

### Press Release relating to a poster or oral presentation

*This press release accompanies either a poster or oral presentation given at the ESC Congress 2009. Written by the investigator himself/herself, this press release does not necessarily reflect the opinion of the European Society of Cardiology.*

<b>EMBARGO</b>	<b>TUESDAY 1 SEPTEMBER 2009 - start of the scientific presentation</b>
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<b>Hotel and dates of stay</b>	Not yet confirmed
<b>Available for interview</b>	Yes

### Preliminary analysis of fatalities linked to Atrial Fibrillation reveals “shady side” of current treatments

“Despite great advances in atrial fibrillation (AF) therapy these last few years, there is still a considerable number of patients dying of complications from AF. Furthermore, advances in therapy also have their shady side, bearing risks for new complications that should be considered when making therapeutic choices” explained Dr Claudia Sprenger from the German Competence Network on Atrial Fibrillation (AFNET).

Atrial fibrillation is the most commonly sustained arrhythmia and is often associated with complications, especially related to thrombus formation and embolism, but also as a result of its treatment which has evolved tremendously within the last years with new antiarrhythmic and antithrombotic drugs and interventional procedures being developed. A preliminary analysis of complications and fatalities within the German Competence Network on Atrial Fibrillation (AFNET) reveals first data about the causes of death of 500 patients. AFNET is an interdisciplinary national research network founded in 2003 and funded by the German Ministry of Education and Research (BMBF).

Over 13 000 patients were enrolled into registry and substudies with participation of 300 study sites, university and community hospitals as well as office-based cardiologists and general practitioners. Complications and deaths are being analyzed in the substudy “Project A7 - Assessment of serious adverse events (SAE) by a critical event committee (CEC)” which is still ongoing.

So far, 498 cases of death have been assessed by the critical event committee (CEC) which consists of two cardiologists and one neurologist. The project leader is Prof. Dr. Michael Oeff, Brandenburg. In this preliminary analysis of fatalities, 11% of deaths were caused by atrial fibrillation (AF), mostly by stroke and heart failure, or were associated with its treatment such as oral anticoagulation or AF-related invasive procedures.

The deaths are recorded by local study sites during follow-ups and entered into a web-based database. The corresponding patient reports are sent to the SAE Center in Brandenburg/Havel where they are verified for completeness. The Critical Event Committee (CEC) meets on a regular basis, discussing every case and assessing it towards its relation with AF. Fatalities are assigned to cardiac and non-cardiac groups, and, if cardiac, sudden or non-sudden. Additional medical records, death certificates, autopsy reports and thorough questioning of relatives or family physicians are used to gather additional information on the circumstances of death. In 51%, the patients died in hospital where obtaining information was relatively easy, whereas 41% died at home which made acquisition of information difficult. 23% of patients died with no witnesses.

46% (229 patients) of deaths were classified as cardiac. Of these, 95 patients died of sudden cardiac death. Non-sudden cardiac death (134 patients) occurred mostly due to cardiac pump failure, less commonly due to fatal acute myocardial infarction, valvular disease, pacemaker dysfunction and pericardial tamponade.

According to CEC assessment, 57 cases (11%) were at least possibly associated with AF or its treatment, the majority being strokes, but also cases of bleedings or peripheral embolism, heart failure, atrio-esophageal fistula after pulmonary vein isolation.

Further procedure related deaths included stroke during ablation, perforation during pacemaker implantation and pacemaker dysfunction. 16 patients died due to massive bleedings on anticoagulation therapy.

Professor Oeff and his colleagues conclude that despite great advances in atrial fibrillation therapy these last few years, there is still a considerable number of patients dying of complications from AF. Furthermore, advances in therapy also have their shady side, bearing risks for new complications that have to be considered when making therapeutic choices.

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