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Editorial

VAD and CHIPS please

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Percutaneous coronary intervention (PCI) outside emergency settings such as shock and ST elevation myocardial infarction is a remarkably low risk procedure. For elective PCI, 2017 UK BCIS registry data shows a mortality rate of 0.1%. For patients presenting with a non ST elevation myocardial infarction the risks of adverse outcomes are higher but still small with an in hospital mortality rate of <1% [1]. There are however a small number of cases for whom the risk can be much higher. The treatment of complex, often calcific, coronary artery disease in high jeopardy positions such as the left main stem in combination with poor left ventricular function increases procedural risk considerably. This risk is compounded if the procedure is prolonged or requires the use of complex techniques such as rotational atherectomy. Not only is there an increased risk of adverse events including myocardial infarction and death but there is also an increased likelihood of incomplete revascularisation or even procedural failure due to premature discontinuation as a result of the onset of pulmonary oedema or other manifestation of low cardiac output. While it can be argued that many such cases are better treated by coronary artery bypass surgery there are often factors such as age, frailty, co-morbidity and poor left ventricular function that make surgical risk prohibitive. For such patients, revascularisation by PCI may be the only strategy that offers the chance of a longer and better quality of life without intractable angina and breathlessness. Such high risk, complex PCI has been given the acronym of CHIP – complex, high risk indicated procedure. Specific training is available for these procedures but even in the most expert hands the risk of haemodynamic complications greatly exceeds that of 'standard' cases. In an effort to reduce the hemodynamic consequences of such procedures, PCI operators have long used the intra-aortic balloon pump. This provides only marginal haemodynamic support and is not associated with improved procedural outcomes in CHIP cases [2].

The development of temporary percutaneous left ventricular assist devices (pLVAD) has allowed much more effective LV support with flows of over 4 l/min. Such devices offload the left ventricle during the procedure reducing myocardial work and oxygen requirements, largely preventing an acute rise in left atrial pressure and the onset of pulmonary oedema during a PCI procedure while helping to maintaining perfusion to vital organs including the heart itself. Only one such device, Impella® (Abiomed, USA) is in current use although others are in development. This device consists of a micro-axial flow pump and motor mounted on a pigtail catheter and provides 2.5 to 4.3 l/min of flow depending upon the choice of device, Impella 2.5 or Impella CP (a 5 l/min device is available but this requires a surgical vascular approach). The device is most commonly inserted via the common femoral artery however in patients with severe peripheral arterial disease, alternatives include a percutaneous axillary artery approach [3]. In this edition of the journal, a clinical expert consensus document written by a working group of the Italian Society of Interventional Cardiology and endorsed by the Spanish and Portuguese Societies, summarises much of the available data on this device and describes a set of indications for its use [4]. No new data are provided; most of the data for Impella use in CHIP cases comes from a single randomised controlled trial of 452 patients and two registry studies from the US and Europe containing 175 and 144 patients respectively. Interventional cardiologists will be familiar with the results of the PROTECT II randomised trial which demonstrated no significant reduction in a composite of adverse events including death at 30 days but a significant reduction in a slightly different set of events at 90 days [5,6]. The trial was halted prematurely on the grounds of futility and has been hotly debated because of a number of methodological problems including an imbalance in use of rotational atherectomy between groups and evidence of a learning curve at many participating centres. Registry data are encouraging with 30 day mortality rates in CHIP cases with poor ventricular function of 4% (USpella) to 5.5% (Europella) [7,8].

Based on these data, limited as they are in both quality and quantity, the authors of the consensus document suggest that the main indications for pLVAD in CHIP cases are (1) unprotected left main stem cases with mid and upper tertile Syntax scores when left ventricular function is severely impaired, (2) complex multi-vessel cases with severe LV dysfunction in which use of the Impella may aid complete revascularisation, (3) chronic total occlusion cases when the anatomy is complex and LV function severely impaired, (4) sole remaining vessel cases, (5) severe calcific disease in association with severe LV dysfunction especially when rotational atherectomy is used. In all of these cases, the Impella should be sited before the case is started to avoid 'crashing' on to support.

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How useful will this paper be? There are existing US and UK guidelines on the use of pLVAD devices for CHIP cases. Guidelines from the US suggest that use of pLVAD support is indicated when there is severe left ventricular dysfunction (EF < 35%) or recent heart failure and there is 'anticipated technically challenging or prolonged PCI' [9]. In the UK, a NICE interventional procedure guidance (IPG633) provides limited support for use of the 'temporary heart pump' in high risk PCI and rightly advocates patient selection and treatment by experienced multidisciplinary teams in specialised centres [10]. This consensus document provides more detailed guidance for clinicians and can also be used by health administrators and funding bodies when considering the appropriateness of device use. The paper should also act as a wake-up call to the ESC to incorporate guidance on pLVAD use in to revascularisation guidelines. While a further randomised trial avoiding some of the pitfalls of PROTECT II would help to define the place of this technology, it is our opinion that a pLVAD should be considered in all CHIP cases when ventricular function is severely impaired or when the presenting episode has been associated with haemodynamic compromise.

Declaration of Competing Interest

The authors report no relationships that could be construed as a conflict of interest.

References

[1] https://www.bcis.org.uk/resources/audit-results/.
[2] D. Perera, R. Stables, M. Thomas, J. Booth, M. Pitt, D. Blackman, A. de Belder, S. Redwood, BCIS-1 investigators. Elective intra-aortic balloon counterpulsation during high-risk percutaneous coronary intervention: a randomized controlled trial, JAMA 304 (2010) 867–874.
[3] A. Kaki, N. Blank, M.C. Alraies, A. Jani, A. Shemesh, M. Kajy, A. Laktineh, R. Hasan, C.L.F. Gade, T. Mohamad, M. Elder, T. Schreiber, Axillary artery access for mechanical circulatory support devices in patients with prohibitive peripheral arterial disease presenting with cardiogenic shock, Am. J. Cardiol. 123 (10) (2019) 1715–1721.
[4] A. Chieffo, F. Burzotta, F. Pappalardo, et al., Clinical expert consensus document on the use of percutaneous left ventricular assist support devices during complex high risk indicated PCI, Int. J. Cardiol. (2019).
[5] W.W. O'Neill, N.S. Kleiman, J. Moses, J.P. Henriques, S. Dixon, J. Massaro, I. Palacios, B. Maini, S. Mulukutla, V. Dzavík, J. Popma, P.S. Douglas, M. Ohman, A prospective, randomized clinical trial of hemodynamic support with Impella 2.5 versus intra-aortic balloon pump in patients undergoing high-risk percutaneous coronary intervention: the PROTECT II study, Circulation. 126 (2012) 1717–1727.
[6] G.D. Dangas, A.S. Kini, S.K. Sharma, J.P. Henriques, B.E. Claessen, S.R. Dixon, J.M. Massaro, I. Palacios, J.J. Popma, M. Ohman, G.W. Stone, W.W. O'Neill, Impact of hemodynamic support with Impella 2.5 versus intra-aortic balloon pump on prognostically important clinical outcomes in patients undergoing high-risk percutaneous coronary intervention (from the PROTECT II randomized trial), Am. J. Cardiol. 113 (2) (2014) 222–228.
[7] B. Maini, S.S. Naidu, S. Mulukutla, et al., Realworld use of the Impella 2.5 circulatory support system in complex high-risk percutaneous coronary intervention: the USpella registry, Catheter. Cardiovasc. Interv. 80 (2012) 717–725.
[8] K.D. Sjauw, T. Konorza, R. Erbel, P.L. Danna, M. Viecca, H.H. Minden, C. Butter, T. Engstrøm, C. Hassager, F.P. Machado, G. Pedrazzini, D.R. Wagner, R. Schamberger, S. Kerber, D.G. Mathey, J. Schofer, A.E. Engström, J.P. Henriques, Supported high-risk percutaneous coronary intervention with the Impella 2.5 device the Europella registry, J Am Coll Cardiol. 54 (25) (2009) 2430–2434.
[9] C.S. Rihal, S.S. Naidu, M.M. Givertz, W.Y. Szeto, J.A. Burke, N.K. Kapur, M. Kern, K.N. Garratt, J.A. Goldstein, V. Dimas, T. Tu, 2015 SCAI/ACC/HFSA/STS clinical expert consensus statement on the use of percutaneous mechanical circulatory support devices in cardiovascular care, J. Am. Coll. Cardiol. 65 (19) (2015) 2140–2141.
[10] https://www.nice.org.uk/guidance/ipg633/chapter/1-Recommendations.