A REVIEW OF PATIENT REGISTRIES IN HEART FAILURE ACROSS EU-5 COUNTRIES

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AGENDA

A REVIEW OF PATIENT REGISTRIES IN HEART FAILURE ACROSS EU-5 COUNTRIES

- Background and objective
- Approach and methodology
- Results
- Conclusion and limitations
BACKGROUND AND OBJECTIVES
### BACKGROUND

#### HEART FAILURE

- Heart failure (HF*) is a complex clinical syndrome of symptoms and signs that suggest the efficiency of the heart as a pump is impaired. It is caused by structural or functional abnormalities of the heart (NICE CG108).
- HF is a chronic condition predominantly affecting people over the age of 50 years and its incidence and prevalence increases with age (NICE TA314).
- Acute HF is complex clinical syndrome characterized by a rapid change in the signs and symptoms of HF, resulting in a need for urgent therapy, and is often life-threatening (Dahlstrom 2010).

#### BURDEN OF HF

- HF is a global public health problem affecting an estimated 26 million worldwide (Ambrosy 2014). The prevalence of HF in Europe is ~1-2% (France 2.2%, UK 1.3%) (Cowie 2015).
- Chronic HF is associated with high mortality and morbidity rate, decreased quality of life, and rising healthcare costs in Europe and globally (Dahlstrom 2010).
- HF accounts for 1-3% of all US and European hospital admissions (Cowie 2015).
- Almost 25% hospitalised patients are re-hospitalised for HF within the 30-day post discharge period, respectively (O’Connor 2010).

#### REGISTRIES

- Registries are prospective, observational cohort studies of patients who have a particular disease and/or are receiving a particular treatment or intervention. It involves prospective data collection of clinical, economic, and PRO* information that rely on real-time data capture (Garrison 2007).
- Patient registries are a good source of evidence for clinicians, disease organizations, health technology agencies, health insurers/payers, regulatory authorities requiring real-world data for evidence-based decision making (Garrison 2007).

*HF: Heart Failure; PRO: Patient Reported Outcomes

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RCTs* are regarded as the gold standard for clinical decision making purposes. However, data from RCTs often have limited external validity (generalisability) for the following reasons:

- Highly selected patient populations
- Often limited to specific geographic settings
- Most data pertain to hospitalised patients

Registries and surveys in patients with acute and chronic HF* can provide a longitudinal view of the whole clinical story of patients with HF including the acute episodes and the consequent changes in the clinical conditions and in the management strategies.

Many registries with real-world data on HF patients exist but a comprehensive review to help understand the scope, availability, and quality of collected data is currently lacking.

The objective of this review was to systematically identify and assess key characteristics of HF registries reporting patients’ data across the EU-5 countries

*HF: Heart Failure; RCTs: Randomised Controlled Trials
APPROACH AND METHODOLOGY
HF REGISTRIES WERE IDENTIFIED THROUGH A SYSTEMATIC REVIEW OF THE PUBLISHED LITERATURE AND INTERNET SEARCH

Searching of databases

- HF* registries were identified through a systematic search of Embase® and MEDLINE® databases using embase.com interface

Key inclusion criteria

- Registries with data on HF patients from EU5* countries (France, Germany, Italy, Spain, and the UK*) and patient counts ≥1000 were included

Analysing evidence from registry websites/publications

- Registry website and publications in peer-reviewed journals were assessed for availability of information on basic registry details, patient characteristics, disease management, resource use, and treatment outcomes

*EU5: European Union Countries; HF: Heart Failure; UK: United Kingdom
**FOLLOWING DATA VARIABLES WERE SOUGHT FOR EACH IDENTIFIED REGISTRY**

<table>
<thead>
<tr>
<th>Category</th>
<th>Data variables</th>
</tr>
</thead>
<tbody>
<tr>
<td>Basic registry information</td>
<td>Region, acronym, full name, website, country, year established and data collection period, current status (active or inactive), patient group, objective, funding agency</td>
</tr>
<tr>
<td>Patient characteristics</td>
<td>Age, gender, race/ethnicity, comorbidities</td>
</tr>
<tr>
<td>Disease management</td>
<td>Diagnosis and staging of HF*, diagnostic procedures and tests, treatment procedures, pharmacological interventions</td>
</tr>
<tr>
<td>Resource use</td>
<td>Hospitalisations, ER* visits, outpatient visits, primary care visits, length of stay, cost</td>
</tr>
<tr>
<td>Treatment outcomes</td>
<td>Laboratory results, quality of life (scale/instrument used), adverse events reported, survival data/all-cause/HF-specific mortality rates</td>
</tr>
</tbody>
</table>

*ER: Emergency Room; HF: Heart Failure
RESULTS
Number of included patients varied from 1037 to 25,000 with the average follow-up ranging from 3-53 months

<table>
<thead>
<tr>
<th>Name</th>
<th>Acronym</th>
<th>No. of HF patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Heart Failure Global Registry of Standard Treatment</td>
<td>ALARM-HF</td>
<td>4,953</td>
</tr>
<tr>
<td>Clinical Practice Research Datalink</td>
<td>CPRD</td>
<td>8,404</td>
</tr>
<tr>
<td>Disease management program in heart failure in Lorraine (Insuffisance Cardiaque en Lorraine)</td>
<td>ICALOR</td>
<td>25,000</td>
</tr>
<tr>
<td>Epidemiology of Acute Heart Failure in Emergency Registry</td>
<td>EAHFE-1,2,3</td>
<td>5,845</td>
</tr>
<tr>
<td>EuroHeart Failure Survey I</td>
<td>EHFS I</td>
<td>10,701</td>
</tr>
<tr>
<td>EuroHeart Failure Survey II</td>
<td>EHFS II</td>
<td>3,580</td>
</tr>
<tr>
<td>European Society of Cardiology-Heart Failure Long-Term Registry</td>
<td>ESC Heart Failure</td>
<td>19,211</td>
</tr>
<tr>
<td>European Society of Cardiology-Heart Failure Pilot Survey</td>
<td>ESC-HF Pilot</td>
<td>5,118</td>
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<tr>
<td>Evidence based Treatment in Heart Failure registry</td>
<td>EVITA-HF</td>
<td>3,082</td>
</tr>
<tr>
<td>German Competence Network Heart Failure database</td>
<td>CNHF</td>
<td>12,756</td>
</tr>
<tr>
<td>Global Registry of Acute Coronary Events</td>
<td>GRACE</td>
<td>&gt;5,000</td>
</tr>
<tr>
<td>Global Registry of Acute Coronary Events 2</td>
<td>GRACE 2</td>
<td>&gt;5,000</td>
</tr>
<tr>
<td>HELUMA heart failure registry</td>
<td>HELUMA</td>
<td>2,318</td>
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<tr>
<td>Italian Network on Heart Failure Outcome registry</td>
<td>IN-HF</td>
<td>5,610</td>
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<td>Italian Survey on Acute Heart Failure</td>
<td>IS-AHF</td>
<td>2,807</td>
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<tr>
<td>Realise Atrial Fibrillation Registry</td>
<td>RealiseAF</td>
<td>4,790</td>
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<tr>
<td>Schlafh registry</td>
<td>SchlaHF</td>
<td>8,341</td>
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<tr>
<td>Screening of todays patients with Chronic systolic heart failure</td>
<td>INDICATE</td>
<td>15,148</td>
</tr>
<tr>
<td>Spanish National Registry on Heart Failure</td>
<td>RICA</td>
<td>&gt;4,000</td>
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<tr>
<td>Spanish REDINSCOR registry (Clinical and Preclinical Heart Failure Research Network Registry)</td>
<td>REDINSCOR</td>
<td>2,263</td>
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<tr>
<td>The prospective observational Longitudinal Registry of patients with stable coronary artery disease</td>
<td>CLARIFY</td>
<td>4,943</td>
</tr>
<tr>
<td>Trieste Registry of CV Diseases</td>
<td>-</td>
<td>2,217</td>
</tr>
<tr>
<td>VIDA-IC study</td>
<td>VIDA-IC</td>
<td>1,037</td>
</tr>
</tbody>
</table>
MULTIPLE HF REGISTRIES EXIST FOR EACH EU-5 COUNTRY

- A total of 43% registries were multinational while 57% were local or nationally representative patient registries.

- Data was collected for patients with acute HF* only (31%), chronic HF only (43%), and both acute and chronic HF (26%) in the identified registries.

- Twelve registries each collected data from Spain, Germany, and Italy and eight and six registries from France and the UK*, respectively.

*HF: Heart Failure; UK: United Kingdom
MAJORITY OF THE REGISTRIES REPORTED DATA FOR PATIENT DEMOGRAPHICS, CLINICAL CHARACTERISTICS, MANAGEMENT, AND OUTCOMES

Data was available for patient demographics (100%), comorbidities (87%), diagnosis and disease classification (78%), mortality (78%), hospitalisation (96%), prescribed drugs (100%), and patient-reported outcomes (17%)

It appears from the published data that there is less emphasis on patient reported outcomes

PRO: Patient Reported Outcomes
REGISTRIES REPORTED DATA FOR SPECIFIC DIAGNOSTIC PROCEDURES, TREATMENT, AND RESOURCE USE

- Blood pressure: 91%
- Blood tests: 87%
- Renal function: 70%
- Imaging (Echo): 70%
- Electrocardiogram: 65%
- Biomarkers (NT-proBNP, BNP): 44%
- Coronary revascularisation: 57%
- Cardiac rhythm device: 52%
- Heart catheterization: 39%
- Heart transplant: 13%
- Electrophysiology mapping: 9%
- Hospitalisations: 96%
- Length of stay: 57%
- Outpatient visit: 39%
- Emergency room visit: 22%
- Primary care visit: 13%
- Any AE or specific AE: 17%
- Patient reported outcomes: 17%
- Direct or indirect: 13%

AE: Adverse Event; BNP: Brain Natriuretic Peptide; NT-proBNP: N-terminal pro-brain natriuretic peptide
OVER THE LAST DECADE THERE HAS BEEN A SHARP INCREASE IN THE NUMBER OF HF REGISTRIES
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Inception year for 15 out of 23 registries was post-2005 i.e. majority of the registries initiated in last 10 years reflecting increase in use of real-world data in the recent years

Note: Text in red font indicates registries supported by industry-funding; Black text indicates registries supported by non-profit organizations /universities/ government agencies or where funding information was not clear
MAJORITY OF REGISTRIES WERE SPONSORED BY INDUSTRIES

Majority of published registries were sponsored by pharmaceutical companies (61%); while 30% of registries were sponsored by non-profit organisations, universities or government agencies.

Rise in the number of heart failure registries in recent years and industry funding indicates increased interest of stakeholders in these registries’ data.
BASED ON DATA VARIABLES REPORTED, TWO REGISTRIES PROVIDED MOST COMPREHENSIVE VIEW OF THE HF PATIENTS IN REAL-WORLD SETTINGS

- Identified HF registries were assessed for percentage availability of information on the key data variables

A total of 63% registries reported data on >50% of the assessed data variables
CONCLUSION
AND LIMITATIONS
CONCLUSION

• Rise in the number of HF* registries and industry funding in recent years indicate increased interest of stakeholders in these registries’ data

• Majority of the registries collected data on key clinical outcomes like hospitalisations and mortality in HF patients demonstrating concordance with the clinical studies

• However, only a few registries collected data on the use of biomarkers (NTpro-BNP*, BNP*, troponin), treatment procedures, patient-reported outcomes, adverse events, and costs of care

• Long-term follow-up data from registries could help to identify the prognostic factors predisposing HF patients to rehospitalization and sudden death and to understand the impact of interventions on patients’ quality of life, thus, complementing the clinical efficacy demonstrated in relatively short-term, controlled clinical trials

• Further, applicability and acceptance of HF registries’ data to inform access and reimbursement decisions and to determine cost-effectiveness of different interventions in clinical practice need to be evaluated

* BNP: B-type natriuretic peptide; HF: Heart Failure; NTpro-BNP: N-terminal pro-brain natriuretic peptide
LIMITATIONS OF THE REVIEW

• All literature reviews are limited by publication bias with respect to the available articles. Also, only English language articles were considered for this review

• This review was limited to registries with more than 1000 patients and at least one of the data collection center in EU-5 countries
REFERENCES


NICE TA314 (2014) Implantable cardioverter defibrillators and cardiac resynchronisation therapy for arrhythmias and heart failure. Available at: https://www.nice.org.uk/guidance/ta314


QUESTIONS?

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THANK YOU