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Revascularization in ischemic heart failure with reduced left ventricular ejection fraction. The impact of complete revascularization

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Abstract

Heart failure is a growing problem worldwide, with coronary artery disease being the underlying cause of over two-thirds of cases. Revascularization in this group of patients may potentially inhibit the progressive damage to the myocardium and lead to improved outcomes, but data in this area are scarce. This article emphasizes the role of qualification for revascularization and selection of method (percutaneous coronary intervention vs. coronary artery bypass grafting) and subsequently focuses on the issue of completeness of revascularization in this group of patients.

Key words: heart failure, coronary artery disease, complete revascularization.

Streszczenie

Niewydolność serca stanowi coraz większy problem na świecie. Choroba wieńcowa jest czynnikiem etiologicznym ponad 2/3 przypadków. Rewaskularyzacja w tej grupie pacjentów może powstrzymać postępujące uszkodzenie miokardium, a tym samym prowadzić do poprawy rokowania. Niestety dane w tym zakresie są nieliczne. W niniejszej pracy podkreślono rolę kwalifikacji do rewaskularyzacji, wyboru jej metody (przezskórne interwencje wieńcowe *vs* pomostowanie aortalno-wieńcowe), a następnie skoncentrowano się na kwestii kompletności rewaskularyzacji w tej grupie chorych.

Słowa kluczowe: niewydolność serca, choroba wieńcowa, kompletna rewaskularyzacja.

Introduction

Heart failure (HF) is a growing problem for health care worldwide. It is currently estimated that 1–2% of all people living in the developed countries suffer from HF [1]. There is a clear relationship between socioeconomic development and ageing of societies and the occurrence of heart failure. Ischemia is the predominant etiologic factor of HF, accounting for over two-thirds of all HF cases [2]. With improved treatment – and reduced mortality – of acute coronary syndrome patients and the optimized care of stable coronary artery disease (CAD) patients, the number of patients with ischemic HF will inevitably grow.

The treatment of HF has improved over the years with the introduction of milestone forms of therapy, such as contemporary medical treatment (e.g. β-blockers) [3], orthotopic heart transplantation (OHT) or prevention of sudden cardiac death [4]. However, it seems that revascularization in ischemic HF was never recognized as one. In fact, despite common use of both percutaneous coronary interventions (PCI) and coronary artery bypass grafting (CABG) in ischemic heart failure, data supporting its role are still scarce [5].

Systolic ischemic heart failure

This review concentrates on treatment of heart failure with reduced ejection fraction (HFrEF), defined per the 2016 ESC heart failure guidelines as HF with left ventricular ejection fraction (LVEF < 40%) and ischemic etiology. Patients without significant impairment of LVEF with diagnosed heart failure form a completely different group (regarding treatment and prognosis) and are not the subject of this article.

Ischemia is the most frequent cause of systolic HF. Treatment of patients with this HF etiology differs from other forms of HF, as there is often an opportunity to remove or reduce the basic cause of myocardial damage – ischemia. Despite this fact, data on revascularization in this group of patients are limited. The guideline-based treatment in HF is generally based on a single scheme, consisting of medical treatment, prevention of sudden cardiac death and, finally, qualification for mechanical circulatory support or OHT. This form of treatment reflects the natural progression of HF, caused by a "vicious circle" mechanism. Myocardial damage leads to activation of the parasympathetic system and the renin-angiotensin-aldosterone axis, providing a short-term compensation of the circulatory system. In the long run,

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however, it causes deprivation of energetic resources. Subsequently, oxidative stress leads to further myocardial damage. Prolonged activation of these mechanisms causes electrolyte imbalance and arrhythmia [6]. Lack of medical intervention at this stage leads to inevitable progression of HF, a breakdown of compensation mechanisms, multi-organ failure and finally electrical instability of the heart and death [7, 8].

In the "vicious circle" mechanism the role of progression of underlying disease, i.e. long-term ischemia and hibernation of myocytes, is another, sometimes underestimated, mechanism leading to further myocardial damage. It can be an additional, alongside the neuro-hormonal, mechanism of HF progression. It seems that in ischemic HF insufficient attention is paid to the role of revascularization in stopping this mechanism.

Invasive diagnostics

Even the qualification for coronary angiography (CA) in HF remains unclear. In everyday clinical practice *de novo* HF is considered an indication for invasive diagnostics, but guidelines do not support it. Currently two ESC guidelines undertake this issue:

1. The guidelines for treatment of stable coronary artery disease indicate that CA is indicated in all patients with impaired LVEF < 50% and angina pectoris. In absence of angina further non-invasive testing is required [9].
2. The 2016 Acute and Chronic Heart Failure Guidelines define angina pectoris, electrical instability and cardiac arrest as the basic indications for CA. In other cases, non-invasive stress testing should precede qualification [6].

However, there are clinical scenarios not reflected in the guidelines. Conditions such as further reduction of LVEF in ischemic HF commonly result in CA qualification, even without clear guideline support.

Myocardial viability

The presence of viable myocardium as a target for revascularization has become the gold standard ever since the Allman *et al.* meta-analysis in 2002, where a benefit of revascularization only in patients with myocardial viability was found [10]. Recently Inaba *et al.* published a meta-analysis confirming the results of the Allman study [11]. The reason for viability testing is to identify regions of hibernated myocardium (as opposed to tissue with no potential for improvement after reperfusion). The currently available methods of myocardial viability testing are:

1. Transthoracic resting echocardiography (indirectly, via assessment of parameters such as wall motion score index, measurement of wall thickness, etc.),
2. Echocardiographic stress testing (dobutamine or exercise induced),
3. Magnetic resonance imaging (MRI),
4. Single photon emission computed tomography (SPECT),
5. 18F-fluorodeoxyglucose positron emission tomography (18-FDG-PET).

Transthoracic resting echocardiography is an often-underappreciated method, but in everyday clinical practice its value is undeniable. Especially in numerous primary care centers where other methods are unavailable, the role of echocardiography prior to invasive or surgical procedures should be essential.

As for the other methods, numerous studies have been published since in this area. Entering the phrase "myocardial viability" in the pubmed.org search engine returns over 2200 results. The information mostly concerns the selection for the optimal myocardial viability testing method. It must be recognized that no significant advantages of any of the available viability testing methods have been proven.

Moreover, despite the very significant position of myocardial viability testing in current guidelines and clinical practice, there are no randomized data to support the influence of revascularization in viable myocardial segments on improved prognosis in HF patients; both the STICH trial [12] and the PARR-2 trial showed no real benefit of viability-guided revascularization [13]. It is also important that there are hypotheses that support revascularization in non-viable regions, especially regarding the question of electrical stability. Although studies such as an analysis by Brugada *et al.* have not proven the influence of revascularization on ventricular arrhythmia substrate modification [14], ischemia of the para-cicatrix region is considered as a potential arrhythmia trigger.

Revascularization – coronary artery bypass grafting

Contemporary evidence-based knowledge on revascularization in HF has been founded on the same clinical information for many years now. The cornerstone of this knowledge was published by Rahimtoola over 30 years ago. He stated that LV function in hibernated myocardium may be reversed with improvement of blood flow or reduction of oxygen demand [15]. The basis for implementation of viability-based revascularization was the aforementioned Allman analysis. However, the present position of surgical revascularization, represented by its status in the 2014 Myocardial Revascularization guidelines [5], is a result of the only contemporary randomized study on revascularization in ischemic heart failure, the STICH trial [12]. Even though it was an overall negative trial, failing to achieve its primary endpoint (death from any cause), subanalyses of all-cause mortality in a per protocol analysis as well as mortality from cardiovascular causes have shown a clear benefit for patients undergoing CABG with optimal medical treatment (OMT) versus OMT alone. It is worth mentioning that there is a general conviction that the STICH population is a "real" ischemic HF population, with significantly impaired LVEF and a significant proportion of comorbidities. However, the low prevalence of implantable cardioverter defibrillator (ICD) or cardiac resynchronization therapy defibrillator (CRT-D) in the STICH trial is a potential confounder of the results.

Due to conflicting recruitment, another randomized trial, the HEART study, was prematurely stopped and did not produce significant results [13]. An overview of available registries on patients undergoing CABG, providing informa-

tion on "real life" patient care, also shows a clear advantage of CABG over OMT, such as an analysis of the APPROACH registry. This analysis, however, bears a common limitation of utilizing a strictly clinical definition of HF, with no regard to LVEF. In this analysis of HF patients over 50% of subjects had an LVEF of > 50%. This does not change the fact that the role of CABG in ischemic HF is significant, with a strong position in contemporary guidelines.

However, many ischemic HF patients, especially with regard to age and profile of comorbidities, are considered unsuitable cardiac surgery candidates and are subsequently qualified for PCI.

Revascularization – percutaneous coronary intervention

The number of patients with ischemic HF patients qualified of PCI has equaled and exceeded the number of patients qualified for CABG [16, 17]. Despite the marginal role of PCI in the 2014 myocardial revascularization guidelines, a consequence of the lack of randomized data on PCI in HF, the role of percutaneous revascularization is growing, and one might argue that in real-life conditions it has already exceeded the role of CABG. The available data on PCI in HF are derived from comparisons to CABG. A paucity of randomized data is also clear, as shown in an analysis by Hlatky *et al.*, where in an analysis of available randomized studies on PCI vs. CABG only 17% of patients had "abnormal left ventricular function" [18]. Therefore, available data are mostly based on registries. Again, a strictly clinical definition of heart failure is often utilized and a large proportion of subjects have preserved LVEF in these studies. The CREDO-Kyoto registry investigators concluded that in a large population of HF patients undergoing first time revascularization CABG is related to a survival benefit in 3-year observation, especially in patients with a higher SYNTAX score. The mean LVEF in both study groups is 46.6% [17]. In an analysis from the APPROACH registry by Tsuyuki *et al.* a clear benefit resulting from any form of revascularization was found, with a small survival benefit in CABG patients over the PCI group. Similarly, in the revascularization group 58.8% had an LVEF of above 35% [19]. One could argue that such results are difficult to extrapolate to the systolic HF population. On the other hand, studies regarding the use of PCI in HF patients with a significant burden of comorbidities (larger than in the STICH population), along with a significant impairment of LVEF and complex coronary anatomy, concentrate on the use of mechanical circulatory support during high-risk PCI procedures, either with the use of the Impella device (PROTECT-II) or intra-aortic balloon pumping (BCIS-1). These studies show very good results of PCI in an extremely difficult patient population, but are concentrated on immediate and short-term procedural success rather than long-term outcomes. The recently published long-term outcomes of the BCIS-1 trial show a benefit for patients treated with percutaneous support, but even for the authors this is difficult to rationalize [20, 21]. Moreover, the results of these studies again do not reflect everyday clinical practice. There is a great need for more data on PCI in HF.

Completeness of revascularization

While data on the role of CABG and, especially, PCI in HF are insufficient, the information on particular treatment strategies is even more lacking. Completeness of revascularization (CR) has been one of the "hot topics" in coronary revascularization for many years, and there is a general consensus that it should lead to improved results.

There is a hypothetical rationale to consider complete revascularization of utmost importance in HF patients, even more so than in patients with preserved LVEF. Restoring blood flow to regions of hibernated muscle may improve contractility and minimize adverse remodeling, leading to more pronounced benefits than in patients with preserved ventricular function. Protection from ventricular arrhythmia may also be of utmost importance, as persistent ischemia can be a trigger for arrhythmia [14].

The definition of CR itself is a point for discussion. At least three definitions are used: angiographic, physiological (FFR-based) and functional (viability-based).

Anatomical CR is achieved by stenting or grafting every angiographically significant lesion, usually with exclusion of small vessels (i.e. < 2 mm diameter). A strictly anatomical definition may be reasonable in HF and, due to the aforementioned rationale, is often used. In select cases, especially in presence of ventricular arrhythmia or in no-option advanced HF patients, decisions to revascularize based strictly on angiographic data are undertaken.

However, with data from the FAME and FAME-2 trials fractional flow reserve (FFR) assessment may add to the decision-making process, leading to achievement of "physiologically" complete revascularization – understood as revascularization of every vessel with significant stenosis in FFR [22]. There are, however, limitations to FFR in heart failure patients, such as the influence of higher left ventricular end diastolic pressure on the result, which may lead to inconsistent outcomes in select cases.

The third definition is functional, myocardial viability based [23]. In myocardial viability testing usually global improvement of contractility is assessed. In the aspect of complete revascularization, testing viability in regions supplied by particular coronary arteries should be performed. This may provide sufficient data to revascularize only in viable territories, while even angiographically significant lesions may be treated conservatively.

Despite many rationales to aim for CR, evidence-based data are not unanimous and in HF particularly are scarce. The most important randomized data, suggesting a benefit resulting from complete revascularization, or rather a burden resulting from incomplete revascularization, are derived from the SYNTAX and FAME trials [22, 24]. These studies, however, did not incorporate significant proportions of HFrEF patients (FAME – mean LVEF 57.1% in angiography group, SYNTAX – 1.8% with HF and LVEF < 30%). A summary of available data on CR with special regard to HFrEF patients is presented in Table I. These studies show that complete revascularization is generally related to improved results, although it is often achieved in pa-

Tab. I. Data on compete revascularization with special regard to patients with heart failure and impaired left ventricular ejection fraction (LVEF)

Study name	Study type	Number of patients	Method of revascularization	Percentage of patients with impaired LVEF	Benefit of CR	Benefit of CR in impaired LVEF
CASS (Bell *et al.*) [25]	Observational	3372	CABG	4.3%	Only CCS III/IV, especially LVEF < 35%	Improved 6-year survival in patients with CCS III/IV angina
NHLBI (Bourassa *et al.*) [30]	Observational	757	PCI	N/A (21% with LVEF < 50%)	Reduced late occurrence of CABG	N/A
Bell *et al.* [31]	Observational	867	PCI	N/A (23% with LVEF ≤ 50%)	No difference	N/A
BARI (Kip *et al.*) [32]	Observational	2047	PCI	N/A (73.9% with LVEF < 50%)	Reduced need for CABG	N/A
BARI (Vander Salm *et al.*) [33]	Observational	1507	CABG	N/A (8% with HF, mean LVEF 61 ±13%)	No difference	N/A
Scott *et al.* [34]	Observational	2067	CABG	N/A ("severe LV dysfunction" in 2% of subjects)	Improved survival	None; LV dysfunction correlated with more IR
Ijsselmuiden *et al.* [35]	Randomized	219	PCI	N/A	No difference	N/A
Kieisli *et al.* [36]	Observational	1034	CABG	N/A (29% with LVEF < 50%)	No difference after adjustment for risk factors	None reported
NYS (Hannan *et al.*) [37]	Observational	21945	PCI	10.2% LVEF < 40%	Improved survival	No benefit
APPROACH (McLellan *et al.*) [38]	Observational	1956	PCI	5% LVEF ≤ 30%	Less need for CABG, trend towards better survival	N/A
Kozower *et al.* [39]	Observational	500	CABG	N/A (mean LVEF 46%)	Improved survival (octogenarians only)	N/A
NYS (Hannan *et al.*) [40]	Observational	11294	PCI	11% LVEF < 40%	Improved survival	No benefit
Valenti *et al.* [41]	Observational	486	PCI	34.3% LVEF < 40%	Improved survival	N/A
Rastan *et al.* [42]	Observational	8806	CABG	4.8% LVEF < 30%	No difference	No difference
Mohr *et al.* [43]	Randomized/ observational	1541	CABG	3.3% LVEF < 30%	Less repeat revascularization	N/A
Aziz *et al.* [44]	Observational	580	CABG	N/A (mean LVEF ≈ 45%)	Improved survival (octogenarians only)	N/A
Lehmann *et al.* [45]	Observational	679	PCI	18.4% LVEF ≤ 30%	Improved survival	N/A

CABG – coronary artery bypass grafting, PCI – percutaneous coronary intervention, N/A – not available, CR – completeness of revascularization.

tients with a smaller burden of comorbidities and favorable coronary anatomy. Nonetheless, it is important to note that patients with reduced LVEF have either been excluded from these studies or formed a small subset of analyzed patients. Often the results in this subgroup have not been separately assessed. Only in an analysis from the CASS registry by Bell *et al.* were patients with an LVEF of 35% or less identified as those who benefit most from complete revascularization by CABG [25].

Indications for complete revascularization are a different issue than its feasibility. Head *et al.* on the basis of the SYNTAX trial population identified the reasons for lack of complete revascularization [24]:

1. For CABG:
   a. Main reason: diffuse disease of small vessels (HR = 2.1; 95% CI: 1.51–2.93; $p < 0.001$).
   b. Other reasons: peripheral vascular disease, unstable angina, higher EuroSCORE, higher SYNTAX score, presence of total occlusion, bifurcation, higher number of lesions.
2. For PCI:
   a. Main reason: presence of total occlusion (HR = 2.45; 95% CI: 1.81–3.39; $p < 0.001$).
   b. Other reasons: diabetes, insulin treatment, fasting glucose > 110 mg/dl, hyperlipidemia, higher SYNTAX score, diffuse disease or small vessels, bifurcation, high number of lesions.

In an ischemic HF population a significant proportion of patients suffer from chronic total occlusions (CTO). The presence of CTO is one of the major factors limiting the possibility to achieve complete revascularization, especially percutaneously. Moreover, it has recently been shown that the presence of CTO is related to inferior outcomes in this patient population [26]. Even with progressing experience of operators with management of CTO, the frequency of CTO recanalization remains low, in all-comer registries reaching not more than 10% [27]. Especially in the high-risk HF patient population there is no agreement on CTO management. Current guidelines for managing HF and stable CAD and for myocardial revascularization, as well as the EuroCTO Club consensus, do not provide recommendations on occlusion recanalization in the ischemic HF subpopulation [5, 9, 28].

This overview of difficulties in achievement of complete revascularization is the basis of the "reasonable incomplete revascularization" concept, presented by Dauermann. It was argued that it is acceptable not to revascularize for certain anatomical (small vessel lesion, asymptomatic side-branch closure), functional (non-viable myocardium segments, less than 5% of myocardium with ischemia) or physiological (FFR > 0.8) reasons. This concept, although theoretically attractive, has not yet been validated in a systolic HF population [29].

With all this information in mind, it is important to remember that ischemic HF patients comprise a group with the most advanced form of CAD. Often, even after careful selection of indications for PCI or CABG, due to the complexity of coronary lesions or presence of CTO, complete revascularization remains an optimal, but impossible goal.

Conclusions

The decision on revascularization in ischemic HF very often cannot be made solely on the basis of current guidelines. A personalized approach towards every patient is mandatory, and therefore the role of a Heart Failure Team in this process with regard to the patient's medical history, clinical status and coronary anatomy is vital. These decisions should also be undertaken with regard to the possibility of achieving complete revascularization, with the consideration that in certain conditions it may not be feasible.

Disclosure

Authors report no conflict of interest.

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