

COnteMporary Modalities In Treatment of Heart Failure: a report from the COMMIT-HF registry

Mariusz Gąsior¹, Łukasz Pyka¹, Jarosław Gorol¹, Michał Hawranek¹, Mateusz Tajstra¹, Grzegorz Słonka¹, Anna Kurek¹, Adam Krajewski¹, Piotr Rozentryt¹, Marek Gierlotka¹, Andrzej Lekston¹, Marian Zembala², Lech Poloński¹

¹3rd Department of Cardiology, SMDZ in Zabrze, Medical University of Silesia, Katowice, Poland

²Department of Cardiac Surgery and Transplantology, SMDZ in Zabrze, Medical University of Silesia, Katowice, Poland

Abstract

Background and aim: Heart failure (HF) has become a global health problem and is a significant burden for health-care systems worldwide. It is reported as the reason for 1–4% of all hospital admissions in developed countries. The prognosis in HF remains unfavourable. Having at our disposal a large group of patients with systolic HF at a high-volume reference cardiovascular centre with the possibility to implement complete diagnostics and therapy we decided to analyse the clinical data, administered therapies, and prognosis in HF patients.

Methods: The COMMIT-HF is a single-centre observational study that is underway in the Third Chair and Department of Cardiology of the Silesian Centre for Heart Diseases in Zabrze. The study population is a cohort of adult HF patients with left ventricular ejection fraction (LVEF) $\leq 35\%$. Patients with acute coronary syndromes are excluded from the analysis. Complete patient demographics: medical history, hospitalisation data (diagnostic and therapeutic), and in-hospital results are collected. Twelve-month follow-up is based on the information acquired from the national health-care provider.

Results: As of 31 December 2013 a group of 1798 patients have been enrolled (mean age 60.9 ± 12.8 years, 20.3% of subjects female, mean LVEF 26.06 ± 6.09 , ischaemic aetiology 64.5%, atrial fibrillation 33.2%, diabetes mellitus 41.2%, chronic kidney disease stage \geq III 29%). A significant proportion of patients underwent invasive procedures (ICD/CRT-D implantation 61.1%, coronary angiography 56.2%, PCI 19.6%, CABG 5.1%, heart transplantation qualification 5.5%, IABP 2.5%). All-cause 12-month mortality was 12.5%. HF-related rehospitalisation rate was 28.9%.

Conclusions: The COMMIT-HF study will provide valuable information on the HF patient population. Initial analyses show that in this difficult patient population satisfactory long-term results can be achieved.

Key words: heart failure, COMMIT-HF registry, study design, demographics, treatment, prognosis

Kardiol Pol 2016; 74, 6: 523–528

INTRODUCTION

Heart failure (HF) has become a major global health problem. It is also a constantly growing economic burden for national health care systems. It is estimated that 1–2% of people living in developed countries suffer from HF, leading to a common consensus that it is currently a global pandemic [1]. In the United States alone there are currently 5.8 million HF patients, and the number is expected to increase to 8.5 million by 2030 [2]. HF is a disease of developed, ageing populations [3]. In Northern America and Europe over 80% of HF patients are over 65 years old [4].

In developed countries HF is the reason for 1–4% of all hospital admissions. The medical care of HF patients accounts for 1–3% of all health-care funds in Europe, and Northern and Latin America. In the United States in 2012 the treatment of HF cost 20.9 billion dollars, and the amount is estimated to grow to 53.1 billion by 2030.

According to various studies, coronary artery disease is the most frequent reason for HF development, with ischaemic aetiology estimated to be responsible for around 2/3 of HF cases [3, 4]. With an ageing population and the increasingly

Address for correspondence:

Łukasz Pyka, MD, 3rd Department of Cardiology, SMDZ in Zabrze, Medical University of Silesia, ul. M. Curie-Skłodowskiej 9, 41–800 Zabrze, Poland, e-mail: wookash.p@gmail.com

Received: 01.09.2015

Accepted: 15.10.2015

Available as AOP: 20.11.2015

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successful treatment of coronary artery disease, this trend will remain strong.

The overall prognosis in HF is unfavourable. Before the implementation of modern HF therapies, five-year mortality was estimated to be 60–70%, with a high frequency of rehospitalisation. The introduction of novel treatment modalities resulted in a decrease in rehospitalisations of 30–50%, and a small but significant decrease in mortality [5–7]. Nonetheless, according to various analyses worldwide, the mortality rates within one year of HF-related hospitalisation are 17–45% [8].

Heart failure treatment is predominantly based on ambulatory care and is managed mainly pharmacologically. However, it seems that there is also a possibility to implement a more efficient “reparative therapy”, exercising all possibilities provided by modern interventional cardiology, electrotherapy, and cardiac surgery. With limited graft availability for orthotopic heart transplantation (OHT) and limited availability of mechanical circulatory support (MCS), it is vital to optimally implement all of the currently available treatment options.

Currently available HF registries present heterogeneous populations with diverse inclusion criteria [9–13]. There is a lack of data from highly specialised HF centres.

Therefore, having at our disposal a large group of patients with systolic HF in a high-volume cardiovascular centre with the possibility to implement complete diagnostics and therapy of HF, including revascularisation, electrotherapy, MCS, and finally OHT, we decided to analyse the clinical data, administered treatment, and prognosis in systolic HF.

METHODS

Study design

The Contemporary Modalities In Treatment of Heart Failure (COMMIT-HF) registry is a single-centre, prospective observational study that is underway in the Third Chair and Department of Cardiology in the Silesian Centre for Heart Diseases in Zabrze, Poland (ClinicalTrials.gov, NCT02536443). Data collection is patient-based (not event-based).

Study objectives

The main objective of the COMMIT-HF registry is to clarify the overall clinical characteristics of systolic HF patients, their demographics and clinical profile, current management, in-hospital outcomes, and long-term follow-up, with regard to the administered treatment.

Participants

The study population is formed by all-comer patients hospitalised in cardiology wards and intensive cardiac care units with a diagnosis of systolic HF. For the purpose of this study HF is defined as a set of symptoms resulting from myocardial systolic function impairment, confirmed in resting transthoracic echocardiography with left ventricular ejection fraction

(LVEF) \leq 35%. Patients with acute coronary syndromes (ACS) and < 18 years old were excluded from the analysis.

Procedures and data collection

Complete patient demographics; medical history, hospitalisation data (diagnostic and therapeutic) and in-hospital results are collected in electronic form by the attending physician. Twelve-month follow-up is based on the information acquired from the national health-care provider. Complete survival follow-up was available for the whole study group. Data on rehospitalisations and ambulatory care were available exclusively for the Silesian population (79.5% of subjects). There were, however, no differences in clinical characteristics and overall prognosis between the complete and the Silesian subpopulation; therefore, we decided to extrapolate these results for the whole study group.

The patients are treated according to current European Society of Cardiology heart failure treatment, myocardial revascularisation, cardiac pacing, and cardiac resynchronisation therapy guidelines.

Statistical analysis

Descriptive statistics are prepared based on patients' clinical characteristics, treatment, and outcome information for the registered patients. When normal distribution is observed, the results are presented as mean \pm standard deviation (SD). Median and interquartile range are applied in other cases. Categorical data are presented as frequency and proportion (%).

RESULTS

Clinical profile

As of 31 December 2013 a total of 1798 patients have been enrolled into the analysis. The clinical characteristics of the patients are presented in Table 1. The mean age is 60.9 ± 12.8 years and 20.3% of subjects are female. The aetiology is predominantly ischaemic (64.5%). Valvular heart disease is the underlying cause of 9% of HF cases, and other aetiologies are at 26.5%. The prevalence of comorbidities is high in the whole study population. Arterial hypertension is the most common concomitant disease (51.2%). The most patients are in functional class (according to New York Heart Association classification [NYHA]) II or III, but over 12% of subjects were NYHA IV on admission.

Echocardiographic findings

The echocardiographic characteristics are presented in Table 1 and show a profile of patients with significantly impaired left ventricular function.

Diagnostic and therapeutic procedures

The profile of diagnostic procedures is presented in Table 2. Over half of the subjects (56.2%) underwent diagnostic

Table 1. Baseline clinical characteristics

Demographics	
Age [years]	60.9 ± 12.8
Females	20.3%
Body mass index [kg/m ²]	27.6 ± 4.8
Comorbidities and medical history	
Ischaemic aetiology	64.5%
Atrial fibrillation/flutter	33.2%
Diabetes mellitus	41.2%
Chronic kidney disease (stage ≥ III)	29.0%
History of myocardial infarction	45.5%
Anaemia	36.0%
Hypertension	51.2%
COPD	14.1%
Stroke/transient ischaemic attack	6.4%
Post PCI	47.2%
Post CABG	22.1%
ICD/CRT-D prior to admission	15.5%
Clinical status on admission	
NYHA I	10.2%
NYHA II	32.5%
NYHA III	44.8%
NYHA IV	12.5%
Heart rate [bpm]	79.6 ± 29.3
Systolic blood pressure [mm Hg]	124.7 ± 4.5
Diastolic blood pressure [mm Hg]	76.2 ± 13.3
White blood cell count [×1000/μL]	7.82 ± 3.39
Haemoglobin [mmol/L]	8.56 ± 1.14
Bilirubin [μmol/L]	16.0 ± 13.7
Blood urea nitrogen [mg/dL]	9.9 ± 6.3
Creatinine level [mmol/L]	101.9 ± 58.9
NT-proBNP (median, IQR) [pg/mL]	1933 (772, 4650)
Potassium [mmol/L]	4,47 ± 0.54
Sodium [mmol/L]	137 ± 33
Echocardiographic assessment	
LVEF [%]	26.06 ± 6.09
LVEDD [mm]	64.9 ± 9.4
LVESD [mm]	52.6 ± 10.7
LVEDV [mL]	203 ± 86
LVESV [mL]	152 ± 74
Left atrium [mm]	45.5 ± 7.3
Severe mitral insufficiency	13.1%
Severe aortic valve disease	3.2%

CABG — coronary artery bypass grafting; COPD — chronic obstructive pulmonary disease; CRT-D — cardiac resynchronisation therapy defibrillator; ICD — implantable cardioverter-defibrillator; IQR — inter-quartile range; LVEF — left ventricular ejection fraction; LVEDD — left ventricle end-diastolic diameter; LVESD — left ventricle end-systolic diameter; LVEDV — left ventricle end-diastolic volume; LVESV — left ventricle end-systolic volume; NYHA — New York Heart Association; NT-proBNP — N-terminal pro-B-type natriuretic peptide; PCI — percutaneous coronary intervention

Table 2. Diagnostic procedures

Coronary angiography	56.2%
Spirometry	26.9%
Six-minute walk test	17.5%
Spiroergometry	17.0%
Right heart catheterisation	13.8%
Holter-electrocardiogram	44.6%

coronary angiography. A large proportion of patients underwent diagnostic procedures aimed at OHT qualification.

As presented in Table 3, a significant proportion of patients were subsequently qualified for invasive treatment. In the ischaemic population 354 patients underwent coronary angioplasty (PCI), which formed 30.5% of the ischaemic HF population and 46.8% of the ischaemic HF patients who underwent diagnostic angiography.

Implantable cardioverter-defibrillator (ICD) or cardiac resynchronisation therapy defibrillator (CRT-D) was found in 15.5% of patients at the moment of inclusion into the analysis. ICD or CRT-D implantations were performed in 41.1% and 20.0% of patients, respectively. 1.7% of subjects were qualified for implantation in following hospitalisations. 30.5% of the patients were included into the home-monitoring programme.

A significant proportion of patients were assessed for OHT indications, among whom 17% underwent spiroergometry for OHT candidate screening, while 13.8% had right heart catheterisations performed. In the whole study population 5.5% of subjects were qualified for the active OHT candidate list, and 1.8% finally underwent OHT.

The patients were also subject to some less frequent procedures, including catheter ablation, valve surgery, transcatheter aortic valve implantation, or balloon aortic valvuloplasty.

Medical treatment

The profile of medical treatment is presented in Table 3. The use of guideline-based HF treatment was high.

Follow-up

Complete 12-month follow-up data are presented in Table 4. In-hospital mortality was at the level of 1.56%, while 12-month all-cause mortality was 12.5%. The rate of 12-month heart-failure rehospitalisation was 28.9%. The mean number of general practitioner and cardiac outpatient clinic visits during the 12-month observation period per patient was 12.6 ± 7.9 and 3.1 ± 2.4, respectively.

DISCUSSION

The COMMIT-HF registry presents the modalities of treatment offered to patients with systolic HF in a highly specialised

Table 3. Therapeutic strategies

Pharmacological treatment	
Intravenous diuretics	8.4%
Catecholamines	3.0%
Beta-blockers	94.7%
Angiotensin converting enzyme inhibitors	73.4%
Angiotensin receptor blockers	8.0%
Loop diuretics	82.1%
Thiazide diuretics	12.5%
Mineralocorticoid receptor antagonists	83.4%
Statins	74.2%
(Novel) oral anticoagulants	34.1%
Antiplatelet	69.9%
Digoxin	23.5%
Amiodarone	11.5%
Oral hypoglycaemics	17.3%
Insulin	15.6%
Non-pharmacological interventions	
Respirator therapy	1.2%
Haemodiafiltration	0.3%
Intra-aortic balloon pump	2.5%
ICD implantation	41.1%
CRT-D implantation	20.0%
ICD/CRT-D qualification	1.7%
Home-monitoring	30.5%
Percutaneous coronary intervention	19.6%
Coronary artery bypass grafting	5.1%
Mitral valve surgery	2.2%
Aortic valve surgery	1.9%
Transcatheter aortic valve implantation	1.0%
Balloon aortic valvuloplasty	0.6%
Heart transplantation: active list	5.5%
Catheter ablation:	2.3%
Ventricular tachycardia	0.7%
Atrioventricular junction	0.7%

ICD — implantable cardioverter defibrillator; CRT-D — cardiac resynchronisation therapy defibrillator

Table 4. Follow-up

In-hospital mortality	1.56%
All-cause mortality (12-months)	12.5%
Heart failure-related rehospitalisation (12-months)	28.9%
General practitioner visits (12-months)	12.6 ± 7.9
Cardiology outpatient clinic visits (12-months)	3.1 ± 2.4
Left ventricular assist device implantation (12-months)	0.3%
Orthotopic heart transplantation (12-months)	1.8%

cardiovascular centre with the possibility to implement all possible diagnostic and therapeutic options.

To the best of our knowledge, the COMMIT-HF is one of the first registries to assess the complete clinical profile and treatment modalities in an all-comer systolic HF population in a highly specialised reference HF centre.

The unique clinical profile of the analysed population is the result of applying a strict echocardiographic inclusion cut-off value, defined as LVEF ≤ 35%. The analysed population includes patients with all forms of HF, both acute decompensated and chronic, and excludes all patients with ACS. The study group is characterised by high prevalence of comorbidities, with over 40% of diabetic patients, 36% frequency of anaemia, and an almost 30% occurrence of chronic kidney disease stage III and above.

It is also apparent that the analysed population is relatively young (mean 60.9 ± 12.8 years), which can be attributed to the large number of young patients with post-inflammatory cardiomyopathies.

Heart failure therapy has been optimised with the usage of all available treatment options. This is reflected by an unusually high percentage of coronary angioplasties (above 30% in ischaemic, systolic HF patients), a large quantity of ICD implantations (reaching 41.1% ICD and 20% of CRT-D implantations, while 15.5% were already post-ICD at the beginning of the analysis), as well as a broad spectrum of other invasive therapies, such as catheter ablation or cardiovascular surgery. A significant proportion of subjects were qualified for OHT and subsequently underwent transplantation.

The unique clinical profile significantly differentiates COMMIT-HF from other HF-related registries, which, exercising a strictly symptom-based HF definition, include a large proportion of patients with preserved left ventricular systolic function. It is our strong conviction that the registry presents a real-life profile of a systolic HF patient, encountered in day-to-day practice.

Our decision to include patients with both acute and chronic HF is derived from current literature and guidelines, where both forms of HF are considered to be successive, consequent phases of one disease. ACS forms a completely separate clinical condition, and thus was excluded from the registry. In our opinion the inclusion of these patients would lead to heterogeneity of the analysed population, and would therefore decrease the transparency and credibility of presented results.

The significantly burdened clinical characteristics of the COMMIT-HF population, in comparison to other registries, is naturally related to the clinical status of patients referred to a reference cardiovascular centre. At the same time, as observed in our registry, the significant percentage of heart transplantation qualification (OHT) and the quantity of transplantations actually performed is obviously caused by the fact that the Silesian Centre for Heart Diseases is one of three centres performing OHT in Poland.

The diagnostics of HF is a complicated process, requiring a complex attitude towards each patient. The analysis of diagnostic procedures shows the complexity of an HF patient, and at the same time demonstrates the challenge ahead for the attending physician.

The contemporary treatment of HF patients, with a growing number of patients and an inadequate number of graft donations, with limited access to mechanical circulatory support, indicates that a full spectrum of reparative medicine and sudden cardiac death prevention is a basic necessity in this group of patients, reflected by the proportion of invasive procedures performed in this population.

The analysis of long-term follow up reveals a relatively small 12-month mortality in comparison to other available data, despite a larger burden of concomitant diseases and severely impaired echocardiographic parameters. This, in our opinion, is a result of the complex and aggressive approach towards the treatment, as exercised throughout the available therapeutic options, and it enables us to introduce optimal patient management before a final treatment option (OHT or MCS) is available. It seems that in the present conditions, with limited OHT and MCS availability, such an approach, demanding the knowledge and dedication of the whole heart failure team, and the use of all available treatment options, may lead to improved long-term prognosis.

This approach, however, is possible only in a centre where full diagnostic and therapeutic modalities are available. A clinically-focused (as opposed to a procedure-guided) profiling of cardiology centres helps to avoid defragmentation of HF-patient care. Only a holistic and adequately aggressive therapeutic approach can lead to improved results in this difficult patient population.

This does not change the fact that the basis of HF therapy remains medical treatment in outpatient clinics, which should be assisted by highly specialised centres only when indicated. Above all else, creating a system of HF-patient care logistics, as created before in ACS, may lead to an overall improvement of prognosis in this population.

CONCLUSIONS

The ongoing COMMIT-HF study will provide unique information regarding the administered therapies and prognosis in HF patients. Initial analyses show that in this difficult patient population satisfactory long-term results can be achieved with a holistic and adequately aggressive diagnostic and therapeutic approach.

Conflict of interest: none declared

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Cite this article as: Gaşior M, Pyka Ł, Gorol J et al. COnteMporary Modalities In Treatment of Heart Failure: a report from the COMMIT-HF registry. *Kardiol Pol*, 2016; 74: 523–528. doi: [10.5603/KPa2015.0224](https://doi.org/10.5603/KPa2015.0224).

Aktualna terapia niewydolności serca: dane z rejestru COMMIT-HF

Mariusz Gąsior¹, Łukasz Pyka¹, Jarosław Gorol¹, Michał Hawranek¹, Mateusz Tajstra¹,
Grzegorz Słonka¹, Anna Kurek¹, Adam Krajewski¹, Piotr Rozentryt¹, Marek Gierlotka¹,
Andrzej Lekston¹, Marian Zembala², Lech Poloński¹

¹III Klinika Kardiologii, Śląskie Centrum Chorób Serca w Zabrzu, Śląski Uniwersytet Medyczny, Katowice

²Klinika Kardiologii i Transplantologii, Śląskie Centrum Chorób Serca w Zabrzu, Śląski Uniwersytet Medyczny, Katowice

Streszczenie

Wstęp i cel: Niewydolność serca (HF) to globalny problem zdrowotny i jedno z głównych obciążeń systemów opieki zdrowotnej. Szacuje się, że 1–4% wszystkich hospitalizacji w krajach rozwiniętych jest spowodowanych HF. Rokowanie w HF pozostaje niekorzystne. Dysponując dużą grupą chorych ze skurczową HF w wyspospecjalistycznym ośrodku, z możliwością przeprowadzenia wszystkich dostępnych form diagnostyki i leczenia, przeanalizowano dane kliniczne, stosowaną terapię i rokowanie w tej grupie pacjentów.

Metody: Rejestr COMMIT-HF to jednośrodkowe, prospektywne badanie obserwacyjne przeprowadzane w III Klinice Kardiologii Śląskiego Centrum Chorób Serca w Zabrzu. Badaną populację stanowią kolejni hospitalizowani pacjenci z rozpoznaną HF z frakcją wyrzutową lewej komory $\leq 35\%$. Kryterium wyłączenia stanowią ostry zespół wieńcowy i wiek < 18 lat. Dane dotyczące charakterystyki klinicznej, stosowanej diagnostyki i leczenia oraz rokowania w tej grupie chorych są zbierane elektronicznie. Rokowanie 12-miesięczne jest analizowane na podstawie danych Narodowego Funduszu Zdrowia.

Wyniki: Do dnia 31 grudnia 2013 r. do rejestru włączono 1798 chorych w średnim wieku $60,9 \pm 12,8$ roku (20,3% kobiet), średnia frakcja wyrzutowa lewej komory wynosiła $26,06 \pm 6,09$. Etiologię niedokrwienną stwierdzono u 64,5% badanych, migotanie przedsionków — u 33,2%, cukrzycę — u 41,2%, przewlekłą chorobę nerek w stadium \geq III — u 29% pacjentów. Duży odsetek chorych poddawano procedurom inwazyjnym (ICD/CRT-D: 61,1%, koronarografia: 56,2%, PCI: 19,6%, CABG: 5,1%, kwalifikacja do transplantacji serca: 5,5%, IABP: 2,5%). Dwunastomiesięczna śmiertelność z wszystkich przyczyn wynosiła 12,5%, a odsetek rehospitalizacji związanych z HF — 28,9%.

Wnioski: Rejestr COMMIT-HF dostarczy istotnych danych dotyczących pacjentów z HF. Wstępna analiza wykazuje, że stosując adekwatnie intensywne leczenie u tych pacjentów można uzyskać satysfakcjonujące wyniki odległe.

Słowa kluczowe: niewydolność serca, rejestr COMMIT-HF, plan badania, charakterystyka populacji, terapia, rokowanie

Kardiologia 2016; 74, 6: 523–528

Adres do korespondencji:

lek. Łukasz Pyka, III Klinika Kardiologii, Śląskie Centrum Chorób Serca w Zabrzu, Śląski Uniwersytet Medyczny, ul. M. Curie-Skłodowskiej 9, 41–800 Zabrze,
e-mail: wookash.p@gmail.com

Praca wpłynęła: 01.09.2015 r.

Zaakceptowana do druku: 15.10.2015 r.

Data publikacji AoP: 20.11.2015 r.