Editorial

High risk percutaneous coronary interventions—significance of left ventricular assist device for clinical practice

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Cohen *et al*. have published the article (1), analyzing the use percutaneous left ventricular assist device (PLVAD) to support high risk percutaneous coronary intervention (HRPCI). The authors performed retrospective observational analysis of 339 patients included in the USpella registry, who were supported for HRPCI with a micro-axial rotational pump (Impella 2.5). There were patients that have met eligibility for the Impella arm of the PROTECT II trial (2). In-hospital outcomes of the USpella registry patients were compared with the results of 216 patients treated in the Impella arm of PROTECT II randomized trial. The authors concluded that despite the higher risk of registry patients, clinical outcomes appeared to be favorable and consistent compared with the randomized trial.

It is well known that, in patients affected by extensive and complex coronary lesions with elevated SYNTAX scores such as those with more advanced age, renal dysfunction and congestive heart failure, coronary artery bypass grafting (CABG) was associated with greater clinical benefit, as recommended by the current guidelines (3,4). Because of high operative risk among patients with severe coronary artery disease and multiple comorbidities, CABG intervention could be rejected either by the heart team (5), or by a patient. HRPCI remains a viable revascularization strategy for patients, who are not suitable for surgery or for those refusing it. However, such a subset of patients is considered to be at very high risk for percutaneous coronary intervention (PCI) complications, due to the risk of hemodynamic collapse during balloon inflations or complex procedures, particularly, if coronary dissection with vessel closure or no reflow occurs. Percutaneous mechanical circulatory support to go with HRPCI has been an important step to facilitate care and reduce morbidity and mortality among high-risk patient subsets (6-8). Nowadays, cardiovascular practice has seen rapid growth in cohorts that may benefit from the use of such devices (9). That is why the good results of USpella registry HRPCI patients is very important and the Cohen's *et al*. article is relevant.

It is often thought that patients enrolled in coronary intervention trials are not representative of real-world patients and randomized trial patients are carefully selected with significantly less risk than those treated in a native clinical practice (10). Thus, we expect worse treatment results in real life. The same could be seen in Cohen's *et al.* baseline characteristics analysis. Registry patients were more likely to have chronic kidney disease, prior myocardial infarction, prior CABG, and had more extensive coronary artery disease. However, in-hospital results were inexplicably perfect for registry patients. The mortality in USpella patients was numerically lower than the mortality in the Impella arm of PROTECT II trial and myocardial infarction and repeat revascularization rates were significantly lower in registry patients. There were no incidents of stroke or transient ischemic attacks, emergency CABG, acute aortic regurgitation or valve injury in the registry. Other adverse events including vascular complications, blood transfusions, acute kidney injury, groin hematoma, and transient hypotension during support were similar for the registry and clinical trial patients. Surprisingly better results in a more severe group of USpella registry patients hint at the presence of patient selection bias.

At present, variables that contribute to elevated risk during PCI have been well defined by 2015 SCAI/ACC/HFSA/STS clinical expert consensus statement (11) and can

be categorized into three major groups: (I) patient specific; (II) lesion specific; and (III) clinical presentation specific. The Cohen's *et al*. article shows well the patient specific (age, left ventricular function, symptoms of heart failure, diabetes mellitus, chronic kidney disease, prior myocardial infarction, peripheral vascular disease) and the lesion specific data (multivessel or left main disease, saphenous vein grafts) in both USpella registry and the Impella arm of PROTECT II trial patients. However, the authors did not provide the analysis of patients' clinical presentation. We cannot understand how many patients with acute coronary syndrome or stable angina were in the study groups. The only information that we have from the authors is that patients with ST segment elevation myocardial infarction and cardiogenic shock were excluded (1).

We did not have any data about the proportion of non-ST elevation acute coronary syndrome patients in the registry and clinical trial groups. Nevertheless, we had the evidence of an extremely poor prognosis in non-ST elevation acute coronary syndrome patients with multivessel disease (non-STEMI patients with MV disease) that often undergo HRPCI. For example, based on a single-center real life registry the hospital mortality in the overall cohort of non-STEMI patients with MV disease was 8.7% (in the PCI group: 5.8%, 8% in the CABG group, and 27.8% in the conservative strategy group) (12). In addition, the analysis showed that the majority of non-STEMI patients with MV disease are candidates for emergency or urgent PCI, which can be successfully performed. However, a significant proportion of patients should be considered as candidates for CABG. A significant proportion of patients requiring revascularization by CABG does not get it at the optimal time, which leads to the conversion of a certain number of non-STEMI patients to conservative therapy associated with a very poor prognosis. Non-STEMI patients with MV disease represent a large group of patients with acute coronary syndrome who may be targeted for PLVAD-supported HRPCI (12).

The Cohen's *et al*. article is a very relevant paper that demonstrates encouraging results using PLVAD (Impella 2.5) for patients undergoing high-risk PCI in real-world practice. These in-hospital results were inexplicably perfect for registry patients compared to the Impella arm of PROTECT II randomized trial. Better results in the registry patients may be due to patient selection bias associated with the lack of detailed acute coronary syndrome presentation analysis.

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Footnote

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