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Health status, geriatric syndromes and prescription of oral anticoagulant therapy in elderly medical inpatients with atrial fibrillation

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Abstract

Aim
The aim of the present study was to investigate the prevalence of geriatric syndromes among older medical inpatients with atrial fibrillation, and their association with use of vitamin K antagonists.

Methods
A retrospective study of patients aged ≥65 years discharged with a diagnosis of atrial fibrillation from the Acute Geriatric Ward was carried out. Stroke and bleeding risk were evaluated according to the CHA_2DS_2-VASC and HAS-BLED scores. Comorbidity, cognitive status, functional autonomy and contraindications to vitamin K antagonists were also considered.

Results
Atrial fibrillation was documented in 1078 of 3650 patients (29.5%, mean age 83.4 ± 6.6 years, 60.3% women). Contraindications to vitamin K antagonists were documented in 24.9% of patients. Prescription of vitamin K antagonists at discharge was 37.8% and 47.9%, in the overall sample and in those without contraindications, respectively. In the overall sample, prescription of vitamin K antagonists was associated with younger age, permanent/persistent atrial fibrillation, home discharge, less comorbidity, higher hemoglobin levels, better functional independence, known atrial fibrillation at admission and lower HAS-BLED score. Among patients without contraindications to vitamin K antagonists, their use at discharge was independently associated with younger age, permanent/persistent atrial fibrillation, home discharge, higher hemoglobin levels and CHA2DS2-VASC score, better functional autonomy, and greater number of drugs.

Conclusions
We showed a high prevalence of atrial fibrillation among older medical inpatients, who have a poor health status and a high prevalence of geriatric syndromes. Vitamin K antagonists were prescribed in less than half of the patients; underuse was mainly accounted for by a high prevalence of comorbidities/contraindications, poor health status and limited functional autonomy.

Introduction

Atrial fibrillation (AF) is one of the most common forms of cardiac arrhythmia. Both the incidence and prevalence of this disorder increase with advancing age1, 2 and, with the growing proportion of elderly individuals, AF actually represents a significant medical burden for health services in most Western countries.2 The most feared consequence of AF is cardioembolic ischemic stroke, carrying an elevated risk of mortality and disability among older patients. Although oral anticoagulant therapy (OAT) has been shown to be effective for the prevention of cardioembolic ischemic stroke in older patients with AF,3, 4 this therapy is widely underused, particularly in the oldest patients who, in reason of their high risk of stroke, should derive the greatest benefit from anticoagulant therapy.5-8 Advanced age itself, physician's perceived high risk of age-related and fall-related bleeding, and difficulties in monitoring warfarin-based anticoagulant therapy have been reported among the main factors accounting for underprescription of anticoagulant therapy in older patients with AF.6-8 Therefore, despite several studies and meta-analyses suggesting that advanced age itself should not prevent prescription of oral anticoagulants in elderly patients, underprescription of anticoagulants among the oldest patients remains a common clinical practice in several contemporary medical settings.9-11

We hypothesized that poor health conditions and the presence of common geriatric syndromes (such as cognitive impairment, functional dependence, comorbidity), which are associated with reduced life-expectancy, could account for a great part of this underprescription, influencing physicians' attitudes towards using oral anticoagulants in older patients with AF. Among older medical inpatients, both geriatric syndromes and AF are highly prevalent; therefore, geriatric hospital units appear an appropriate clinical setting to test this hypothesis. To our knowledge, the comprehensive evaluation of the impact of health status, geriatric syndromes and the presence of contraindications to OAT, on prescription of anticoagulant therapy for AF, have not been systematically investigated among elderly medical inpatients patients.

In the present retrospective cohort study on older patients with AF admitted to an Acute Geriatric Ward (AGW) of a University teaching hospital, we aimed to evaluate the general health status and prevalence of common geriatric syndromes, and whether these variables are associated with prescription at discharge of oral anticoagulant drugs.

Methods

Medical records of patients aged ≥65 years consecutively discharged in the period 2010–2013 with a primary or secondary diagnosis of AF from the AGW of San Giovanni Battista-Molinette University Hospital in Turin (Italy) were retrieved from the discharge database. Patients discharged with a primary or secondary diagnosis of AF (code 427.31 of the International Classification of

Diseases, Ninth Revision, ICD-9) were identified. Each case identified was carefully reviewed by one of two qualified geriatricians. Patients were included in the study if they had a clinical documented history of AF (including evidence of AF in a 12-lead standard electrocardiogram or Holter electrocardiogram) or new first-detected AF ascertained through standard 12-lead electrocardiogram readings during hospital stay. Patients were considered to have "new" AF when there was no previous documentation of AF in their medical charts. AF was defined paroxysmal, persistent or permanent according to current international recommendations.

For each patient demographic variable (age/sex), the number of medications and relevant medical history, including documentation of prior AF, were extracted from their medical records. Individual stroke and bleeding risk were evaluated according to the Congestive heart failure/left ventricular dysfunction, Hypertension, Aged ≥75 years, Diabetes Mellitus, Stroke/transient ischemic attack/systemic embolism, Vascular Disease, Aged 65–74 years, Sex Category (CHA_2DS_2-VASC)12 and Hypertension, Abnormal renal/liver function, Stroke, Bleeding history or predisposition, Labile international normalized ratio, Elderly, Drugs/alcohol concomitantly (HAS-BLED)13, 14 score. The following conditions were considered major contraindications to vitamin K antagonists (VKA): recent (<3 months) major cerebral or systemic bleeding, recent surgery, severe thrombocytopenia, history of alcohol abuse, liver failure/cirrhosis, advanced malignancies, psychiatric disorders, refusal of VKA therapy, and expected or observed difficult therapeutic compliance in patients without proxies or caregivers supervising therapy adherence and regular scheduled international normalized ratio controls. A history of falls and recent minor bleeding were considered minor contraindications to OAT with VKA. Indexes of comorbidity and global physical health (Charlson Comorbidity Index),15 cognitive status (Short Portable Mental Status Questionnaire),16 functional autonomy (activities of daily living [ADL], instrumental activities of daily living [IADL]),17, 18 were also included for analysis. Patients were defined not to have cognitive impairment with a Short Portable Mental Status Questionnaire score of 0–2; Short Portable Mental Status Questionnaire score of 3–4, 5–7 and ≥8, identified mild, moderate and severe cognitive impairment, respectively. Patients were defined as partially or totally dependent in basal daily activities with an ADL score of 1–2 and ≥3, respectively. Patients were defined as dependent in instrumental daily activities with an IADL score of 4 or less.

Antithrombotic therapy at admission and at discharge was recorded according to the following classes: oral anticoagulant therapy only, single- or double-antiplatelet therapy, combined anticoagulant-antiplatelet therapy, "other" (mainly represented by low molecular weight heparin [LMWH]), and none. During the most part of the period of observation (from 2010 to the second half of 2013), new oral anticoagulants for prevention of cardioembolism in patients with AF were not yet made available by our National Health Service. Therefore, in the present study, oral anticoagulant therapy included only VKA. The number of drugs prescribed at discharge was also recorded.

Physicians operating within the 28-bed AGW include two geriatricians, two internists, one endocrinologist and one geriatrician cardiologist. The study was carried out according to the principles of the Declaration of Helsinki Title 45, and US Code of Federal Regulations, Part 46, Protection of Human Subjects, Revised 13 November 2001, effective 13 December 2001.

Statistical analysis

Absolute and relative frequencies of dichotomous and categorical variables, and mean and relative distribution of continuous variables were calculated. The univariate association between variables and prescription of oral anticoagulants was evaluated using ANOVA, the χ^2-test and the Mann–Whitney test. Independent associations between significant variables from univariate analysis and prescription of oral anticoagulants were then evaluated using a logistic regression model (forward stepwise method).

Results

In the period 2010–2013, there were 4072 admissions to AGW from the emergency department. The main reasons for hospital admission were cardiovascular (29.1%), mainly congestive heart failure, and respiratory (24.8%) diseases, mainly exacerbations of chronic obstructive pulmonary disease and respiratory tract infectious, followed by gastrointestinal (10.0%), oncohematological (9.9%) and neurological (8.6%) disorders, dehydration and electrolyte imbalance (6%), and others (11.6%). A total of 422 patients (10.4%) died in hospital, yielding a sample of 3650 patients who were discharged alive from the AGW. Among these patients, a primary or secondary diagnosis of AF was present in 1078 patients (29.5%). The main clinical characteristics of patients discharged with AF are presented in Table 1. The mean age of patients was 83.4 ± 6.6 years, and 60.3% were women. A total of 565 patients (52.4%) had some cognitive impairment, which was moderate-to-severe in 58.9% of them. Functional dependence in basal (ADL) and instrumental (IADL) daily activities was observed in 27.3% and 37.3% of patients, respectively. The mean index of comorbidity was 7.4. Coexisting functional dependence (either ADL or IADL) and cognitive impairment was observed in 110 patients (10.2%). Among patients with a diagnosis of AF, this disorder was present before admission in 894 patients (82.8%), whereas in 184 patients (17.2%) it was detected during hospital stay. Mean CHA_2DS_2-VASC and HAS-BLED scores were 4.8 ± 1.4 and 2.1 ± 0.9, respectively. At admission, 438 patients (40.6%) were receiving OAT (21 of them in association with an antiplatelet agent), 270 patients (25.1%) were treated with antiplatelet drugs only and 186 patients (17.2%) were not treated with any antithrombotic therapy. Prescription rates of OAT according to CHA_2DS_2-VASC and HAS-BLED scores are shown in Figure 1.

Table 1. Baseline characteristics of the 1078 patients with atrial fibrillation

Mean age (years)	83.4 ± 6.6
Female sex, *n* (%)	650 (60.3)
Mean hospitalization (days)	10.2 ± 8.9
Known AF at admission, *n* (%)	894 (82.8)
Persistent/permanent AF, n (%)	784 (72.7)
ADL (no. lost functions)	
Dependent (5–6), *n* (%)	294 (27.3)
Partially dependent (2–4), *n* (%)	312 (28.9)
IADL (no. preserved functions), *n* (%)	
Non-autonomous (0–4), *n* (%)	402 (37.3)
Partially autonomous (5–9), *n* (%)	358 (33.2)
SPMSQ (no. errors)	
No cognitive impairment (0–2), *n* (%)	472 (43.8)
Mild cognitive impairment (3–4), *n* (%)	232 (21.5)
Moderate cognitive impairment (5–7), *n* (%)	191 (17.7)
Severe cognitive impairment (8–10), *n* (%)	142 (13.2)
Test not administrable, *n* (%)	40 (3.7)
Mean Charlson Comorbidity Index	7.4 ± 2.2
Mean CHA_2DS_2-VASC score	4.8 ± 1.4
Mean HAS-BLED score	2.1 ± 0.9
Mean haemoglobin (g/dL)	11.9 ± 2.0
Mean creatinine (mg/dL)	1.27 ± 0.76
Discharge	
Ordinary, *n* (%)	873 (81.0)
Post acute, intermediate-long term care facility, *n* (%)	205 (19.0)
Antithrombotic therapy at admission	
Oral anticoagulant therapy only, *n* (%)	417 (38.7)
Single- or double antiplatelet therapy, *n* (%)	270 (25.1)
Oral anticoagulant + antiplatelet, *n* (%)	21 (1.9)
None, *n* (%)	186 (17.2)
Other, *n* (%)	184 (17.1)

ADL, activities of daily living; AF, atrial fibrillation; CHA_2DS_2-VASC, Congestive heart failure/left ventricular dysfunction, Hypertension, Aged ≥75 years, Diabetes Mellitus, Stroke/transient ischemic attack/systemic embolism, Vascular Disease, Aged 65–74 years, Sex Category; HAS-BLED, Hypertension, Abnormal renal/liver function, Stroke, Bleeding history or predisposition, Labile international normalized ratio, Elderly, Drugs/alcohol concomitantly; IADL, instrumental activities of daily living.

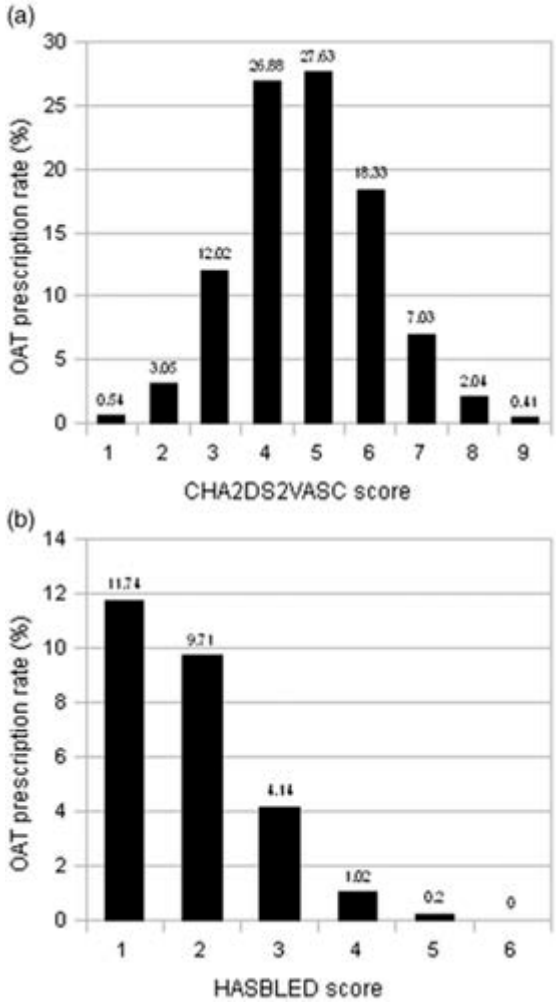

Figure 1. Prescription rates of oral anticoagulant therapy (OAT) according to (a) Congestive heart failure/left ventricular dysfunction, Hypertension, Aged ≥75 years, Diabetes Mellitus, Stroke/transient ischemic attack/systemic embolism, Vascular Disease, Aged 65–74 years, Sex Category (CHA_2DS_2-VASC) and (b) Hypertension, Abnormal renal/liver function, Stroke, Bleeding history or predisposition, Labile international normalized ratio, Elderly, Drugs/alcohol concomitantly (HAS-BLED) scores are shown.

During hospital stay, one or more major temporary or permanent contraindications to VKA were documented in 269 patients: recent major bleeding in 63 (23.4%), advanced malignancies in 72 (26.8%), low adherence to treatment in 62 (23%) and refusal of VKA therapy in 42 (15.6%) were the most prevalent.

At discharge, in the overall sample of patients with AF, oral anticoagulant therapy only, single or double antiplatelet agents, and combined anticoagulant–antiplatelet therapy were prescribed in 33.2%, 40.1% and 4.6% of patients, respectively; 124 patients (11.5%) were discharged without antithrombotic therapy, whereas the remaining 114 patients (10.6%) received other antithrombotic treatment, mainly LMWH (Table 2, first column). Among the 809 patients without contraindications to oral VKA, prescription at discharge of oral anticoagulant therapy only, single or double antiplatelet agents, and combined anticoagulant–antiplatelet therapy occurred in 341

(42.1%), 272 (33.6%) and 47 (5.8%) patients, whereas 71 patients (8.8%) were not prescribed any antithrombotic drugs and 78 patients (9.6%) were prescribed other therapies, mainly accounted for by LMWH (Table 2, second column).

Table 2. Antithrombotic therapy at discharge

	Overall sample (1078 patients)	Without contraindications to VKA (809 patients)
Oral anticoagulant therapy only, *n* (%)	357 (33.2)	341 (42.1)
Single- or double antiplatelet therapy, *n* (%)	433 (40.1)	272 (33.6)
Oral anticoagulant + antiplatelet, *n* (%)	50 (4.6)	47 (5.8)
None, *n* (%)	124 (11.5)	71 (8.8)
Other, *n* (%)	114 (10.6)	78 (9.6)

VKA, vitamin K antagonists.

Table 3 shows the variables associated with prescription of OAT at discharge at univariate analysis. In the overall sample, prescription of oral anticoagulants was independently associated with younger age, known AF at admission, permanent/persistent AF, home discharge, lower Charlson Comorbidity Index (less comorbidity), higher hemoglobin levels, lower ADL score (better functional autonomy) and lower HAS-BLED score (Table 4). When the analysis was limited to patients without actual contraindications to VKA, prescription at discharge of oral anticoagulants was still independently and strongly associated with younger age, permanent/persistent AF, home discharge, higher hemoglobin levels and CHA_2DS_2-VASC score, lower ADL score (better functional autonomy), and greater number of drugs at discharge (Table 4).

Table 3. Variables associated with prescription of oral anticoagulants (vitamin K antagonists) at discharge in the overall sample: univariate analysis

	No VKA	VKA	*P*
Female, *n* (%)†	237 (36.5)	412 (63.5)	NS
Known AF at admission, *n* (%)†	345 (38.6)	549 (61.4)	0.0044
ADL, *n* (%)†			
Dependent	245 (83.6)	48 (16.4)	0.0000
Partially dependent	192 (61.7)	119 (38.3)	
Independent	244 (51.7)	228 (48.3)	
IADL, *n* (%)†			
Non-autonomous	313 (78.3)	87 (21.8)	0.0000
Partially autonomous	203 (56.7)	155 (43.3)	
Autonomous	165 (51.9)	153 (48.1)	
SPMSQ, *n* (%)†			
No cognitive impairment	256 (54.2)	216 (45.8)	0.0000
Mild cognitive impairment	138 (59.7)	93 (40.3)	
Moderate cognitive impairment	137 (71.7)	54 (28.3)	
Severe cognitive impairment	115 (81.0)	27 (19.0)	
AF classification, *n* (%)†			
Parossistic	228 (77.6)	66 (22.4)	0.0000
Persistent/permanent	453 (57.9)	329 (42.1)	
Discharge, *n* (%)†			
Ordinary	513 (58.9)	358 (41.1)	0.0000
Post-acute, intermediate, long-term care facility	168 (72.5)	36 (27.5)	
Mean age (years)	84.7 ± 6.6	81.3 ± 6.0	0.0000
Mean HAS-BLED score‡	2.2 ± 0.9	1.8 ± 0.9	0.0000
Mean Charlson Comorbidity Index‡	7.6 ± 2.3	6.9 ± 1.9	0.0000
Mean hemoglobin (g/dL)‡	11.7 ± 2.1	12.3 ± 1.8	0.0000
Mean CHA_2DS_2-VASc score‡	4.7 ± 1.4	4.9 ± 1.3	NS
Mean drugs at discharge‡	7.9 ± 2.9	8.0 ± 2.7	NS
Hospitalization (ranks)§	551.1	516.7	NS
Creatinine (ranks)§	545.6	526.2	NS

†χ^2-test. ‡ANOVA. §Mann–Whitney test. ADL, activities of daily living; AF, atrial fibrillation; CHA_2DS_2-VASC, Congestive heart failure/left ventricular dysfunction, Hypertension, Aged ≥75 years, Diabetes Mellitus, Stroke/transient ischemic attack/systemic embolism, Vascular Disease, Aged 65–74 years, Sex Category; HAS-BLED, Hypertension, Abnormal renal/liver function, Stroke, Bleeding history or predisposition, Labile international normalized ratio, Elderly, Drugs/alcohol concomitantly; IADL, instrumental activities of daily living; NS, not statistically significant; SPMSQ, Short Portable Mental Status Questionnaire; VKA, vitamin K antagonists.

Table 4. Variables associated with prescription of oral anticoagulants (vitamin K antagonists) at discharge: multivariate analysis

Overall sample	OR	95% CI
Discharge in medium-/long-term facilities	0.4300	0.27–0.67
Permanent/persistent AF	2.8199	2.00–3.98
Charlson Comorbidity Index	0.9283	0.87–1.00
Hemoglobin	1.1111	1.03–1.20
ADL score	1.5647	1.29–1.90
Age	0.9383	0.92–0.96
Known AF	1.8207	1.22–2.72
HAS-BLED score	0.6305	0.53–0.75
Patients without contraindications to VKA	**OR**	**95% CI**
Discharge in medium-/long-term facilities	0.4181	0.20–0.87
Permanent/persistent AF	7.1269	4.02–12.63
Hemoglobin	1.2229	1.08–1.39
ADL score	1.6603	1.18–2.33
Age	0.9223	0.89–0.96
No. drugs at discharge	1.1824	1.07–1.31
CHA_2DS_2-VASc score	1.7966	1.47–2.20

ADL, activities of daily living; AF, atrial fibrillation; CHA_2DS_2-VASC, Congestive heart failure/left ventricular dysfunction, Hypertension, Aged ≥75 years, Diabetes Mellitus, Stroke/transient ischemic attack/systemic embolism, Vascular Disease, Aged 65–74 years, Sex Category; HAS-BLED, Hypertension, Abnormal renal/liver function, Stroke, Bleeding history or predisposition, Labile international normalized ratio, Elderly, Drugs/alcohol concomitantly; VKA, vitamin K antagonists.

Discussion

We observed a very high prevalence of AF as well as poor health status among older medical inpatients, who carry a high burden of comorbidities. Roughly one-third of these patients suffer from AF, and among them more than half have some cognitive impairment and approximately one-third are functionally dependent. Overall prescription of oral VKA at discharge in this setting of older hospitalized patients was low (37.8%), but slightly higher (47.9%) when only patients without contraindications to VKA were considered. Indeed, contraindications contributed heavily to underprescription of OAT, because at least one temporary or definite contraindication to VKA was documented in approximately one-quarter of inpatients with AF during their hospital stay. We found that older age, non-permanent/persistent AF, discharge to medium-/long-term facilities, worse functional status and lower hemoglobin levels, which are plausible surrogates of short life expectancy in these patients, were consistently and independently associated with less use of

VKA.19Whereas in the overall sample of AF patients, higher burden of comorbidities and higher HAS BLED score was also associated with non-prescription of VKAs, among patients without contraindications to oral anticoagulants, higher CHA_2DS_2VASC score and greater number of drugs at discharge were positively and independently associated with prescription of VKA. These findings seem to confirm our initial hypothesis: current prescription of VKA in older medical patients is strongly associated with individual health status and functional autonomy; furthermore, comorbidities in these patients can often include true contraindications to the use of these drugs. Our findings suggest that in the real-world clinical practice there seems to occur a "selective" underprescription of these drugs among the most vulnerable and frail older subjects rather than a generic and indiscriminate age-associated under-use of OAT. To the best of our knowledge, the present study is likely the first attempt to use a comprehensive geriatric assessment to shed some light on the prescription pattern of oral anticoagulants in the setting of older medical inpatients with AF.

Prescription of anticoagulant therapy in older medical patients of the real clinical world is often a troublesome decision, likely involving a global evaluation of health, residual life-expectancy, functional and cognitive status, rather than a simple addition of variables within cardioembolic and bleeding scales of risk. Many of these comorbid older patients, despite an intrinsic high cardioembolic risk, likely appear not to be good candidates for anticoagulant therapy, which can sometimes be regarded as a "futile" or potentially harmful therapy in these vulnerable patients with an estimated short life expectancy. Recent studies suggested that the presence of "geriatric syndromes" is associated with the reluctance to prescribe anticoagulant oral drugs in elderly patients,20 and that many hospitalized elderly patients at high risk of stroke might not be optimal candidates for anticoagulant therapy.5 Finally, to date there is very few evidence from clinical trials about the effectiveness and safety of anticoagulant therapy in these older, vulnerable and comorbid patients, contributing to persisting therapeutic uncertainties among prescribing physicians.9, 10, 21

Loss of autonomy and low functional independence are well-known strong risk factors for negative outcomes among elderly patients in several clinical settings.22-24 Hospital discharge to long-term facilities might be considered a surrogate of poor health status too, being usually indicated for patients who can no longer be cared at home because of severe comorbidities, loss of autonomy and/or moderate to severe cognitive impairment. High burden of diseases is often reported as one of the main reasons for not prescribing oral anticoagulants in elderly patients. However, the present findings show that among older medical inpatients, comorbidities can often include true contraindications to use of VKA.

Compared with previous studies, we observed a very high prevalence of AF in this sample of older medical inpatients, with roughly one-third of them affected.25-27 Although it appears plausible that in this hospital setting acute medical conditions might predispose to new-onset AF, more than 80% of patients presented with a known history of AF. Overall, these findings highlight the great burden

of patients with AF faced by physicians operating within medical and geriatric wards. The low prescription rates of VKA in this sample of older inpatients is in keeping with the few studies that investigated this item in patients of the same age.5-8, 25-27 Whether and in which way availability of the novel direct oral anticoagulants might induce different therapeutic approaches to these older patients with AF is at the moment not demonstrated. In keeping with a recent study, we observed that patients with paroxysmal AF were less likely to be prescribed appropriate OAT.28

Some limitations of the present study must be addressed. Present findings originate from patients admitted to a single acute geriatric unit of a large teaching hospital in northern Italy. Although previous studies showed a close similarity of patients admitted to the geriatric unit with those admitted to acute medical wards of the same hospital, our findings should be wisely generalized to different hospital settings.29, 30 Despite the use of a multidimensional assessment, we are well aware that clinical decisions within the context of retrospective data might be biased by several unmeasurable clinical variables. Finally, a small, but not negligible, number of patients with AF were discharged on LMWH therapy, which is not recommended as an alternative to OAT for patients with AF, although it is not infrequently used in daily clinical practice as a temporary alternative to oral anticoagulants.6-8 In the present study, most of these prescriptions occurred in patients with concomitant advanced malignancies and pulmonary embolism or deep venous thrombosis, or in patients who were scheduled for further invasive diagnostic or therapeutic procedures shortly after discharge.

In our view, the present study had some strengths which might make it of clinical interest. This was one of the first attempts to consider through a comprehensive multidimensional evaluation a robust sample of “real-world” older medical inpatients with AF, and to shed some light on the health status and clinical characteristics of these patients. The population we studied is important for several reasons, including the high AF prevalence, the high post-discharge mortality, the likely underrepresentation of such patients in prior trials of OAT for AF and the common reluctance to prescribe OAT in such elderly frail patients. In conclusion, we documented a high prevalence of AF among older medical inpatients, who have poor health status and a high prevalence of geriatric syndromes. VKA were prescribed in less than half of the patients. Underprescription of VKA is mainly accounted for by very advanced age, high prevalence of comorbidities/contraindications, poor health status and limited functional autonomy, and non-permanent AF, thereby providing a plausible clinical rationale for the widely observed under-use of these drugs among the oldest old.

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Dr Bo and Dr Gaita had full access to all of the data in the study, and take primary responsibility for the integrity of the data and the accuracy of the data analysis. Bo, Fonte and Gaita contributed to the study design. Sciarrillo, Maggiani, Falcone, Iacovino, Grisoglio and Grosjean carried out the study and acquisition of data. Data management and analysis was carried out by Fonte, Bo and Sciarrillo.: Bo and Gaita carried interpreted the data. Bo, Falcone and Grisoglio prepared the manuscript. All authors approved the manuscript.

Disclosure statement

The authors declare no conflict of interest.

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