYHA) functional Class III heart failure. His past medical history included: coronary artery bypass grafting (CABG) (x3, 2012) combined with surgical aortic valve replacement (sAVR) with a biological stented Mosaic® A19 valve (Medtronic, Minneapolis, MN, USA). Baseline echocardiography post sAVR revealed a peak gradient (PG) of 36 mmHg. Comorbidities included: chronic atrial fibrillation (CAF) with a CHA_2DS_2-VASc score of 4 on anticoagulation therapy, insulin-dependent diabetes mellitus, arterial hypertension, dyslipidaemia and mild chronic obstructive pulmonary disease (COPD). The last echocardiography (16/05/2018) showed a severely degenerated aortic bioprosthesis with an estimated aortic valve area (AVA) of 0.6 cm^2, aortic valve peak velocity (AV-Vmax) of 4.3 m/s, mean gradient (MG) of 50 mmHg and PG of 74 mmHg with preserved left ventricular ejection fraction (LVEF) (65%). Moreover, he had moderate eccentric mitral regurgitation (MR) and severe pulmonary hypertension with a systolic pulmonary artery pressure (sPAP) of 55 mmHg. The recent coronary angiography (14/05/2018) showed two-vessel disease with patent grafts to the left anterior descending (LAD) and obtuse marginal (OM) branches (OM1 and OM2). In electrocardiogram (ECG)-gated cardiac multidetector spiral computed tomography (MDSCT) with contrast agent (19/4/2018), the inner diameter (ID) of the aortic bioprosthesis was 14.5 mm and the outer diameter (OD) was 18 mm. Moreover, the diameter of the sinus of Valsalva (SOV) was 30x30x26 mm and the coronary height was more than 1 cm. The femoroiliac system was suitable for transfemoral (TF) approach. The calculated logistic EuroSCORE was 25.10%, the Society of Thoracic Surgeons (STS) mortality score was 9% and the STS morbidity/mortality score was 35%. Based on the above-mentioned medical history and the high surgical risk, our Heart Team decided to proceed with TF valve-in-valve transcatheter aortic valve replacement (ViV-TAVR) using the bioprosthetic valve fracture (BVF) technique. The procedure was performed in our hybrid operating room (HOR) with the patient placed in supine position, under general anaesthetic (GA) and transoesophageal echocardiography (TEE) guidance. Antibiotics were administered intravenously before the procedure and intravenous heparin 50 U/kg was administered during the procedure targeting an activated clotting time of 250 seconds. Access to the left common femoral artery and vein was obtained. Access to the contralateral right femoral artery was obtained and the preclose technique was performed with two ProGlide® devices (Abbott Vascular, Santa Clara, CA, USA). A 14 Fr eSheath (Edwards Lifesciences, Irvine, CA, USA) was introduced. A temporary pacing wire was placed in the apex of the right ventricle. According to the size and brand of the bioprosthesis, the ViV true ID was predicted to be 16 mm. However, on 3mensio (Pie Medical Imaging BV, Maastricht, the Netherlands) analysis, the ID was 14.5 mm due to tissue growth around the valve inflow area. Our strategy was to proceed initially with ViV TAVR using a SAPIEN 3 20 mm valve (Edwards Lifesciences) and possibly proceed with BVF if there were to be a residual elevated MG across the valve. This was indeed the case, as there remained a 13 mmHg MG across the aortic annulus. The decision was taken to perform BVF. An Atlas Gold Balloon Dilatation Catheter (CR Bard Inc., Tempe, AZ, USA) 18 mm system was selected. The size of the high-pressure post balloon diameter was decided according to the true ID of the bioprosthesis. A high-pressure stopcock was used to attach a syringe and an Indeflator (Edwards Lifesciences) separately to the balloon. With the stopcock open to the syringe, an initial hand inflation was performed to inflate the balloon rapidly. Then the stopcock was opened to the Indeflator, and the pressure was gradually increased (up to 10 atm) in the balloon system until the BPV ring fractured.

Results

Fracture of the BPV ring was noted with a sudden decrease in inflation pressure and the visible release of the balloon waist **(Figure 1)**. The MG was improved from 39 mmHg at baseline to 13 mmHg post ViV and 3 mmHg post BVF **(Figure 2)**. After sheath removal and ProGlide closure, the peripheral entry integrity was checked by angiography. The fluoroscopy time was 25 minutes and the volume of contrast agent was 80 mL. The patient was extubated immediately post procedure in the HOR and transferred to the intensive care unit (ICU). On postoperative day one, the patient was transferred to normal station and subsequently discharged on day four.

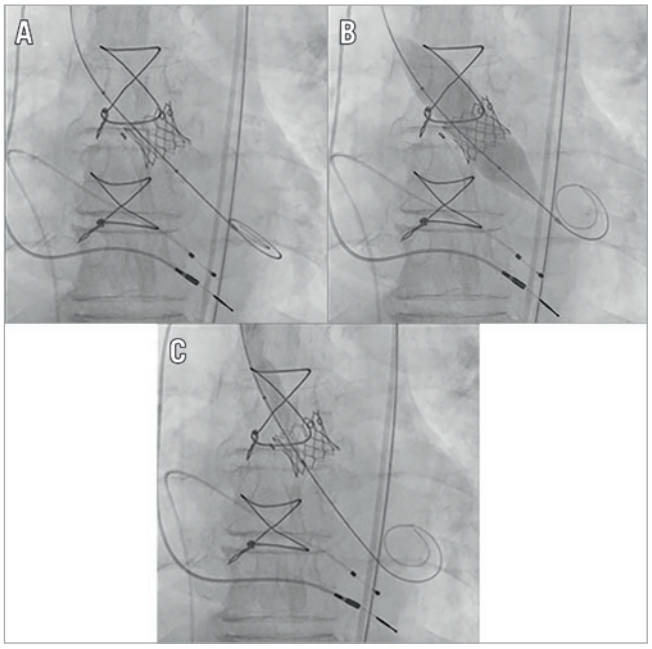

Figure 1. *Fluoroscopic images of the stages of valve-in-valve (ViV) transcatheter aortic valve replacement (TAVR) followed by bioprosthetic valve fracture (BVF). A) Immediately after ViV TAVR. B) During BVF before fracture of the surgical ring. Note the waist of the balloon at the level of the surgical valve ring. C) Final fluoroscopic results.*

Discussion

In the aortic position severe PPM occurs in between 2% and 20% of the cases. A recent meta-analysis suggested that predictors of PPM post sAVR include: older age, female sex, hypertension, diabetes mellitus, renal failure, larger body surface area, larger body mass index, and the utilisation of a bioprosthesis[1]. Furthermore, the presence of PPM is prognostically important because PPM results in higher valve gradients, increasing perioperative and overall mortality[1]. Several strategies have been developed to avoid PPM following ViV TAVR. Recent publications have reported on the concept of fracturing the surgical BPV ring with a high-pressure balloon inflation in order to dilate the BPV and permit further expansion of the THV, thereby improving haemodynamic results[2].

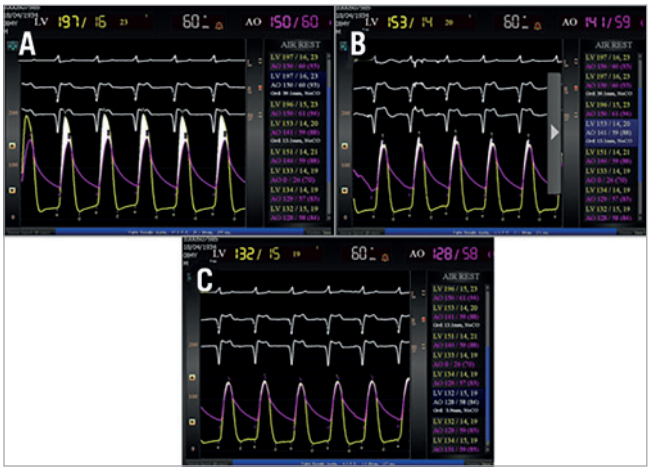

Figure 2. *Example of procedural haemodynamics with ViV transcatheter aortic valve replacement and bioprosthetic valve fracture. A) Baseline (pre-ViV) haemodynamics demonstrating severe bioprosthetic aortic stenosis with a mean aortic valve gradient of 36 mmHg. B) Haemodynamics post ViV with SAPIEN 3 20 mm implantation revealed a mean gradient of 13 mmHg. C) Haemodynamics post BVF demonstrating a mean gradient of 3 mmHg.*

At present, ViV TAVR BVF indications are not fully defined. The majority of patients, in particular those with large surgical valves, are likely to achieve an adequate haemodynamic result with ViV TAVR, and patients without PPM following ViV TAVR have an excellent survival to one year[3]. Therefore, patients who stand to benefit the most from BVF are those who are predisposed to PPM and high residual MGs following ViV TAVR, including those with a small (≤21 mm) bioprosthesis and/or stenosis as the mechanism of BPV failure[3]. Whether patients with large BPVs (>21 mm labelled valve size) or intermediate MGs (10-20 mmHg) after ViV TAVR stand to benefit from BVF is not known. In our case the MG was further improved from 13 mmHg (intermediate gradient) post ViV to 3 mmHg post BVF **(Figure 2)**.

An important question remains as to the timing of BVF, that is, before or after TAVR. There are potential advantages of both strategies. Fracture of the bioprosthetic ring pre TAVR may allow the use of a larger-sized TAVR prosthesis. On the other hand, although BVF post TAVR may allow further expansion of the TAVR valve, there is a risk that the leaflet may tear, resulting in aortic insufficiency, as well as potential dislodgement of the fractured valve and embolisation of debris. Also, when BVF follows TAVR, the TAVR prosthesis itself is subjected to a high-pressure balloon dilatation, which in some cases may cause acute structural damage or accelerated degeneration. In either scenario, BVF may reduce PPM and optimise haemodynamics by decreasing the residual aortic valve gradient during ViV TAVR. Whether the timing of BVF is a determinant of clinical outcomes remains to be seen[4].

Finally, due to concern that BVF may result in aortic root injury or coronary artery obstruction, some operators have preferred to

perform BVF only in the setting of full haemodynamic backup with extracorporeal membrane oxygenation (ECMO). To date, no published reports of aortic root injury or haemodynamic collapse attributable to BVF exist[5].

Limitations

Whether BVF has an impact on the survival of patients who are at risk of PPM following ViV TAVR remains to be seen. Further data are needed as to the quality of life benefit that is gained from ViV TAVR with BVF compared with ViV TAVR alone. The feasibility of BVF in patients with larger BPVs has not been well studied. Finally, the safety margins for performing BVF in patients at risk of coronary obstruction and aortic root injury are not fully understood and warrant further study.

Conclusion

BVF can be an effective and safe procedure in small surgical valves to facilitate ViV TAVR by balloon-expandable or self-expanding transcatheter valves, resulting in reduced residual transvalvular gradients and increased valve effective orifice area.

Impact on daily practice

ViV treatment is problematic with a small surgical bioprosthesis because of a further reduction in the effective valve orifice. Bioprosthetic valve fracture using a high-pressure balloon dilatation can be safely performed to facilitate ViV.

Conflict of interest statement

The authors have no conflicts of interest to declare.

References

1. Dayan V, Vignolo G, Soca G, Paganini JJ, Brusich D, Pibarot P. Predictors and Outcomes of Prosthesis-Patient Mismatch After Aortic Valve Replacement. *JACC Cardiovasc Imaging.* 2016; 9:924-33.

2. Nielsen-Kudsk JE, Christiansen EH, Terkelsen CJ, Nørgaard BL, Jensen KT, Krusell LR, Tang M, Terp K, Klaaborg KE, Andersen HR. Fracturing the Ring of Small Mitroflow Bioprostheses by High-Pressure Balloon Predilatation in Transcatheter Aortic Valve-In-Valve Implantation. *Circ Cardiovasc Interv.* 2015;8: e002667.

3. Webb JG, Mack MJ, White JM, Dvir D, Blanke P, Herrmann HC, Leipsic J, Kodali SK, Makkar R, Miller DC, Pibarot P, Pichard A, Satler LF, Svensson L, Alu MC, Suri RM, Leon MB. Transcatheter Aortic Valve Implantation Within Degenerated Aortic Surgical Bioprostheses: PARTNER 2 Valve-In-Valve Registry. *J Am Coll Cardiol.* 2017;69:2253-62.

4. Allen KB, Chhatriwalla AK, Cohen DJ, Saxon JT, Aggarwal S, Hart A, Baron S, Davis JR, Pak AF, Dvir D, Borkon AM. Bioprosthetic Valve Fracture to Facilitate Transcatheter Valve-In-Valve Implantation. *Ann Thorac Surg.* 2017;104:1501-8.

5. Saxon JT, Allen KB, Cohen DJ, Chhatriwalla AK. Bioprosthetic Valve Fracture During Valve-in-valve TAVR: Bench to Bedside. *Interv Cardiol.* 2018;13:20-6.

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CORONARY INTERVENTIONS

Shockwave intravascular lithotripsy for calcified coronary lesions: first real-world experience

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Aims: Calcified coronary lesions often cause suboptimal stent expansion, which is one of the greatest predictors of adverse outcomes such as stent thrombosis and restenosis. Shockwave intravascular lithotripsy (S-IVL) is a recently approved technique used in the treatment of heavily calcified coronary lesions. We present our early real-world experience with the S-IVL device.

Methods and results: All patients treated with S-IVL between October 2018 and January 2019 during their PCI at our centre were included. During this period, a total of 26 patients undergoing PCI were treated with S-IVL prior to stent deployment (69% male; age, 72±8 years). Indications for PCI were acute coronary syndromes (ACS) in 14 patients (54%), stable angina in 11 patients (42%), and PCI before TAVI in 1 patient (4%). 71% of the ACS cases undergoing PCI with S-IVL were to the perceived ACS culprit lesion during the index procedure, while 29% were staged PCIs to severe non-culprit lesions. Upfront S-IVL usage occurred in 58% of cases; the rest were bail-out procedures due to suboptimal initial balloon predilatation. S-IVL was used most commonly in the left anterior descending coronary artery (50%), with 1.3±0.5 stents implanted/target vessel. Angiographic success (<20% residual stenosis) occurred in all cases, with no procedural complications.

Conclusions: S-IVL appears to be a useful modality in coronary calcium modification to optimise stent expansion. This device obviates the need for more complex lesion preparation strategies such as rotational atherectomy, except in severe undilatable cases where S-IVL is impossible. Further study is warranted to compare different calcium modification devices with conventional balloon angioplasty.

CORONARY INTERVENTIONS

Mechanical circulatory supported PCI in high-risk patients using veno-arterial ECMO compared to Impella: a single-centre experience

Pender P., Gibbs O., Faour A., Dang V., French J.K., Mussap C.J., Taylor D., Leung D., Juergens C., Lo S.

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Aims: Both Impella and veno-arterial extracorporeal membranous oxygenation (VA-ECMO) provide consistent cardiac output augmentation which can alleviate haemodynamic fluctuations during high-risk PCI (HR-PCI). Paucity of Australian data exists. We sought to investigate the outcomes of patients undergoing HR-PCI with mechanical circulatory support (MCS) in our single-centre registry.

Methods and results: Retrospective analysis of consecutive non-shock patients undergoing Impella or VA-ECMO supported elective/semi-urgent HR-PCI from the Liverpool Cardiac Catheterisation and ICU databases (January 2010-January 2019) was performed. Total of 15 surgical-turndown patients (heart team referred) underwent HR-PCI with MCS (6 patients received VA-ECMO [3 with adjunctive intra-aortic balloon] and 9 with Impella support). Baseline characteristics were similar with mean age 70.8±14.6 years (44-82) in the VA–ECMO group vs Impella 66.5±14 years (51-92). Left ventricular ejection prior to PCI was 24.5±5.3% for VA-ECMO vs 36.7±12.3% in the Impella group. Mean Society of Thoracic Surgeons (STS) predicted mortality risk was 7.4% vs 8.2% (VA-ECMO vs Impella). Duration of haemodynamic support was 18±8.7 hours (3-24) with VA-ECMO vs 3.6±1.2 hours (2-4.9) with Impella. General anaesthesia was required in 6 VA-ECMO cases vs 4 in Impella (p=0.001). Surgical vascular closure was required in 100% VA-ECMO cases vs 11±33.3% Impella group (p=0.00002).

Conclusions: VA-ECMO and Impella support for HR-PCI achieves excellent results. VA-ECMO appears significantly more resource intensive with higher access-site complication rates and extended hospital LOS in our experience. Impella use in this early experience was associated with significantly reduced ICU, CCU and total hospital length-of-stay and blood transfusion requirements.

CORONARY INTERVENTIONS

Endothelial shear stress and vascular remodelling in BRS and metallic stent in the ABSORB II trial

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Aims: The impact of endothelial shear stress (ESS) on vessel remodelling in vessels treated using BRS as compared to metallic DES remains elusive. To determine whether the relationship between ESS and remodelling patterns differs in BRS from those seen in metallic DES at 3-year follow-up.

Methods and results: In the ABSORB II randomised trial [BRS vs DES], lesions were investigated by serial coronary angiogram and IVUS. Three-dimensional reconstruction of coronary arteries post-procedure and at 3 years was performed. ESS was quantified using non-Newtonian steady flow simulation. IVUS cross-sections in device segments were matched using identical landmarks. Paired ESS calculation post-procedure and at 3 years was feasible in 57 lesions in 56 patients. Post-procedure, median ESS at frame was higher in BRS than in DES with marginal statistical significance (0.97±0.48 vs 0.75±0.39 Pa, p=0.063). In the BRS arm, vessel area showed a larger increase in the highest tercile of median ESS post-procedure as compared to the lowest tercile. In contrast, in DES, no significant relationship between median ESS post-procedure and remodelling was observed. In multivariate analysis, smaller vessel area, larger lumen area, higher plaque burden post-procedure, and higher median ESS post-procedure were independently associated with expansive remodelling in matched frame. Only in BRS, younger age was an additional significant predictor of expansive remodelling.

Conclusions: In a subset of lesions with large plaque burden, expansive remodelling and late lumen enlargement are associated with shear stress in BRS, while ESS has no impact in metallic DES.

CORONARY INTERVENTIONS

Cost analysis of mechanical circulatory supported PCI in high-risk patients using veno-arterial ECMO compared to Impella: a single-centre experience

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Aims: Both Impella and veno-arterial extracorporeal membranous oxygenation (VA-ECMO) provide cardiac output support during high-risk PCI (HR-PCI). These devices have increased consumable costings but total episode-of-care expenditure reflects patient comorbidities; resulting hospital length-of-stay (LOS); and also managing any device-related complications. This study compared the clinical and economic impact of mechanical circulatory support devices Impella and VA-ECMO for patients undergoing HR-PCI.

Methods and results: Consecutive non-shock patients treated with either Impella or VA-ECMO during semi-urgent HR-PCI from the Liverpool Cardiac Catheterisation and ICU databases (Jan 2010-Jan 2019) were analysed retrospectively. Estimated total–admission cost was based upon published local diagnosis-related group guidelines to compare cost differences between these 2 treatment modalities, expressed in Australian dollars (AUD). 15 patients underwent HR-PCI with cardiac support; 6 received VA-ECMO and 9 Impella. Impella compared to VA-ECMO was associated with reduced total hospital LOS [11.9±9.2 vs 25.8±9.4 days]; reduced coronary care unit (CCU) LOS [5.8±3.8 vs 10.5±3.9 days (delta-4.7)]; reduced ICU-LOS [0.6±1.3 vs 9.5±9.0 days (delta-8.9) (p=0.007)]; reduced ward bed LOS [3.5+4.8 vs 5+7.3 (delta-1.4)] and reduced rehab bed LOS (delta-1.33). Application of cost per unit/per bed day in ICU and CCU [$5,830*delta =$52,146 (ICU)+$27,531{CCU)]; ward–bed day ($1,344*delta =$1,941) and rehab LOS ($316*delta =$421)]. Overall net benefit of reduced hospital LOS equated to savings of $81,197 favouring Impella.

Conclusions: VA-ECMO and Impella support for HR-PCI achieves excellent results. VA-ECMO appears significantly more resource intensive with higher access-site complication rates and extended hospital LOS. Impella in this early experience was associated with significantly reduced ICU, CCU and total hospital length-of-stay and blood transfusion requirement. As such, Impella use amounts to substantial reduction in costs of care.

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CORONARY INTERVENTIONS

Advantages of optical frequency domain imaging compared with IVUS in PCI using rotational atherectomy

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Aims: This study aimed to compare the outcomes of PCI using rotational atherectomy with OFDI guidance versus IVUS guidance.

Methods and results: We evaluated the same vessels (7 cases, 74 areas) using both IVUS and OFDI to determine whether there was a difference between areas measured by IVUS and those by OFDI. The area measured by OFDI was 16.2% smaller than that done by IVUS ($p<0.001$). Secondly, we retrospectively assessed not only the lesion and procedural characteristics between OFDI (n=34) and IVUS (n=51) guided RA groups but also the vessel areas before and after PCI. Lumen areas estimated by IVUS were corrected to multiply by 0.838 in accordance with the results of the pilot study. Compared with the IVUS group, the mean final burr size (1.75±0.26 versus 1.63±0.23 mm, $p<0.05$) and final balloon diameter (3.29±0.60 versus 3.09±0.44 mm, $p<0.05$) were significantly larger in the OFDI group. The minimal lumen area (MLA) before PCI was significantly larger in OFDI group versus corrected IVUS group (1.76±0.76 versus 2.30±0.84 mm^2, $p<0.05$), but the MLA after PCI was not significant (5.26±1.72 versus 4.85±1.46 mm^2, n.s.). Acquired area, defined by difference in MLA before and after PCI, was significantly greater in PCI using RA in OFDI group than that in corrected IVUS group (3.49±1.58 versus 2.56±1.12 mm^2, $p<0.001$).

Conclusions: Greater acquired area using OFDI rather than IVUS might be associated with larger final burr and balloon size. OFDI has advantages of superior comprehension regarding thickness and circumferential extent of calcification, which can provide essential information for the decision process of the most suitable burr and balloon size following safer and maximal ablation effect compared with IVUS. Therefore, OFDI guided RA might reduce in-stent restenosis and stent thrombosis to minimise stent malapposition and underexpansion.

CORONARY INTERVENTIONS

Impact of plaque burden and composition on coronary slow flow in STEMI patients undergoing PCI: an intravascular ultrasound and virtual histology analysis

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Aims: Coronary slow flow is an important complication of PCI which is associated with poor prognosis. The aim was to assess greyscale IVUS and virtual histology (VH-IVUS) features of culprit lesions in STEMI.

Methods and results: 252 consecutive patients with STEMI underwent coronary angiogram and IVUS analysis. Following PCI, patients were divided into 2 groups; slow flow (TIMI flow ≤2, n = 61) and normal flow (TIMI flow >2, n = 191). Coronary plaque burden and its composition in relation to slow flow were evaluated. On greyscale IVUS analysis, plaque area (14.30±9.80 mm^2 vs 12.92±9.11 mm^2, p=0.047), plaque volume (121.38±41.28 mm^3 vs 102.94±30.70 mm^3, p=0.001), lesion external elastic membrane cross-sectional area (15.77±4.70 mm^2 vs 14.28±3.25 mm^2, p=0.038) and remodelling index (1.38±0.36 vs 1.27±0.32 mm^2, p=0.035) were significantly higher in slow flow group. On VH-IVUS analysis, absolute fibrous volume (52.48±21.55 mm^3 vs 43.48±15.74 mm^3, p=0.002), absolute necrotic core volume (12.42±6.50 mm^3 vs 6.75±4.79 mm^3, $p<0.001$), absolute dense calcium volume (1.94±2.46 mm^3 vs 1.26±1.71 mm^3, p=0.016) and thin-cap fibroatheroma either single (31.10% vs 16.80%, p=0.015) or multiple (4.90% vs 0.5%, p=0.045) were higher in slow flow arm. On multivariable analysis the absolute necrotic core volume (odds ratio = 1.184; 95% CI: 1.087-1.288, $p<0.001$) was the only independent predictor of slow flow. Receiver operating characteristic curve analysis identified the absolute NC volume (AUC = 0.765, $p<0.001$) and the plaque volume (AUC = 0.641, $p<0.001$) as the best discriminators for slow flow.

Conclusions: Virtual histology (VH-IVUS) derived absolute NC volume is closely associated with the coronary slow flow phenomenon in patients with STEMI after PCI.

CORONARY INTERVENTIONS

Impact of a stentless PCI strategy using directional coronary atherectomy and a DEB for left main and ostial lesions

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Aims: This study aimed to examine the safety and effectiveness of stentless PCI using directional coronary atherectomy (DCA) and drug-coated balloons (DCBs).

Methods and results: From November 2017 to January 2019, stentless PCI for left main trunk and ostial lesions was performed in 23 consecutive cases. Stentless PCI was performed using "SeQuent Please" DCBs after "ATHEROCUT" DCA, and procedural success was obtained in all cases (4 cases with LMT, 15 with left anterior descending ostial, 3 with left circumflex (LCX) ostial, and 1 with RCA ostial lesion). The %PA decreased from 70.7±7.6% at baseline to 44.8±9.1% after the DCA. In 13 patients who completed a follow-up coronary angiography after 6 months, no restenosis was observed. No major adverse cardiac events occurred in any cases including TLR. In 9 cases in which the lumen was confirmed with IVUS at 6 months of follow-up, the PA had expanded significantly from 7.6±1.9 mm^2 at baseline to 8.8±2.4 mm^2 at 6 months (p=0.0215). Local paclitaxel may induce late lumen enlargement (LLE) after DCA/DCB.

Conclusions: Stentless PCI using DCA and DCB for bifurcation lesions including LMT and RCA ostial lesions was effective, safe, and useful. Furthermore, a chronic LLE effect by DCB is expected.

CORONARY INTERVENTIONS

QT dispersion as a valuable marker to predict the ischaemic burden on single-photon emission CT myocardial perfusion imaging of multivessel disease patients

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Aims: We aimed to investigate the value of QT dispersion to predict the ischaemic burden as detected by SPECT myocardial perfusion imaging (MPI).

Methods and results: This was a cross-sectional study of patients with multivessel coronary artery disease who underwent SPECT MPI. The QT dispersion was defined as the difference between the maximal and minimal QT interval duration. QT interval was measured as corrected QT interval (QTc) using Bazett Formula. Ischaemic burden was measured by SPECT MPI using semiquantitative scores on 17-segment assessment according to standard nomenclature and interpreted as small and moderate-large ischaemic burden. Total of 62 patients (49 males, mean age 55.5±8.9 years). There was negative correlation with good strength between QT dispersion and ischaemic burden ($r = -0.658$, $p<0.001$). Using ROC analysis, the optimal cut-off value of QT dispersion was 80 ms that yielded the highest sensitivity and specificity to discriminate between two groups. Sensitivity, specificity, positive and negative predictive value of QT dispersion ≤80 ms to predict moderate-large ischaemic burden were 89%, 87%, 86%, and 90%, respectively.

Conclusions: QT dispersion is a simple and reliable parameter with good diagnostic value to predict moderate-large ischaemic burden as detected by SPECT MPI. This parameter could also be applied to determine the management strategy of multivessel coronary artery disease patients in daily practice.

CORONARY INTERVENTIONS

The predictive accuracy of PRECISE-DAPT and CRUSADE bleeding risk scores in PCI treated STEMI patients: a single-centre, observational study

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Aims: The primary aim was to investigate the predictive accuracy of PRECISE-DAPT and CRUSADE bleeding risk scores in a single-centre cohort of PCI treated STEMI patients.

Methods and results:

We retrospectively analysed 310 consecutive STEMI patients having primary PCI at Liverpool Hospital, Sydney (Jan 2015-April 2016). Patients administered thrombolysis, prasugrel, and having coronary artery bypass grafting were excluded. The primary endpoint was in-hospital major bleeding, defined as any actionable bleeding event fulfilling BARC2-5 criteria. The study cohort comprised 288 patients, with median age 61 [21-94] years, 83% male, mean BMI 29±6.4, and 29.8% had diabetes (DM). PCI was performed via the femoral artery in 67.4%, and third-generation drug-eluting stents (DES) were used in 44.8%. Overall, T-DAPT (67%) was preferred over C-DAPT (33%), with no subgroup differences in baseline characteristics. All-cause mortality was low (7.3%), at median follow-up 222 days [IQR = 389-60 days], with no difference between C-DAPT vs T-DAPT (10.5 vs 5.7%; p=0.14). In-hospital BARC2-5 major bleeding occurred in 10.4%. There was no difference in major bleeding for C-DAPT vs T-DAPT (11.6 vs 9.9%; p=0.6). Tirofiban was administered in 27% of cases, and 22% of these patients had major bleeding. Receiver operating characteristic (ROC) analysis showed that PRECISE-DAPT (AUC 0.75 [95% CI: 0.65-0.83]) had better predictive accuracy for in-hospital major bleeding compared to CRUSADE (AUC 0.60 [95% CI: 0.50-0.90]; comparative p=0.01). Multivariate analysis showed that tirofiban (OR 3.7 [95% CI: 1.65-8.28]; p=0.001) and older age (OR 1.1 [95% CI: 1.2-1.1]; p=0.004) were independently associated with in-hospital BARC2-5 bleeding events.

Conclusions: In our cohort of PCI treated STEMI patients, the more potent T-DAPT was preferred over C-DAPT, without a significant increase in rates of in-hospital BARC2-5 bleeding or death. Major bleeding was more likely in older patients and those administered tirofiban. The PRECISE-DAPT bleeding risk score appears to be superior to CRUSADE in predicting in-hospital, major bleeding.

CORONARY INTERVENTIONS

Prognosis of patients with chronic coronary artery disease undergoing PCI (five-year follow-up)

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Aims: To evaluate the prognosis of patients with chronic ischaemic heart disease, who underwent PCI and were only on optimal medical therapy (OMT).

Methods and results: Measurement of FFR was performed for 432 patients. All patients were randomised in 2 groups (1:2): Group I (n=168) – included patients, who had a FFR <0.8 and were followed by PCI; Group II (n=264) – included patients with FFR >0.8 – received OMT and were under monitoring for up to 5 years. Inclusion criteria: stable angina II-III FK, post-MI, silent myocardial ischaemia. Concomitant diseases: diabetes mellitus (19.2%), multifocal atherosclerosis (21%), hypertension (27%), post-MI (24%), PCI in previously (15%). According to angiography, 44% had a one-vessel disease, 35% had two-vessel diseases, and 21% had a three-vessel disease. Primary endpoints: MACE (death, MI, repeated interventions). Observation periods: 6, 12, 24, 36, 48, 60 months. Long-term results were evaluated by repeated coronary angiography and measurement of FFR. During 6 and 12 months there was not a single case of MACE in either group. By the 18th month, conversion of 7% of cases from the OMT to the PCI group on the basis of FFR measurements was recorded. By the 24th and 36th months in the OMT group, PCI was performed in 12 and 21% of patients, respectively. By the 48th and 60th months, the number of such patients was 24 and 31%, respectively. Among the total number of performed PCI in Group II, 20% of them were due to unstable angina. Thus, over the entire observation period, 149 patients from Group II (56%) had PCI performed. The frequency of MACE in Group I to 36 months was 2.4%, and in Group II 18% (p<0.001). By the end of the observation period, the frequency of MACE in groups I and II was 4.2 and 31%, respectively (p<0.001). Multifactor analysis showed that with SYNTAX score>28, multifocal atherosclerosis, diabetes mellitus, MACE was significantly more frequent and there was a need to perform PCI in the long-term period.

Conclusions: The prognosis of patients with chronic coronary artery disease undergoing PCI, performed using measurement of FFR, is significantly better than in patients who were only on OMT.

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CORONARY INTERVENTIONS

Outcome of magnesium BRS implantation in ACS: a single-centre experience

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Aims: BRS, the newest coronary stent technology, seems to be an especially interesting treatment option in the setting of ACS.

Methods and results: The first 100 consecutive patients who underwent PCI with the Magmaris BRS in the settings of ACS were enrolled for analysis as a part of the Magmaris-ACS Registry. Clinical 30-day and 12-month FU was obtained by telephone contact. Mean age of the analysed group: 63.2±8.2 years, 86% male with typical risk factors of ACS; clinical presentation: 17% unstable angina and 83% non-ST-segment myocardial infarction; 90% TIMI 3 flow; 93% single lesion disease, 77% type A + B1 lesion according to AHA/ACC classification. Predilatation was performed in 100% of lesions with a non-compliant balloon. In total, 107 scaffolds at mean diameter 3.2±0.3 mm and length 21.1±3.3 mm were implanted for *de novo* lesions located in LAD (39%), LCx (22%), and RCA (39%), respectively. Post-dilatation was performed in 99% of lesions, with the non-compliant balloon 0.25–0.50 mm larger than the scaffold size. Preprocedural MLD was 0.96 mm, with mean 67.3 %DS. Post-procedural MLD was 2.44 mm, resulting in an acute gain of 1.48 mm. Angiographic success in the target lesion was 100%. OCT-guided PCI confirmed the significant proximal (3%) or distal (1%) edge dissection, and a regular metallic DES overlapping BRS or additional BRS were implanted in four cases (4%). Three cases (3%) of interim small side branch (SB) occlusion after implantation of BRS occurred. On discharge, all patients remained on dual antiplatelet therapy. Twelve-month follow-up available for 60% of patients revealed one case of scaffold restenosis treated by DES implantation (9 months after index PCI). All patients remained on prescribed DAPT for the whole period of observation.

Conclusions: BRS seems to be an especially interesting treatment option in the setting of ACS.

CORONARY INTERVENTIONS

The effect of adding excimer laser coronary angioplasty to DEB therapy for restenosis of DES

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Aims: To evaluate the efficacy of excimer laser coronary angioplasty (ELCA) for the treatment of in-stent restenosis (ISR) of drug-eluting stent (DES) with drug-coated balloon (DCB).

Methods and results: We investigated our coronary intervention cases of coronary drug-eluting stent restenosis. From May 2014 to January 2019, in 49 lesions (44 cases) revascularisation was performed for DES-ISR with DCB and follow-up angiogram. We defined the ELCA group as those who underwent ELCA before using DCB for ISR of DES and the non-ELCA group was defined as those who did not undergo ELCA. We compared ELCA group (n=17) and non-ELCA group (n=32) and retrospectively analysed the LLL and the TLR rate. The mean duration of follow-up CAG was 7.7±2.9 vs 8.7±6.2 months. There was no significant deference between the ELCA group and the non-ELCA group at follow-up in the LLL (0.17±0.79 mm vs 0.42±0.64 mm) and the TLR rate (17.6% vs 28.1%).

Conclusions: These data suggest that there was no adjunctive effect of adding ELCA before using DCB for ISR of DES.

CORONARY INTERVENTIONS

Two-year follow-up of provisional T-stenting of left main coronary artery in patients with true bifurcation stenosis

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Aims: To evaluate the long-term results of the use of drug-eluting balloon catheters in patients with left main (LM) bifurcation stenosis.

Methods and results: 142 patients with true bifurcations of the LM. Randomisation in 2 main groups: Group I (n=52) included patients who received kissing-dilatation with traditional NC balloon catheters and Group II (n=52), who had a kissing-dilatation of the main bifurcation artery with traditional NC balloon catheters, and a side branch – with drug-eluting balloon catheters. Retrospectively, the third (III) control group (n=38) was formed, where the two-stent technique was performed. Inclusion criteria: true LM bifurcation stenosis according to QCA and OCT; SYNTAX score <32. Primary endpoints: incidence of MACE – death, MI, reinterventions. Secondary endpoints: the incidence of restenosis and late stent thrombosis.

Results: after 24 months the total incidence of MACE was 11.5 vs 3.8% in groups I and II, respectively ($p<0.05$). When comparing the results in groups II and III, the frequency of MACE was 3.8 vs 13.2%, respectively ($p<0.05$). Restenosis of the side branch of more than 50% according to QCA was detected in 4 patients (7.7%) from Group I and in 1 patient (1.9%) from Group II ($p<0.05$). In patients from Group I, the average MLA in the side branch after 24 months was 5.58±1.34 and 4.12±1.21 mm^2, respectively ($p<0.05$), compared with data after PCI; in the main branch – 6.34±1.56 and 5.88±1.14 mm^2, respectively ($p>0.05$). In patients from Group II, the average MLA was, respectively, 5.38±1.24 and 5.12±1.44 mm^2 in side branch ($p>0.05$) and 6.68±1.75 and 6.36±1.22 mm^2 in main branch ($p>0.05$). When comparing the data of MLA in the side branch in groups I and II, there was a significant difference (4.12±1.21 vs 5.12±1.44 mm^2; $p<0.05$). There were no cases of late thrombosis of the stents.

Conclusions: The use of drug-eluting balloon catheters for provisional T-stenting in patients with true LM bifurcation stenosis was associated with significantly lower frequency of MACE and side branch restenosis, according to OCT data, compared with patients who used traditional NC balloon catheters for "kissing-dilatation" and two-stent technique strategy.

CORONARY INTERVENTIONS

Role of remote ischaemic conditioning in primary angioplasty: a randomised controlled trial

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Aims: We have tried to find out the role of remote ischaemic preconditioning in acute coronary syndrome patients who undergo primary angioplasty.

Methods and results: 284 patients satisfying the inclusion criteria were randomly included into interventional arm and control arm using block randomisation with 142 patients recruited in each arm. Remote ischaemic conditioning was done for patients in the interventional arm. The outcomes assessed were LVEF 24 hours post PCI and on discharge, troponin-T levels 24 hours after PCI, the percentage reduction in ST elevation, corrected TIMI frame count and myocardial blush grade after PCI as well as the rise in creatinine 48-72 hours after primary PCI. There was a significant difference for the endpoints of LVEF 24 hours after primary PCI and on discharge, the percentage reduction in ST elevation, troponin levels 24 hours after primary PCI, corrected TIMI frame count and myocardial blush grade with the intervention arm doing better ($p<0.05$). The difference remained significant irrespective of the type of MI. The intervention arm was also found to cause less contrast-induced nephropathy.

Conclusions: Remote ischaemic conditioning can preserve the LV systolic function, reduce enzymatic infarct size post-MI and improve microvascular function and reperfusion after primary PCI. It may also offer renal protection by reducing the contrast-induced nephropathy.

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CORONARY INTERVENTIONS

Use of a super high-pressure non-compliant percutaneous transluminal coronary angioplasty balloon in complex PCI procedures – three-year single-centre experience

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Aims: The aim of the study is to analyse the indications, performance and outcomes of a super high-pressure non-compliant PTCA balloon (OPN NC®; SIS Medical AG, Winterthur, Switzerland) in our centre.

Methods and results: The OPN NC®balloon was used in 33 patients from January 2016 to December 2018. Twenty-four were male and the mean age was 66. The clinical indication was stable IHD in 17 patients and acute coronary syndrome in 16 (including 2 STEMI). 21 patients had *de novo* lesions and the other 12 had a pre-existing stent. The OPN NC® was used for pre-dilatation alone in 15 patients, post-dilatation alone in 15 patients and for both in 3 cases. Prior dilatation with a regular NC balloon had been performed in 29 patients. IVUS was used in 23 procedures and OCT in 2. The balloon sizes used were 2.0 mm (4), 2.5 mm (7), 3.0 mm (12) and 3.5 mm (10). The median inflation pressure was 35 atm. The maximum pressure of 40 atm was used in 3 cases. In addition to the OPN NC® balloon, cutting balloon was also used in 3 patients and scoring balloon in 6 patients. The OPN NC® balloon was passed successfully in all 33 patients, although one patient required rotational atherectomy to enable balloon delivery. Following treatment with the OPN NC® balloon, a drug-eluting-stent was inserted in 21 patients and drug-eluting balloon in 9 patients, with 2 patients having only balloon angioplasty within pre-existing stents. One calcified proximal LAD with an old underexpanded stent was treated with a 3.5x10 mm OPN NC® balloon at 35 atm, followed by a drug-eluting-balloon. This resulted in a small perforation, requiring treatment with a covered stent.

Conclusions: The OPN NC® PTCA balloon is a safe and effective tool in the treatment of heavily calcified lesions and underexpanded stents. It should however be used with caution, especially at very high pressures and the operator should be vigilant for possible complications.

CORONARY INTERVENTIONS

Transradial coronary angiography in severe aortic stenosis: left vs right approach and 5 Fr vs 6 Fr diagnostic catheters

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Aims: The aim of the study was to evaluate the safety and feasibility of using the left radial compared to the right radial approach and 5 French (Fr) compared to 6 Fr diagnostic catheters.

Methods and results: 200 patients with severe AoS and without previous history of CABG (112 males, aged 73 years) underwent transradial coronary angiography. 136 were performed using the right (R) radial artery and 64 the left (L) radial artery, while 100 were performed using 5 Fr diagnostic catheters and 100 6 Fr diagnostic catheters. Thus, four groups of patients were formed (R5, R6, L5, and L6). The primary endpoints of the study were procedural success, fluoroscopy time (FT), dose-area product (DAP), number of catheters, and amount of contrast agent. One-way between groups analysis of variance showed statistically significant difference in mean scores of FT and DAP among the four groups [$F(3, 193) = 10.8$, $p<0.0001$ and $F(3, 192) = 4.8$, $p<0.05$, respectively]. *Post hoc* comparisons using the Tukey HSD test indicated that the mean FT and DAP for group R5 were significantly different from the other 3 groups (6.67±3.10 versus 3.06±1.89 minutes, $p<0.001$ and 38,627±16,423 versus 29,437±15,761 $Gycm^2$, $p<0.05$, respectively). Among the other three groups, the FT and DAP were not significantly different. There were no significant differences in procedural success, number of catheters, and amount of contrast agent among the 4 groups. Multiple linear regression revealed that radial approach, Fr diagnostic catheters and body mass index were the independent predictors of FT after controlling for other variables ($R2 = 0.378$, $p<0.001$).

Conclusions: Right radial approach in conjunction with 5 Fr diagnostic catheters is accompanied by augmented FT and DAP in patients with severe AoS undergoing coronary angiography. Furthermore, left radial approach and right radial approach with 6 Fr catheters may reduce FT and DAP. These findings imply that catheter size and radial approach should be taken into account in these patients.

CORONARY INTERVENTIONS

The impact of multiple stent implantation with novel abluminally coated sirolimus-eluting stent on one-year clinical outcomes of patients with AMI undergoing PCI: data from en-ABL e-registry

Testa L.[1], Dani S.[2], Desai D.[3], Pandya R.[4], Parekh P.[5], Vasavada A.[6], Bhalani N.[7], Sharma A.[7], Sheth C.[7], Shah D.[8]

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Aims: We evaluate the impact of multiple stent implantation with Abluminus, a novel abluminally coated sirolimus-eluting stent with unique fusion technology (Envision Scientific) on one-year clinical outcomes of unselected patients with acute myocardial infarction (AMI).

Methods and results: 2,500 patients enrolled in a multicentre, prospective, real-world en-ABL e-registry. Among them 999 patients had acute MI. For current analysis patients were stratified based on number of implanted stents (≥2 stents) in the native coronary vessels. 228 patients with AMI had multiple stent implantation with Abluminus sirolimus-eluting stent while 771 patients were implanted with single stent. The primary endpoint of this analysis was MACE at one year. MACE comprised cardiac death, TV-MI and TLR/TVR. Secondary endpoints included definite or probable ST as defined by the Academic Research Consortium. We assessed 228 (22.8%) patients implanted with ≥2 stents for AMI while the remaining 771 patients were treated with single stent (77.2%). Patients treated with ≥2 had high prevalence of multivessel disease (58%). One-year follow-up data were available for 100% in patients with ≥2 stents implanted while it was achieved in 99.8% of patients treated with single stent. The incidence of MACE was reported as [3.1% vs 1.8%, p=0.290] respectively for both the groups. MACE components were reported as cardiac death [0.9% vs 0.6%, p=0.662], TV-MI [1.3% vs 0.6%, p=0.393] and TLR/TVR [0.9% vs 0.5%, p=0.624] respectively for both cohorts. The rate of ST was numerically higher in case of patients treated with multiple stents [2.2% vs 0.6%, p=0.054]. Definite ST occurred more frequently in both cohorts [1.8% vs 0.6%, p=0.085]. There was no statistical difference reported between both the cohorts in terms of MACE and ST.

Conclusions: The results of the present study revealed numerically higher rate of ST in patients treated with multiple stents for AMI compared to the patients treated with single stent. Yet, there was no statistically significant difference found between the studied cohorts suggesting that multiple Abluminus stent implantation had no impact on the one-year clinical outcomes in patients with AMI.

CORONARY INTERVENTIONS

The long-term outcome of NSTEMI patients treated with the Absorb BRS

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Aims: To investigate the long-term outcome of patients presenting with NSTEMI treated with the everolimus-eluting Absorb BVS in a high-volume interventional cardiology centre.

Methods and results: Between July 2012 and March 2016, 147 NSTEMI patients underwent PCI with a total of 200 Absorb BVS implanted for 150 lesions located in LAD (46%), LCX (27%), and RCA (27%), respectively. Median patient age was 60 (40 to 94) years, 77% male, 35% diabetes, 37% presented previous MI. Predilatation was performed in 88% of lesions with a non-compliant balloon. 25% of lesions required implantation of two or more overlapping scaffolds. In 3 patients multivessel stenting with the BVS during the index procedure was performed. In 82% of cases, the 3.0-3.5 diameter of BVS was used. Angiographic success in the TL was 100%. All patients remained on prescribed DAPT for 12-36 months after the index procedure. At a median FU of 48 months (mean 52±14 months), MACE occurred in 41 (27.9%) patients, all-cause death in 19 (12.9%) patients, MI in 21 (14.3%) patients, and TV revascularisation in 15 (10.2%) patients. Definite or probable scaffold thrombosis occurred in 3 (2%) patients.

Conclusions: Optimal Absorb BVS implantation in the NSTEMI population is associated with comparable rates of adverse events at long-term FU to metal DES implantation in this group of patients.

CORONARY INTERVENTIONS

Two-year clinical outcomes of sirolimus-eluting coronary stent in diabetic patients and its influencing factors: insights from en-ABL e-registry

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Aims: To assess the performance of Abluminus sirolimus-eluting stent (Envision Scientific) which has unique technology of coating on stent and parts of pre-crimped balloon in patients with DM and coronary artery disease.

Methods and results: 859 diabetic patients with coronary artery disease. Among them, 752 patients completed 2-year follow-up. The clinical outcome in terms of MACE is assessed for this cohort. Among 748 patients 76.3% were male and 60% patients had hypertension. More than half of the patients (60%) had ACS. Left anterior descending was most frequently treated artery (37.9%). 62.1% patients had lesions located in small coronary vessels (≤2.75 mm). The event-free survival was 97.2% at 2 years. MACE occurred in 21 (2.8%) patients including 13 (1.7%) TLR and 3 (0.4%) TVMI with 5 (0.7%) cardiac deaths reported. Logistic regression revealed that multiple stent implantation (Hazard ratio 3.832; 95% CI: 1.408 to 10.429; p=0.009) is associated strongly with increased MACE rate at 2 years. Hypertension (Hazard ratio 0.716; 95% CI: 0.294 to 1.740; p=0.460), acute coronary syndrome (Hazard ratio 0.907; 95% CI: 0.359 to 2.294; p=0.837), stable angina (Hazard ratio 0.512; 95% CI: 0.061 to 4.314; p=0.538), small vessel (Hazard ratio 4.040; 95% CI: 0.909 to 17.962; p=0.067) and long lesions (Hazard ratio 1.298; 95% CI: 0.435 to 3.877; p=0.640) are not strongly associated with increased incidence of MACE.

Conclusions: The implantation of Abluminus DES in real-world diabetic patients is associated with promising clinical outcomes with acceptable survival rate at 2 years.

CORONARY INTERVENTIONS

Outcomes of PCI and comparison of scoring systems in predicting procedural success for elderly patients with CTO

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Aims: The purpose of the study is to represent the clinical characteristics and in-hospital outcomes of PCI for elderly patients (≥75 years) with CTO diseases in contemporary era. Another aim is to assess different scoring systems in predicting procedural success in the real world.

Methods and results: 246 consecutive patients were stratified into elderly group (age ≥75 years, n=68) and non-elderly group (age <75 years, n=178). Compared to the non-elderly, the elderly patients with CTOs had heavier burden of comorbid conditions, manifesting higher rates of renal dysfunction, chronic lung disease, and also previous cerebral stroke. The target CTO lesions were most frequently located at the left anterior descending artery (LAD) in both the elderly group (52.94%) and the non-elderly group (44.94%). However, the percentage of cases with triple-vessel diseases and SYNTAX scores in the elderly group were significantly higher than those in the non-elderly group (73.53% vs 53.93%, p=0.005; 31.39±7.68 vs 27.85±7.16, p=0.001, respectively), indicating that the elderly CTO patients had seriously diseased coronary arterial lesions. Procedure time and contrast volume in the elderly group were less than those in the non-elderly group. The in-hospital MACE rates, vascular access complication rates and major bleeding rates were similar between elderly and non-elderly groups (1.47% vs 1.69%, p=1.000; 1.47% vs 0.56%, p=0.477; 2.94% vs 1.12%, p=0.306, respectively). The total procedural success rate was 81.71% in 246 CTO patients, which was statistically lower in elderly group than that in the non-elderly group (73.53% vs 84.83%, p=0.040). With increasing strata, procedural success rates significantly declined for all scoring systems in the entire patient population (p for trend<0.001). All four score systems showed moderate predictive capacity (AUC for J-CTO score: 0.806, p<0.0001; AUC for PROGRESS CTO score: 0.727, p<0.0001; AUC for CL score: 0.800, p<0.0001; AUC for ORA score: 0.672, p<0.0001, respectively). Compared to ORA score, J-CTO score and CL score showed significant advantage in the overall patient population.

Conclusions: Elderly patients with CTOs tend to have more severe complex lesions and heavier burden of comorbid conditions. All of J-CTO, PROGRESS, ORA and CL scoring systems possess moderate discriminatory capacity in predicting procedure success. Integration of multiple scoring systems would be helpful to evaluate procedural risk–benefit ratio accurately.

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INTERVENTIONS FOR HYPERTENSION

Renal sympathetic denervation in patients with refractory arterial hypertension: two-year follow-up

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Aims: To evaluate the efficacy of the sympathetic renal denervation procedure in patients with refractory arterial hypertension and heart failure.

Methods and results: 72 patients with refractory arterial hypertension. Randomisation in 2 main groups: the Group I (n=36) included patients who underwent denervation procedure of the main trunk of the renal artery and the Group II (n=36) included patients who underwent denervation procedure in main trunk and also in second-order renal arteries. Additionally, patients were divided into 2 subgroups: the subgroup A (n=30) included patients who underwent denervation procedure with a Symplicity catheter, and the subgroup B (n=42) which included patients who underwent denervation procedure with a Vessix catheter. Also, the renal denervation procedure efficacy in patients with chronic heart failure (CHF) was analysed. In all groups, 24-hour blood pressure monitoring, echocardiography and a 6-minute walk test were monitored. Inclusion criteria: refractory hypertension, age of patients 18-85 years, systolic blood pressure (SBP) ≥140/90 mmHg and ≥130/90 mmHg in patients with diabetes mellitus, functioning kidneys, renal arteries ≥40 mm in diameter and the length of the site up to the first bifurcation of at least 20 mm, absence of stenoses in the renal arteries, GFR ≥40 ml/min/1.73 m², suitable anatomy of the renal arteries for endovascular procedure. 24-month result after the denervation procedure demonstrated significantly decreased SBP in patients of both groups. In Group I, it was, compared with pre-operative data (174.9±1.6 vs 151.7±2.3 mmHg, respectively; $p<0.05$), and in group II 181.9±2.1 vs 140.4±3.8 mmHg, respectively; $p<0.05$. However, when comparing SBP values between groups, SBP in Group I was significantly higher than in Group II (151.7±2.3 vs 140.4±3.8 mmHg, respectively; $p<0.05$). In addition, the average number of drugs in Group I decreased to 2.1±0.8 after 24th month, and in Group II to 1.4±0.6 ($p<0.05$). When comparing SBP value in subgroup A and subgroup B, the average daily SBP was also significantly different and amounted to 147.8±1.8 vs 138.4±3.2 mmHg, respectively; $p<0.05$. Among all the patients included in the study, 38 patients were with CHF. The 6-minute walk test results, compared with pre-operative data, showed a significant improvement and amounted to 321.24±83.22 vs 212.42±54.72 m, respectively; $p<0.05$.

Conclusions: Sympathetic renal denervation may be regarded as an effective method of treatment of patients with resistant hypertension, as well as patients with concomitant chronic heart failure. Performing denervation in the arteries of the second order significantly improves the prognosis of patients, and in patients with concomitant heart failure significantly increases the quality of life and exercise tolerance.

INTERVENTIONS FOR HYPERTENSION

The results of balloon angioplasty of the pulmonary artery in patients with chronic thromboembolic pulmonary hypertension

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Aims: To evaluate transcatheter balloon angioplasty of the pulmonary artery procedure for patients with chronic thrombembolic hypertension (CTEPH).

Methods and results: The study included 10 patients with CTEPH (6 men, 4 women, average age 55±11), with lesions of the distal type, who were denied pulmonary artery thrombectomy and a staged balloon angioplasty was performed. All patients take sildenafil therapy. According to the pressure data of the right heart chambers, the patients showed precapillary mild hypertension of the pPA 95±12.7 mmHg. All patients underwent 4-6 stages of balloon angioplasty of the branches of the pulmonary artery with a decrease in the New York Heart Association class from 3.2±0.5 to 1.9±0.2 ($p<0.001$). In the postoperative period the mean pulmonary artery pressures decreased from 54±14.2 mmHg to 30±10.2 mmHg ($p=0.007$) and there was a decrease in PVR from 15±3.3 Wood units to 2.5±0.7 Wood units ($p=0.007$). The incidence of complications (reperfusion pulmonary oedema) did not exceed 23%.

Conclusions: Transcatheter balloon angioplasty of the pulmonary artery is an effective and safe procedure on condition of the patient selection algorithm and methodology of procedure performance.

INTERVENTIONS FOR STROKE

Device hooks protrusion zone relative to pulmonary artery after LAA occlusion with AMPLATZER vs WATCHMAN device

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Aims: This study aimed to assess device hooks zone position within the LAA and its distance to PA in two occluders with varying design types.

Methods and results: Consecutive patients (n=57) after LAAO with AMPLATZER (n=30) or WATCHMAN (n=27) who underwent post-procedural cardiac computed tomography (CCT) between July 2015 and June 2018 were included. Demographic and clinical data were collected within a prospective, institutional LAAO Registry. Based on CCT images, position of hooks zone within the proximal 15 mm from LAA ostium was classified as shallow vs deep for more distal hooks zone position. The closest distance from device hooks protrusion zone to PA (hooks-PA) was measured and close proximity was defined as ≤2 mm. All 57 patients were analysed with 22 (38.6%) females and mean age of 72.9±10.2 yrs. Hooks protrusion zone of AMPLATZER device was found in shallow position within the LAA in 15 patients (50%), whereas all patients with WATCHMAN had deep hooks zone position (p<0.001). Hooks-PA close proximity was present in 11 (19.3%) patients, similarly in AMPLATZER vs WATCHMAN groups (5 [16.7%] vs. 6 [22.2%], p=0.74). Close hooks-PA proximity in shallow hooks zone position was found exclusively in AMPLATZER group (n=3, 10%).

Conclusions: Hooks protrusion zone is positioned more shallow within the appendage in AMPLATZER vs WATCHMAN but with similar frequency of close proximity to PA. Impact of device-specific hooks design and its position within the appendage on PA perforation risk needs further research.

INTERVENTIONS FOR VALVULAR DISEASE

Health-related quality of life following TAVI using transfemoral and transaortic approaches – single-centre study

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Aims: The aim of the study was to evaluate short- and long-term changes in quality of life status in patients undergoing transaortic TAVI procedure, in comparison to transfemoral TAVI and aortic valve replacement (AVR) patients.

Methods and results: 97 patients' samples were included in the study. 32 patients underwent transaortic TAVI procedure, 31 transfemoral TAVI procedure and 34 patients underwent AVR procedure. The quality of life status was assessed with EQ-5D-3L questionnaire at baseline, after 1-month and 1-year follow-up. The overall mean patient age was 80 (61-92) years and logistic EuroSCORE mean was 12.45% (1.39-78.98%). The analysis of baseline values compared to follow-up data showed a significant improvement of declared quality of life in all three groups (p<0.001). At baseline, up to 23.7% patients reported extreme problems in EQ-5D-3L questionnaire, mainly in pain and discomfort dimension, and up to 76.3% patients declared some problems before the procedure. Declared health state at baseline was significantly lower in transfemoral patients (TAVI TF) (p<0.001) and after 1 month there were no differences between the 3 groups (p=0.987). After 1 year, the AVR patients' results of EQ-5D-3L index value were lower in comparison to TAVI patients (p<0.05). There were significant differences between results of EQ-5D-3L index value for the period of time (TAVI Tao p<0.001; TAVI TF p<0.05; AVR p<0.05). In all groups, the values were significantly increasing after 1-month and 1-year follow-up, in comparison to baseline value. Significant differences were also found between visual analogue scale values (VAS) for TAVI TAo and AVR group (p<0.001) and TAVI TF and AVR (p<0.001) after 1 month and 1 year. AVR patients reported lower values of VAS; the two TAVI groups presented no differences between them.

Conclusions: A great improvement of quality of life status was presented in the following study for all three groups. Regardless of the TAVI approach, EQ-5D-3L index value and visual analogue scale values were significantly rising after 1-month and 1-year follow-up; the AVR patients, however, reported lower health status in comparison.

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INTERVENTIONS FOR VALVULAR DISEASE

Procedural and haemodynamic outcomes of the Portico transcatheter aortic valve in patients with adverse anatomy

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Aims: To evaluate procedural and 30-day outcomes of the first 50 cases treated with the Portico self-expanding valve (St. Jude Medical, St. Paul, MN, USA) in patients selected mainly on the basis of adverse aortic root and/or peripheral vascular anatomy.

Methods and results: Single-centre, retrospective report of the first 50 cases receiving the Portico valve at a tertiary care hospital. The Portico valve was initially selected for the following indications: (1) unfavourable annular or LVOT calcium; (2) small calcified sino-tubular junction (STJ), especially if concentric; (3) borderline sizing for a balloon-expandable valve; (4) small calibre ilio-femoral arteries; (5) predominant aortic regurgitation (AR), to take advantage of ascending aorta anchoring with this valve. Mean age of the patients was 84.4 with a slight female preponderance (64%). The mean EuroSCORE II was 8.7. 14% of patients had severe LV impairment. Adverse aortic root calcification was present in 22 (44%) cases on pre-procedural CT scans. There was left atrial appendage thrombus in 2 cases. There were 10 cases with a minimum mean ilio-femoral diameter ≤6.5 mm – the smallest being 5.3 mm. 38% of patients had a horizontal aortic root (annular plane angle >50°) and 18% had a low coronary height (≤12 mm). At 30 days, there was one death. The pre-procedural mean AV gradient of 46.3±16 decreased to 8.31±4.35 after implantation and 8.68±5.47 mmHg at 30 days. There was moderate AR in 8 patients – out of these, 2 patients had reduction in the degree of AR to mild on later follow-up at 6 months. This resulted in a rate of >mild AR of 12% at 6 months. There were no cases of severe AR. There was one case of subacute leaflet thrombus. The AV gradient improved to baseline at six months with oral anticoagulation, and the patient had no adverse sequelae.

Conclusions: In this cohort, with a high incidence of adverse aortic root and peripheral vascular anatomy, the Portico valve demonstrated excellent procedural safety and 30-day haemodynamic performance. There were no major vascular complications.

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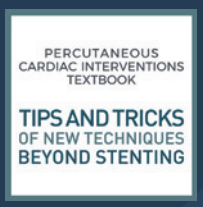

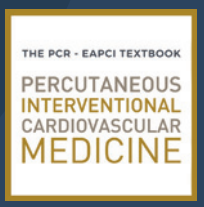

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