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REVIEW ARTICLE

Face-to-face education to optimize knowledge in patients initiating oral anticoagulant treatment (OAT)

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Abstract

Background: *Insufficient knowledge of patients about oral anticoagulants that they have been prescribed is recognized as a risk factor for adverse effects. Education of patients under oral anticoagulation may improve quality and control of anticoagulant treatment; limitations of educational interventions include lack of assessment of patients' knowledge. Our goal was to determine the effect of an individualized educational intervention on knowledge of patients who recently started treatment with oral anticoagulants, to assess patients' knowledge, and to analyze factors associated with knowledge acquisition.* **Methods:** *In 49 consecutive patients attending a thrombosis clinic who initiated or re-initiated oral anticoagulant treatment, knowledge about the treatment was assessed by means of a validated questionnaire, before an individualized, face-to-face educational intervention, and at least four weeks after. Educational intervention started after the questionnaire had been answered by patients for the first time.* **Results:** *Knowledge level increased by about 50%; the improvement was higher in patients with more years in school.* **Discussion:** *Timely acquisition of knowledge about oral anticoagulant drugs is optimized with interventions provided earlier during the patients' treatment. Assessment of knowledge should be performed and instruction should be adapted to patient characteristics such as level of education and availability to receive education.*
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Introduction

The prevention of thromboembolic events of different etiology and their recurrence is an indication for the use of oral anticoagulants that is well supported in medical literature[1,2].

The lack of adequate knowledge among the patients has been recognized as a risk factor for the development of adverse effects, including hemorrhages[3]. One of the most feared adverse events associated with the use of oral anticoagulants is bleeding[4,5]. That fear is shared both by doctors and patients, which sometimes leads to undertreatment of patients in whom their use is indicated[4-7].

The importance of an adequate education in patients who receive oral anticoagulants to favor better treatment control has been demonstrated. Some reports refer to patients who have to self-control their coagulation level and the oral anticoagulant dose[8-11].

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The recommendations on education of patients under anticoagulant treatment, as an element to optimize treatment quality, have been proposed since several years ago by different research groups, as well as by institutions focused on ensuring healthcare education and are valid to this day[12,13]. However, the results of educational strategies in patients not self-controlling their medications' doses have been considered inconclusive in some reports[14-16].

The limitations pointed out with regard to educational interventions directed to patients on anticoagulation that have been mentioned include: lack of assessment of patients' baseline knowledge, lack of evaluation instruments validation, lack of reports on information retention, absence of causal relationship between better knowledge and improvement on anticoagulant treatment-related indicators[14,17].

In a previous work, we reported that patients that had remained on anticoagulant treatment for highly variable periods (ranging from < 1 to 228 months, median = 18 months) and who received an educational group intervention, improved their knowledge on anticoagulant drugs, regardless of the time on treatment. The patients' knowledge was assessed using an instrument that was designed and validated for that purpose. In addition to assessing the patients' baseline knowledge, the effect of the educational intervention on patients' knowledge and its retention 6 months later was determined[18].

The purpose of this work is to determine the effect of an individualized educational intervention (IEI) in patients who are initiating or have recently resumed oral anticoagulant treatment (OAT) and to analyze some factors that may be associated with opportune acquisition of this kind of knowledge.

Methods

This is a prospective, longitudinal, open-label study. The study was approved by the Ethics and Research Commissions of the Faculty of Medicine of the National Autonomous University of Mexico (Ruling 019-2012).

Patients

After having granted informed consent, 49 adult patients continuously incorporated to the Zone General Hospital Carlos Mc Gregor Sánchez Navarro of the Mexican Institute of Social Security (IMSS – *Instituto Mexicano del Seguro Social)* for their study and control and who started or resumed OAT between December 2012 and February 2014 were included in the study.

Knowledge assessment

Knowledge of the patients about their anticoagulant drugs was explored in two occasions: at baseline and/or prior to an educational intervention and after it. The patients answered a questionnaire on anticoagulant medications that has been validated[18].

The questionnaire included subjects about oral anticoagulants and educational intervention. The contents of the questionnaire and the written materials included:

- General characteristics of the treatment.
- Treatment adherence.
- Oral anticoagulants mechanism of action and adverse effects.
- Precautions during anticoagulant treatment.
- INR[§] control knowledge and interpretation.
- Interactions with food.
- Interactions with drugs.
- Interactions with alcohol.

Patient-directed face-to-face IEI

The IEI was started once the questionnaire was answered. Each question of the questionnaire and its answer were analyzed and reviewed with each patient. The content of each question was explained to the patient and analyzed in detail with the support of written materials on anticoagulant drugs that were developed for this purpose and that were handed to the patient to complete the already verbally-provided information for later consultation and study. In subsequent visits to the thrombosis clinic for anticoagulation treatment control, patients were applied the questionnaire for a second time in order to assess the effect of instruction (at least 4 weeks later). The questionnaires answered by each patient were left on the responsible investigator's hands immediately after being completed for grading and analysis.

Data analysis

Data corresponding to categorical variables are reported as frequencies, and data of quantitative variables are expressed as means and standard deviations. The SigmaStat 3.5 package was used to obtain descriptive statistics and to carry out the statistical tests.

[§]INR: International Normalized Ratio. It is a measure of standardized prothrombin time used in the control of treatment with vitamin K antagonist oral anticoagulants.

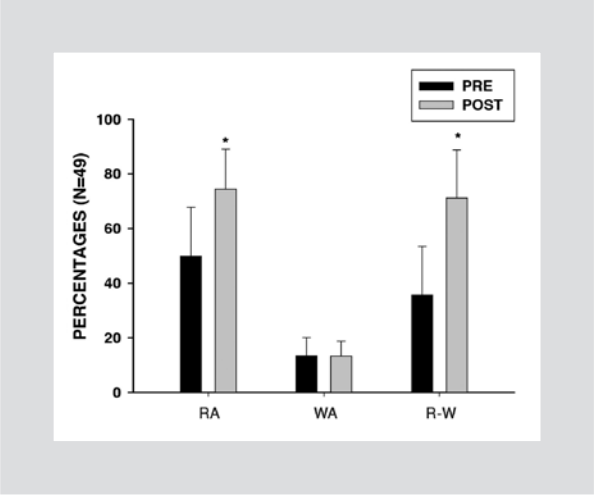

Figure 1. *Pre- and post- individualized intervention results. The bars correspond to the right answers (AC), wrong answers (ERR) and right minus wrong answers (A-E) percentage averages, the vertical lines represent standard deviations. The differences between right answers and right minus wrong answers before and after the educational intervention were significant. *p < 0.001, according to Student's t-test.*

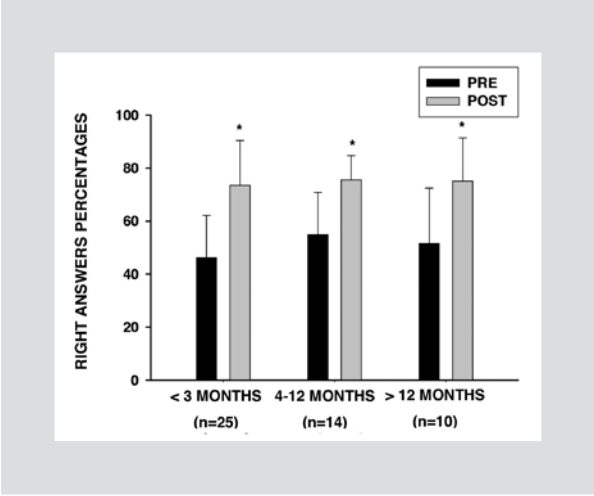

Figure 2. *Pre- and post-individualized intervention right answers according to time on treatment. The bars correspond to average right answers percentages in two different applications of the questionnaire to patients with different time on anticoagulant treatment. The differences between pre- and post-intervention application right answers were significant. *p < 0.001 for < 3 months and 4-12 months on treatment; p = 0.012 for > 12 months on treatment, according to Student's t-test.*

To assess the patients' knowledge, only right and wrong answers to closed questions (87) were graded. The right and wrong answers were assigned a value of 1; the "Don´t know" answers were assigned a value of 0. To have an additional measurement, wrong answers were subtracted from right answers. In order to simplify information interpretation, right and wrong answers to the questionnaire are expressed as percentages, in such a way that 87 (the number of closed questions) is equal to 100%.

Results

- Patient characteristics. Sex and age: The questionnaires were answered by 49 patients, 35 (71.4%) females and 14 (30.6%) males; ages ranged from 18 to 88 years, with a mean of 46.2, median 46 and mode 51 years.
- Time on anticoagulant treatment: 25 (51%) patients had been less than 3 months on treatment, 14 (28.6%) patients had been between 4 and 12 months on treatment, and 10 (20.4%) had been more than 12 months on treatment (14, 18, 24, 24, 30, 42, 52, 84, 180 and 204 months). The latter patients had been recently admitted to the thrombosis clinic where this work was carried out for study and control of the anticoagulant treatment.
- Level of education: The patients referred having one or several years of: basic education (primary school): 7 patients; one or several years of secondary school or high school or vocational-technical business school: 19 patients; one or several years of pofessional studies: 23 patients.

Figure 1 shows baseline knowledge assessment results of all patients (pre) and for the assessment after (post) the IEI (n = 49).

Figures 2 and 3 show the pre-and post-intervention results of patients who received the individualized intervention, considering time on treatment and level of education.

The comparison of right answers before and after the intervention showed highly significant differences for the subgroups with less than 3 months and with 4-12 months on treatment ($p < 0.001$) and with > 12 months on treatment ($p = 0.012$) (Student's t-test). There are no differences between the baseline pre-intervention assessments ($p = 0.3$) of the 3 subgroup according to the time spent on treatment or in the post-intervention assessments ($p = 0.9$, according to a univariate ANOVA).

Differences between pre- and post-intervention right answers were significant in the questionnaires answered by patients with middle and higher education ($p < 0.001$), but not in the questionnaires answered by patients with basic education ($p = 0.192$), according

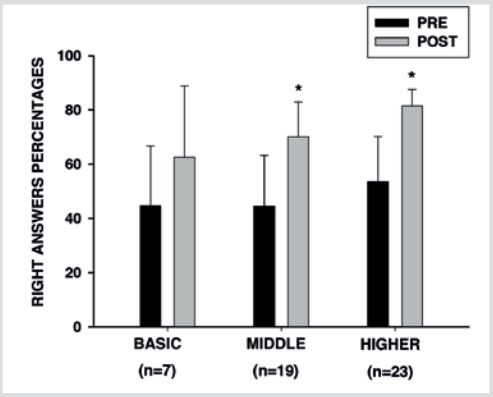

Figure 3. *Pre- and post-individualized intervention right answers according to level of education. The bars represent averages of the right answers percentages and vertical lines represent standard deviations. The differences between pre- and post-intervention application right answers were significant. *p < 0.001 for middle and higher level of education; p = 0.192 for basic level of education, according to Student's t-test.*

to Student's t-test. In the 3 education levels subgroups, pre-intervention right answers were similar, with no significant difference being found, p = 0.234 as per univariate ANOVA. There were differences between the 3 subgroups post-intervention assessments, p = 0.002. Post-intervention assessment of the subgroup with higher level of education was different (p < 0.05) that those in other education level subgroups (basic and middle), according to paired comparisons using the Holm-Sidak method.

Table 1 shows the results of the individualized intervention and the previously reported group intervention[18] for comparison. Baseline knowledge (prior to intervention) of the group that received group intervention was 9.6 percent points higher than in the group that received the individualized intervention, and the difference is significant, p = 0.012, according to Student's t-test. Knowledge after both interventions was similar. The comparison of post-intervention right answers of both groups of patients showed no significant difference.

Discussion

We have previously reported the results of a first phase of this research work, which included the determination of baseline knowledge in a larger group of patients for psychometric validation of the used instrument. We also reported the effect of a group educational intervention on the knowledge of patients with different times on treatment, some of them with more than 10 years on OAT (range: 0.25-228 months, median: 18 months)[18].

In the study we report in this work, patients who had recently initiated their oral anticoagulation treatment with vitamin K antagonists were included and, additionally, patient instruction was carried out in a face-to-face, individualized fashion, with the purpose to provide information to the patients as early as possible at the start of their anticoagulation treatment. We have compared the results obtained in patients who received similar information by means of the group intervention reported in the first study[18]. After either type of intervention, group and face-to-face, the knowledge average grade, as assessed with the instrument we developed to this purpose, is similar in both groups (Table 1). This, notwithstanding that, in the first study,

Table 1. Comparison of group and individualized educational interventions

Percentages of	Group n = 33 (Mean ± SD)	Individual n = 49 (Mean ± SD)
Pre-intervention right answers	59.4 ± 14.2	49.8 ± 18*
Post-intervention right answers	78.1 ± 9.1	74.4 ± 14.7
Pre-intervention wrong answers	16.1 ± 6.9	13.4 ± 6.7
Post-intervention wrong answers	11.5 ± 6.4	13.3 ± 5.5
Pre-intervention right-wrong answers	43.2 ± 16.8	35.7 ± 17.8
Post-intervention right-wrong answers	65.8 ± 13.6	61.2 ± 17.6

The table compares the results of a previously-reported group intervention18 with the individualized intervention referred by the present work. The difference is significant between pre-intervention assessments of both groups.
*p = 0.012

median time on anticoagulant treatment of patients was 18 months and, in the present study, median time on anticoagulant treatment of patients was 3 months and that, in addition, right answers average in the group that received the group intervention before the intervention was higher in the group that received the individualized intervention.

It is important to emphasize that the inclusion of patients with less time on treatment allowed for their knowledge on their anticoagulant medications to be improved at an earlier and possibly more opportune stage. This is relevant, since medical literature has reported that some treatment safety-related incidents are frequently observed at initial stages[4,6].

Another advantage of the approach we used to educate patients in this work was the incorporation of patients to the educational intervention during the visit of these patients to the hospital on the day of their appointment with their hematologist or during some of their visits for OAT control. For many patients, it is difficult having special time available to be instructed on their anticoagulant medications, as it happens when intervention is in groups, since instruction times have to be conciliated with patients' available time and a special area has to be found to deliver it (e.g., lecture hall or classroom).

By means of the IEI, it was possible to achieve for patients to acquire more knowledge on the safety of their medications shortly after treatment was started, in contrast with patients that have spent several years on treatment but have not received specific and detailed education on the subject.

Frequently, at the absence of a patient-directed specific educational intervention, training is often briefly offered by treating physicians, although there are also institutions that offer informative talks to their patients. In either case, information assimilation by the patient is not assessed. In the case of this project, the most important difference with regard to other patient instruction initiatives is the use of an assessment instrument.

Both types of intervention, in groups or individualized, improve patient knowledge. Individualized intervention allowed the suppression of the waiting for a group intervention to be programmed or for patients to have available time to attend. On the other hand, in an individualized intervention, the level of explanations can be adjusted to the understanding capacity of each patient, and it is possible trying to make them simpler than those contained in the written materials.

During the development of the questionnaire, we took into account the experiences reported by other authors with regard to the instruments they have used to assess patient knowledge. It is relevant mentioning that, although there are questionnaires to assess patient knowledge on their anticoagulation medications in other countries, we considered that it would not have been sufficient or adequate to translate an instrument. For any questionnaire published elsewhere and originated in other culture to be applicable in our setting, we also had to consider that the use of vitamin K antagonists is not restricted to a single one such as warfarin, but that others, such as acenocoumarin, are used, in addition to alimentary habits and costumes being different, including the dietary composition, common mealtimes and other differences, such as the use of herbal infusions and herbal medicine.

The instrument we developed is written in Spanish and we have demonstrated that it is applicable in patients of our setting, which had not been done previously. The use of the questionnaire has allowed for patient knowledge to be assessed and for some of the factors that may influence on the effect of information provided through intervention to be studied.

Patients with higher levels of education had greater baseline knowledge, as well as higher post-intervention knowledge productive use. In patients with basic and less than basic level of education, IEI increased patient knowledge by 18% in absolute terms, which is equal to nearly 40% in knowledge increase, although this knowledge increase was not statistically significant. The large variability in results and the low number of subjects in this patient subgroup is a possible explanation. This highlights that favoring the understanding of complex facts in people with low levels of education is a big challenge.

The knowledge patients possess about their medication is one of the factors that, according to some authors, influences on anticoagulant treatment better quality, especially for patients who start treatment[10,11]. With regard to satisfaction in better informed patients, a recent study has reported that patients with more knowledge on their treatment are more satisfied with it and express less fears[19].

In this study, a little over half the patients have been less than 3 months on anticoagulant treatment, conversely to our previous report, where the patients had been longer on anticoagulant treatment (median = 18 months). In the previous work, we showed that time on treatment does not warrant the acquisition of knowledge about it, which had already been pointed out in previous works[20]. We have achieved improving patient knowledge in early stages of their OAT and we have been

able to confirm the usefulness of the questionnaire as an evidence objective element thereof.

In Mexico, and possibly in other countries as well, the approach on information provided to the patient is quite varied. On the other hand, until now, there was no validated instrument that allowed for the knowledge that patients who consume these medications have to be evaluated. We consider that the patient on treatment with anticoagulant drugs must possess the knowledge that he/she has been conveyed by means of the intervention. The specially-developed assessment instrument allows for this knowledge to be evaluated, without assuming that because of having been taking anticoagulant drugs for a long time patients master the necessary knowledge to adequately comply with their treatment and avoid associated risks.

Assuming there would be a benefit from the intervention, we considered working with patients consecutively attending the clinic to start or resume anticoagulant treatment; therefore, study limitations include that the patients were not randomized to receive the intervention. On the other hand, the frequency of hemorrhages was not recorded before or after the educational intervention.

Recommendations on education of patients receiving oral anticoagulants are valid as a strategy to improve treatment quality and continue to be mentioned by organizations that promote healthcare quality and patient safety in general[12], as well as by groups specialized on the care and investigation of patients under anticoagulant treatment[13]. There is evidence that better informed patients comply better with their treatment follow-up, with this already been quoted with regard to patients who control their treatment themselves[9] and also in patients where treatment control relies on the physician, and this has been recently reiterated[21].

With this contribution, some of the limitations that have been mentioned with regard to educational interventions directed to patients on OAT such as lack of baseline knowledge assessment and lack of knowledge retention evaluation have been surmounted[17].

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