

Stroke/Thromboembolism and Intracranial Hemorrhage in a Real-world Atrial Fibrillation Population

The Complications of Atrial Fibrillation in the Bologna Area (CAFBO) Study

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BACKGROUND: Ischemic events (IEs) and intracranial hemorrhages (ICHs) are feared complications of atrial fibrillation (AF) and of antithrombotic treatment in patients with these conditions.

METHODS: Patients with AF admitted to the EDs of the Bologna, Italy, area with acute IE or ICH were prospectively recorded over 6 months.

RESULTS: A total of 178 patients (60 male patients; median age: 85 years) presented with acute IE. Antithrombotic therapy was as follows: (1) vitamin K antagonists (VKAs) in 31 patients (17.4%), with international normalized ratio (INR) at admission of < 2.0 in 16 patients, 2.0 to 3.0 in 13 patients, and > 3.0 in two patients; (2) aspirin (acetylsalicylic acid) (ASA) in 107 patients (60.1%); and (3) no treatment in 40 patients (22.5%), mainly because AF was not diagnosed. Twenty patients (eight male patients; median age: 82 years) presented with acute ICH: 13 (65%) received VKAs (INR, 2.0-3.0 in 11 patients and > 3.0 in two patients), while six (30%) received ASA. Most IEs (88%) and ICHs (95%) occurred in patients aged > 70 years. A modeling analysis of patients aged > 70 years was used to estimate annual incidence in subjects anticoagulated with VKAs in our Network of Anticoagulation Centers (NACs), or those expected to have AF but not included in NACs. The expected incidence of IE was 12.0%/y (95% CI, 10.7-13.3) in non-NACs and 0.57%/y (95% CI, 0.42-0.76) in NACs (absolute risk reduction [ARR], 11.4%/y; relative risk reduction [RRR], 95%; $P < .0001$). The incidence of ICH was 0.63%/y (95% CI, 0.34-1.04) and 0.30%/y (95% CI, 0.19-0.44), respectively (ARR, 0.33%/y; RRR, 52.4%/y; $P = .04$).

CONCLUSIONS: IEs occurred mainly in elderly patients who received ASA or no treatment. One-half of patients with IEs receiving anticoagulant treatment had subtherapeutic INRs. Therapeutic approaches to elderly subjects with AF require an effective anticoagulant treatment strategy.

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ABBREVIATIONS: AF = atrial fibrillation; ARR = absolute risk reduction; ASA = aspirin (acetylsalicylic acid); GP = general practitioner; ICH = intracranial hemorrhage; IE = ischemic event; INR = international normalized ratio; LMWH = low-molecular-weight heparin;

NACs = Network of Anticoagulation Centers; RRR = relative risk reduction; VKA = vitamin K antagonist

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Ischemic stroke and systemic embolism are the most feared complications of atrial fibrillation (AF), a condition whose prevalence sharply increases with age.¹ One in five of all strokes is attributed to AF, with a risk for stroke that increases with age, reaching values of 23.5% in patients aged ≥ 80 years.² Furthermore, AF-related strokes are more often fatal and more disabling than those due to other causes.³

Anticoagulant treatment with vitamin K antagonists (VKAs) is extremely effective in reducing the risk for AF-associated stroke, but is still underused in clinical practice⁴ or not adequately monitored with subsequent insufficient protection.⁵ Many patients with AF receive aspirin (acetylsalicylic acid) (ASA), though its efficacy is

limited,^{6,7} while many others remain completely untreated. Nonadherence to guidelines and undertreatment in clinical practice are independently associated with a high risk for stroke and mortality.⁸

This observational study prospectively recorded all the patients with AF who, during a 6-month period, were consecutively admitted with an acute ischemic event (IE) (ie, stroke or systemic embolism) or intracranial hemorrhage (ICH) to the EDs of the area of Bologna, Italy, and examined the type (if any) and quality of treatment they were receiving. Using a specific modeling analysis, we estimated treatment outcomes in patients with AF aged > 70 years living in that area.

Materials and Methods

Setting

The area of Bologna, in Northern Italy, has an incident population of 866,160 (735,960 aged ≥ 18 years) and covers an area of 2,915 km² with 50 municipalities. Population-based epidemiologic studies are possible in this setting because medical care is completely and uniformly provided by (1) a network of hospitals comprising two major facilities—Ospedale Maggiore and the University Hospital, both in the city of Bologna—and other middle-size hospitals distributed in the area and (2) general practitioners (GPs). These health services are part of the regional health system. A major ED is present in each of two major hospitals in Bologna; both are approved for thrombolysis in acute stroke. A network of EDs is active in the other hospitals. In general, patients with acute stroke are urgently referred to one of the two largest EDs, so that thrombolytic treatment can be provided, if indicated.

Monitoring of patients treated by oral anticoagulants (at the time of the study, only VKAs were used) is performed by a Network of Anticoagulation Centers (NACs), covering all the Bologna area, which use the same computerized system to help patient management and dosing (P.A.R.M.A.; Werfen Group). Most subjects receiving anticoagulant

treatment living in the area are included in one of the NACs; however, some patients, prospectively very few, are referred to their GP for anticoagulation management.

Design and Study Population

All the EDs in the area agreed to participate in the study. At least one doctor in each participating clinical center was identified as point person for the study, and a doctor (L. S.), active in the Angiology and Blood Coagulation unit (coordinating center), was in charge of monitoring the study. The institutional review boards of all participating centers approved the study: Azienda Ospedaliero-Universitaria di Bologna Policlinico S.Orsola-Malpighi (110/2011/U/Oss); Azienda AUSL c/o Dipartimento Farmaceutico Ospedale Maggiore di Bologna (11052). Written informed consent for participation was obtained from the patients or from relatives when a patient was unable to give it.

From January 22, 2012, to July 22, 2012 (183 days), all patients admitted to the EDs with IE or ICH were included in the study if AF was present at admission, there was a known diagnosis of paroxysmal AF preadmission, or AF was detected after hospitalization. Patients were excluded if the event was more likely attributable to other conditions than AF. The included patients were identified from the general database of the NACs, and results of anticoagulation control during the previous 4 months were analyzed and evaluated as “stable” patients with an international normalized ratio (INR) between 1.8 and 3.2 (with no variations in VKA doses), and “variable” in other cases.

Statistical Analysis

Differences between groups were assessed by the χ^2 test with Yates' correction for categorical variables and by the Mann-Whitney test for continuous variables. The data were analyzed with Prism software version 3.0 (GraphPad Software Inc), and SPSS software version 11.0 (IBM).

Specific modeling analyses were designed to calculate separately the incidence of IE or ICH in subjects with AF who were aged > 70 years included or not in NACs. The number of inhabitants in the Bologna area aged > 70 years was obtained from 2012-related data of the regional health system; the total numbers of subjects with AF in this population was calculated by estimating, in-line with more recent population studies,^{9,10} an AF prevalence of 7%. A rough estimate of elderly patients with AF with unknown treatment was obtained by subtracting the number of patients with AF included in NACs from the total calculated elderly population with AF. The modeling analysis was performed at the end of the 6-month study period.

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