

ORIGINAL ARTICLE

Medical and social apprehension of oral anticoagulation in patients with atrial fibrillation

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Abstract: Background – Anticoagulant therapy stands for one medical field that undergoes rapid development and evolution. Quite frequently, the fear of not having a hemorrhagic episode triggers the failure to recommend the anticoagulant treatment or the ungrounded ceasing of such anticoagulant treatment in the proximity of some invasive maneuvers, with hemorrhagic potential. **Aim** – Determination of the level of information of patients suffering from atrial fibrillation (AF) on oral anticoagulant treatment. **Method** – 155 patients (aged 70.75 ± 10.57) with a diagnosis of AF, have replied to a questionnaire on the social – demographic conditions and the education level, so as to for one to be able to establish the latter's influence on the incidence of failure to comply with the indications and the complications occurred during treatment. **Results** – More than half of the patients (53.5%) were aware of a personal medical condition called atrial AF, and yet 40 % of them have answered by „I don't know”. Only 64.8% of the patients having received oral anticoagulant drugs were aware of the possible hemorrhagic complications associated with the therapy. **Conclusions** – Of the patients being questioned, less than half are aware of the risk of the possibility for the occurrence of hemorrhagic complications while undergoing the antithrombotic treatment. In terms of the anticoagulant treatment being preferred among our subjects, the Acenocoumarol drug remains the most frequently used drug, although monitoring the therapeutic efficiency is cost – involving, without adding the further visits one has to pay to the doctor's office.

Keywords: atrial fibrillation, anticoagulant treatment, hemorrhagic risk, information level.

Rezumat: Introducere – Terapia anticoagulantă este un domeniu medical ce evoluează constant. Frecvent, teama de un episod hemoragic conduce la nerecomandarea tratamentului anticoagulant sau sistarea nemotivată a tratamentului anticoagulant în proximitatea unor manevre invazive, cu potențial hemoragic. **Obiectiv** – Determinarea nivelului de informare a pacienților cu fibrilație atrială privind tratamentul anticoagulant oral. **Material și metodă** – 155 de pacienți ($70,75 \pm 10,57$ ani) diagnosticați cu fibrilație atrială, au răspuns unui chestionar privind condițiile socio-demografice și nivelul de educație, pentru a stabili influența acestora asupra incidenței nerespectării indicațiilor și complicațiile apărute în timpul tratamentului. **Rezultate** – Mai mult de jumătate dintre pacienți (53,5%) erau conștienți de o afecțiune medicală personală denumită fibrilație atrială, însă 40% dintre ei au răspuns cu „nu știu”. Doar 64,8% dintre pacienții care au primit medicamente anticoagulante orale erau conștienți de posibilele complicații hemoragice asociate cu terapia. **Concluzii** – Dintre pacienții chestionați, mai puțin de jumătate cunosc riscul posibilității apariției complicațiilor hemoragice în timpul tratamentului antitrombotic. În ceea ce privește tratamentul anticoagulant preferat în rândul subiecților noștri, Acenocumarolul rămâne cel mai frecvent folosit, deși monitorizarea eficienței terapeutice necesită costuri, dar mai ales vizite suplimentare la cabinetul medical. **Cuvinte cheie:** fibrilație atrială, tratament anticoagulant, risc hemoragic, nivel de informare.

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INTRODUCTION

The AF stands for the most frequent form of tachyarrhythmia, with a prevalence of up to $1.5 \pm 2.0\%$ of the general population, with a constant increase against a global demographic change in terms of the aging population. According to Framingham Heart Study, AF incidence subject to age is divided as follows: <50 years, the prevalence is 0.2%; in between 50-60 the prevalence is 1%; in between 60-80 the prevalence is 2-5% and beyond 80 the prevalence is 6-10%¹.

In addition to the thromboembolic transitory ischemic stroke and the vascular stroke, whose risk increases by five times in patients suffering from AF and which is associated with both brain circulatory disorders, and with the risk of dementia, one has noticed that AF stands for an independent association with the cognitive decline by one distinct hemodynamic manifestation, such as the silent brain infarcts, as a result of micro-embolism, of the modified cerebral blood flow and of the hypo-perfusion².

Using anticoagulant medication is getting more and more frequent in the treatment and prophylaxis of arterial – venous thrombotic events, with an impact on mortality. Studies in this field recommend constant oral anticoagulation for the majority of patients suffering from AF, either by new oral anticoagulants (NOAC), or by K vitamin antagonists, such as the Acenocoumarol or warfarin. Cutting down the risk of a stroke associated with AF is efficient, the anticoagulant therapy reducing the latter's incidence by 64%. NOAC removes the issues associated with traditionally used therapies, such as the need to monitor the coagulation parameters³. The hemorrhagic risk is directly proportional with the intensity of anticoagulation. The specific literature data estimate up to the present moment, some shares of 39% and 62% of antithrombotic treatment among AF patients who are eligible to undergo such anticoagulant treatment⁴.

The causes for failing to comply with the treatment are numerous, and yet the reported factors include the drug and diet interactions, the coagulation monitoring issues, the history of relapses, any associated co-morbidities, such as dementia, any concerns in terms of treatment optimization and the patient's preference. In Ireland, Hannon and the collaborators have reported that one third of the new stroke cases in the North of Dublin have been associated with AF, 45% of these cases standing for recently diagnosed AF cases⁵. The high prevalence of strokes associated with AF is possible given the low rates of AF diagnosis and

the inadequate treatment. Understanding the factors laying the basis for AF awareness and treatment shall duly inform the public knowledge, the health related professional training and the education programs and it shall improve the adherence to the current management guidelines.

Moreover, AF, duly associated with the increased incidence of morbidity and mortality, has been correlated with a lower quality of life and an enhanced risk of developing a cardiac insufficiency and cerebral – vascular strokes. While several studies have assessed the passive influence of anxiety and of other psychological disorders on the cardiovascular system, the inter-relation of AF and anxiety remains evasive. This condition evolution impairs personal satisfaction and the quality of life. The explanation and directionality of one such correlation brings a justification as for a further evaluation^{6,7}.

The CHA₂DS₂-VASc scoring has been developed so as to stratify the risk of a stroke. According to the guidelines of the European Society of Cardiology (ESC), participants with CHA₂DS₂-VASc scoring of >2 require oral anticoagulant treatment, those having CHA₂DS₂-VASc scoring of 1 require either oral anticoagulants or platelet anti-aggregating, and those with CHA₂DS₂-VASc scoring of zero shall fail to require any antithrombotic medication⁸. By help of HAS-BLED scoring, one may calculate the likely risk of bleeding. Patients showing a HAS-BLED scoring of ≥ 3 are deemed to show an increased risk of bleeding and one recommends prudence and a periodical evaluation after the due initiation of the anti-thrombotic therapy⁹.

Thrall and the collaborators have reported that approximately 28–38% of the patients suffering from AF showed a high level of anxiety¹⁰. One has conducted a comparative study between the level of anxiety in patients suffering from AF and the level of anxiety in hypertensive patients, and the ratio was significantly higher in patients suffering from AF (38% of the patients suffering from AF as compared to 22% of the hypertensive patients, $p=0,03$). Also, Dabrowski and the collaborators have noticed that women suffering from AF show some depressive disorders as well as sleep disorders as compared to men suffering from AF¹¹. Moreover, Ong and the collaborators have noticed a poorer quality of life among women suffering from AF, as compared to patients of a male sex¹².

Unfortunately, there is little evidence as to how patients understand AF treatment and the treatment by oral anticoagulants. What one has proven is that pati-

ents suffering from AF show a lower quality of life as compared to the overall population as well as a high level of anxiety. One specialized literature review has indicated the need for the consolidation of the existing proof as to patients' experience and doctors' experience on AF and on anti-thrombotic treatment. The inherent complexity of this field makes the need for a patient-focused approach, efficient communication skills and individually adjusted education, based on recommendations, to be highly significant.

SUBJECTS AND METHODS

We've conducted one prospective study at the 3rd Medical Clinic within "Sf. Spiridon" Clinical Emergency Hospital in Iasi, during the period between December 2017 and August 2018, where we have included 155 patients suffering from atrial fibrillation, both men and women, aged between 31 and 90. The rule out criteria have been as follows: patients aged below 18, patients' denial and the presence of psychiatric, cognitive or other conditions that might prejudice the understanding of the due study goals or the ability to supply accurate information. Patients got their questionnaires while being committed to the hospital.

The questionnaire was divided into several sections: 1) participant's information (age, sex, environment, education, civil registry status, the length of time elapsed as of the diagnosis or the anticoagulant treatment, significant cardiovascular antecedents); 2) 8 questions about the perception to the condition and the latter's complications, as well as about the need for anticoagulant treatment; 3) 5 questions about the indications and precautions in terms of the treatment; 4) 3 questions for patients under Acenocoumarol treatment; 5) 3 questions for patients undergoing treatment by NOAC.

DATA ANALYSIS

The statistical analysis has been carried out by using SPSS 22.0 software (Statistic pack for Social Sciences, Chicago, Illinois). Data have been expressed as an average \pm standard-deviation (SD) or the number of cases with a percentage, for the constant and listed variables.

RESULTS

The average age of patients has been 70.75 ± 10.57 years old, the minimum age being 31 and the maximum age being 90. Of the aforementioned, within the age group <50, the percentage has been 3.23% (n=5);

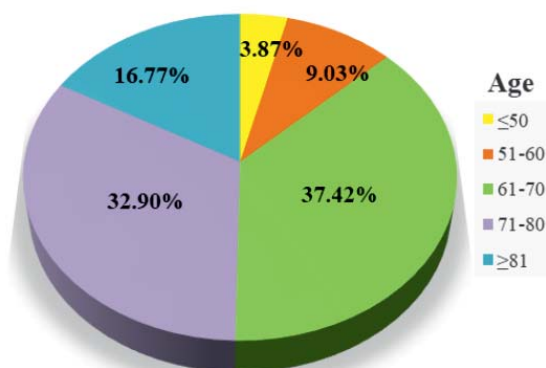


Figure 1. Demographic data.

within the age group: 51-60 the percentage has been 9% (n=14); within the age group 61-70 the percentage has been 38.6% (n=59); within the age group 71-80 the percentage has been of 32.9% (n=51) and within the age group >80, the ratio has been 16.77% (n=26) (Figure 1).

Within the relevant study group, 51.6% (n=80) have been women, while the group of men was represented by 48.4% (n=75) of the subjects. In terms of the provenance environment, 58.1% of patients came from the rural environment (47 women and 43 men) and the urban environment was represented by 41.9% of the subjects (33 women, namely 32 men).

Within the present study, 71.6% (n=111) of the patients enrolled in the study were married and a significant percentage 22.6% (n=35) have stated that they were either a widow or a widower. Starting from the idea that education helps us become aware of the risk we expose ourselves to when we deny getting a treatment, 26.5% (n=41) of the patients had graduated gymnasium education, 24.5% (n=38) had graduated the elementary school, 40% (n=62) had graduated high school and 9% (n=14) had graduated a faculty. Of the aforementioned, the largest number of patients who

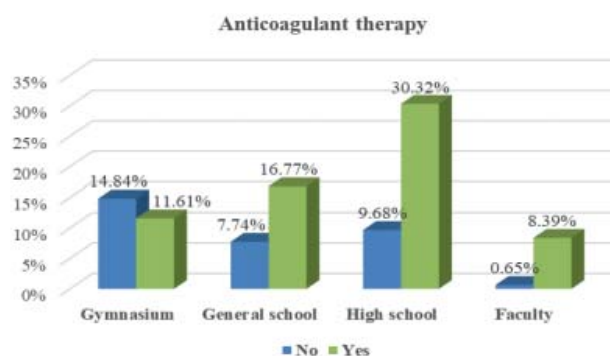


Figure 2. The structure of the lot subject to educational level.

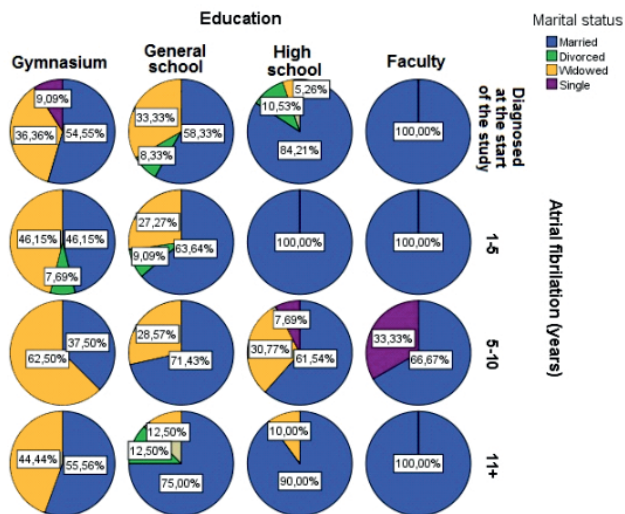


Figure 3. Distribution of patients subject to educational level, marriage status and the atrial fibrillation seniority.

were under anticoagulant treatment, were high school graduates, with a share of 30.32% (n=47), as compared to the gymnasium education graduates group, who stood for the majority of the group of those patients undergoing an anticoagulant treatment, with a share of 14.84% (n=23) respectively (Figure 2).

Just as shown in Figure 3, of the patients diagnosed at the beginning of the study, most of them were high school graduates, married (84.21%). In terms of subjects of a known diagnosis, the predominance has also been held by married high school graduates, while at the opposite end, holding the lowest percentage there were the gymnasium education graduates, with a share of 7.69%.

Subject to the type of anticoagulant treatment being accepted, we may observe that Acenocoumarol is preferred by patients from the rural environment, most probably given the latter's lower cost, while people from the urban environment enrolled in our study prefer the apixaban (Figure 4).

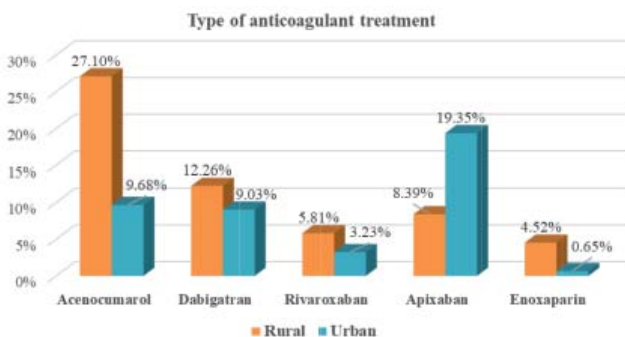


Figure 4. Patients' distribution subject to type of oral anticoagulant treatment and the provenance environment.

Acenocoumarol is mainly administered in our lot of subjects, with a share of 9,03% (n=14) in gymnasium education graduates, 10.97% (n=17) in general education graduates, namely 16.13% (n=25) in high school graduates, while faculty graduates prefer the Apixaban in a majority share of 9.68% (n=15) (Figure 5).

Another relevant issue, as well as possibly a risk factor for the occurrence of complications during the administration of the anticoagulant treatment might be represented by each single subject's physical and social activity. We've divided our group subject to the type of activity, namely active (aged <65) and passive (aged >66). Acenocoumarol is once again preferred by the elderly group, although monitoring the therapeutic efficiency is cost – consuming, not to mention the additional visits paid to the doctor's office (Figure 6).

The stroke risk stratification has been accomplished by the CHA₂DS₂-VASc scoring: 41.3% (n=64) have had the CHA₂DS₂-VASc scoring of ≥5, of the aforementioned, 40.6% (n=26) were undergoing therapy by Acenocoumarol, and the rest of 59.4% (n=38) were undergoing therapy by NOAC. The assessment

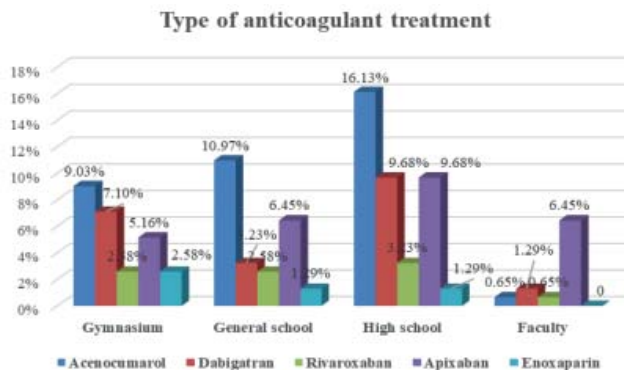


Figure 5. The structure of the lot, subject to the type of oral anticoagulant treatment and the educational level.

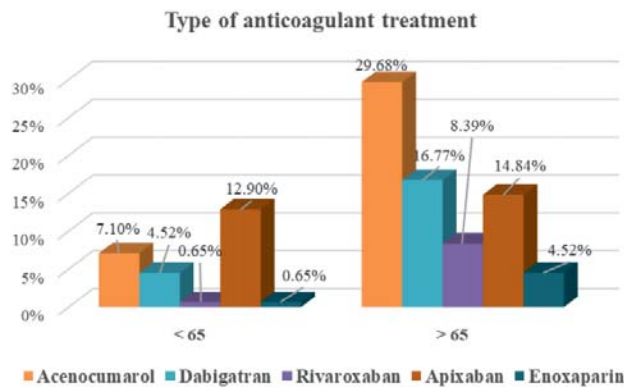


Figure 6. Patients' distribution subject to age group and the type of oral anticoagulant treatment.

based on HAS-BLED scoring has shown that 74.83% (n=116) of the people under questioning showed an HAS-BLED scoring of ≥ 3 points, three quarters being aged over 65.

Within the present study, the complications that have been most frequently met in patients suffering from atrial fibrillation and who underwent anti-thrombotic treatment, namely the stroke and major bleeding, have held the highest percentage among high school graduates in the urban environment, in terms of strokes the percentage being 30% and 44% was for major bleeding. The lowest incidence in terms of these complications has been noticed in subjects who had graduated the gymnasium and who lived in the urban environment, namely 1.6%, respectively 1.53% (Figures 7 and 8).

Only 12.9% of the patients suffering from AF have stated that one can detect AF by regularly taking one's pulse. It should be noted that almost one in three patients (38.1%) had no idea that AF can cause pulmonary embolism and strokes.

Less than half of these patients (38.1%) knew that risk factors such as overweight can facilitate AF. Moreover, only 34.8% of the patients having received anti-thrombotic drugs were aware of the eventual he-

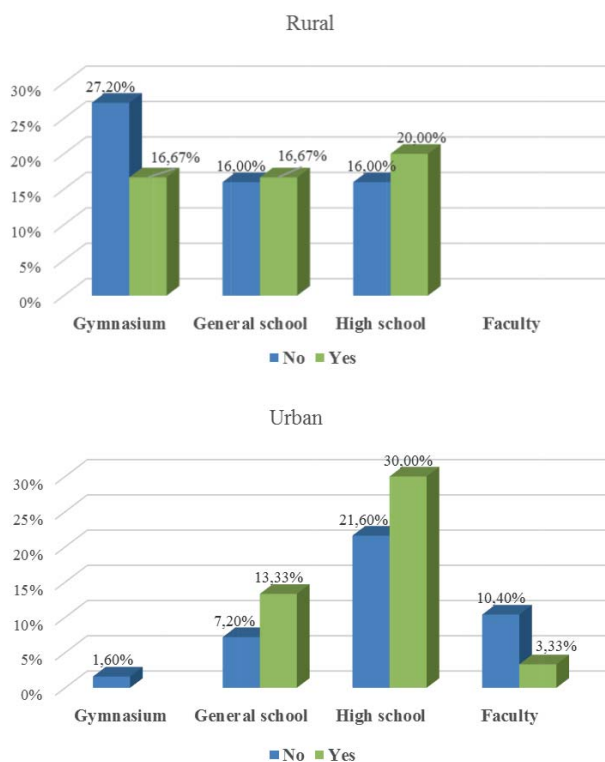


Figure 7. Patients with stroke (in the past).

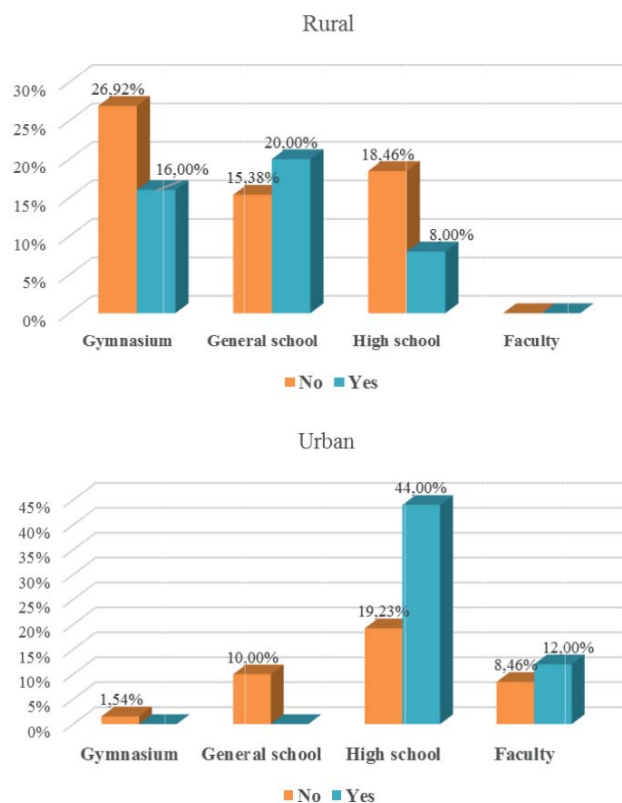


Figure 8. Patients with major bleeding (in the past).

morrhagic complications that are associated with the therapy.

Unfortunately, the information on analgesics that can be safely used in combination with the anticoagulant therapy is not sufficiently clear and precise, since only 27.7% know they can use those of the type of Acetaminophen. In the event of any surgery, most likely 62.6% of the patients would not check with their physician in terms of the eventuality of any adjustment of the anticoagulant therapy.

On the studied group, 29.45% (n=19) of the patients reported ischemic events, of which 15.5% (n=10) of the patients were urban and 13.95% (n=9) in the rural area, the distribution being approximately equal.

Regarding hemorrhagic events, there is a prevalence of rural patients 13.95% (n=9), compared to the urban environment, 7.75% (n=5).

Relative adherence to treatment in rural patients resulted in under-treatment of oral anticoagulant therapy (52.23%), and therapeutic INR in the same patient population was found in 2.98% of cases. In urban patients, there is a better treatment compliance, as evidenced by the higher proportion of patients with therapeutic INR (7.46%) (Figures 9).

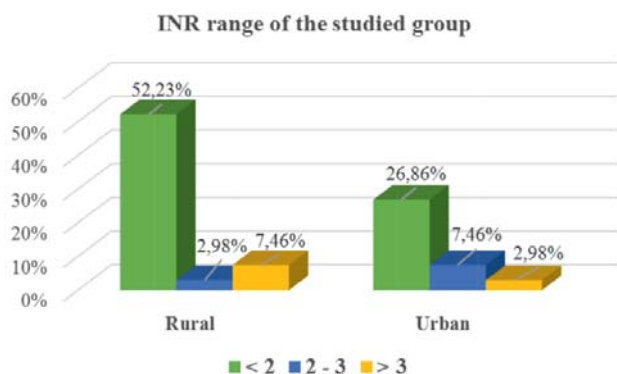


Figure 9. Ischemic and hemorrhagic events in relation to provenance environment.

DISCUSSIONS

The literature information has proven that in patients suffering from atrial fibrillation and who undergone treatment with warfarin or NOAC, the major bleeding risk has been significantly lower than in patients treated by NOAC¹³.

One recently conducted study on patients' satisfaction with the warfarin – based treatment, has shown that the latter were satisfied with it, however they have been willing to consider using a new oral anticoagulant which was more convenient. The major barrier for taking this turn has been represented by the cost and the necessity to administer some of the most recent agents twice a day, unlike once every day as it was the case of warfarin¹⁴.

The present questionnaire approaches one of the most significant issues regarding the AF management and the anti-thrombotic therapy, including not only theoretical questions, but also such questions as related to the management of various possible cases in anticoagulant patients. Whereas the main focus of AF refers to preventing the thromboembolic stroke, we focused on the possible side effects, the drug interactions and the relevant of one good adherence to the anticoagulant treatment.

The anti-thrombotic treatment should be applied in due compliance with the current guidelines, and the risk-benefit ratio shall be assessed for each and every single patient, as concerned. The hemorrhagic risk shall dominate the clinician's logics and reasoning in terms of the anticoagulant therapeutic approach to the detriment of any potential benefit whatsoever¹⁵. The result of the numerous clinical trials confirm the fact that patients have significant benefits as a result of one judicious anticoagulant treatment^{16,17}. Knowing

how the anticoagulant medication works, as well as knowing the protocol and the necessary medication required in hemorrhagic emergency cases, it's what gives the physician the surety he needs upon making the calls. All these facts bring a series of benefits to the patient in terms of vascular aging, as well as the length and quality of the latter's life^{18,19}.

The main causes of NOAC's under-utilization in the present study were: modest economic status, high cost of NOAC, limited access to medical information of rural population and reduced educational level.

CONCLUSION AND FUTURE PERSPECTIVES

Our study underlines the need to take action and conduct an intervention at the education level among the patients suffering from AF, particularly those showing a high risk of stroke. The results shall be used for the purpose of drawing up a series of information and prevention programs which have proven to be an absolute requisite, so as to enhance the quality of life and increase life hope among the relevant population, as concerned.

Modern people nowadays have to be educated and trained in terms of what cardiovascular prevention means, since this plays an important part in the management of patients showing a risk of, or suffering from various forms of cardiovascular conditions. Focusing on resources for people's information and training, the non – pharmacological and pharmacological active prophylaxis in the intra – and extra – hospital environment, can literally reduce the financial demand for the treatment of any thrombotic events and the related complications, acting first and foremost by lowering the incidence of the condition among the relevant population, as concerned.

Further studies are required in view of assessing if any such educational efforts are able to improve the overall results of patients suffering from AF.

Conflict of interest: none declared.

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