Hungarian Atrial fibrillation and flutter Registry

Protocol synopsis

Background and rationale:

Atrial fibrillation (AF) is the most common clinically significant cardiac arrhythmia. It occurs in 1–2% of the general population, more commonly in the elder age (4% in the age group of 60-70 years, and 14% above 80 years), in the presence of cardiovascular risk factors, established heart disease and congestive heart failure. Its prevalence is estimated to at least double in the next 50 years as the population ages.

While AF is usually well treatable and tolerable, it is proved to have significant morbidity and mortality, posing a risk for devastating complication, such as stroke, as well as hearth failure and impaired quality of life.

Management strategies for AF have made many advances over the last decade, introducing and reevaluating pharmacological and non-pharmacological methods for rhythm or rate control and stroke risk management. Evidence based new guideline for management of atrial fibrillation has been introduced by the European Society of Cardiology. Despite guideline-adherent therapy improves outcomes, it may be not or hardly applicable in special cases leaving gaps in evidence. Adherence to guideline also show a heterogeneity among practitioners.

Given the changes in demography, risk factors and therapeutic possibilities, incidence, course and consequences of atrial fibrillation must be reevaluated warranting broad new data collection. Setting up of new registries does not only help to gain information about the burden of the disease, but also about the application of new methods, adherence to guidelines and to identify the challenges hindering their application. As there is a significant heterogeneity in medical and financial possibilities among countries, it is necessary to establish a national register to assess the local circumstances of AF management.

Atrial flutter is an arrhythmia which in spite of the different electrophysiological origin, has very similar consequences and management as atrial fibrillation, guidelines often discuss the two together as well. For this reason data will be collected about atrial flutter as well.

Patients and methods

Patients with documented atrial fibrillation or flutter will be enrolled for data collection after taking informed consent. Data will be collected about demographics, comorbidities, risk factors, symptoms and course of the disease, therapeutic strategy and decision making, efficacy of therapy, disease and treatment related complications and outcome. Data will be collected at the index event and during a 5 year follow-up period. Data collection will not interfere with any routine diagnostic or therapeutic procedures, and there are no additional study-related examinations or procedures.

Inclusion criteria:

- Patients above the age of 18 years with atrial fibrillation or flutter ever documented by any ECG method.
- Written informed consent (by patient or supervisor)

Exclusion criteria

- Denial of consent

Ideally, the Hungarian Atrial fibrillation and flutter Register should include all patients who ever experienced atrial fibrillation or flutter. Given the enormous number of candidates, inclusion focus should be expanded gradually:

1. Patients hospitalized for AF
2. Patients hospitalized for any reason, but also having or developing AF during hospital care
3. Patients hospitalized for any reason and without current AF episode but having an ECG documented history of previous AF

4. Outpatients with ongoing AF

5. Outpatients without current AF episode but having an ECG documented history of previous AF.

Objectives:

The Hungarian Atrial fibrillation and flutter Register aims to provide information about:

- Demographic parameters of AF patients
- Incidence of comorbidities and risk factors among AF patients, including
  - echocardiographic parameters
- Treatment strategy of AF patients, including
  - rhythm vs. rate control
  - application of non-pharmacological therapy
  - anticoagulation: NOAC vs. VKA, dose management, efficacy of anticoagulation
  - factors affecting decision making
- Assessment of clinical outcome
  - incidence and severity of thrombotic complications (stroke, TIA, systemic thromboembolism, pulmonary embolism)
  - incidence and severity of bleeding complications (hemorrhagic stroke, gastrointestinal bleeding, other bleeding)
    - relation of thromboembolism and bleeding to anticoagulation strategy and effectivenessű
  - heart failure
  - myocardial infarcton
  - cardiac and all-cause hospitalization
  - cardiac and all-cause mortality