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SURVEY ON PATIENT INFORMATION ABOUT THE HOME ADMINISTERED ANTI-COAGULANT TREATMENT

T. NEDELOIU[1] M. BRĂTEANU[1] L. BOICIUC[1]
C. BRATU[2]

Abstract: *Even though new classes of anti-coagulants are needed, from the category of the X-factor inhibitors (apixaban, rivaroxaban) or of the thrombin direct inhibitors (dabigatran) that pose a low bleeding risk and that do not need INR monitoring, the class of coumarinic anticoagulants (acenocoumarol, hydroxycoumarin) still remain precious anticoagulants. That is why the patients' education in relation to their home administered treatment for the control of its efficacy and the prevention of bleeding-related complications is compulsory. This education is supposed to start in hospital and continue thereafter, but the real testing of the patients' knowledge after they are released is not a part of the usual protocols. This study assesses the level of this knowledge for the purpose of optimizing the educational process and of strengthening the clinician-patient relationship.*

Key words: *anticoagulant treatment, adherence, patient education, questionnaire.*

1. Introduction

The indications and prescription of the anticoagulant treatment are growing larger. As a consequence, the number of the patients that do not range within the therapeutic interval of the INR [3,7] increases proportionally with the bleeding risk.

The decisive factor in the prevention of this complication is the clinician-patient relationship both at the beginning of therapy and during the following thereof. Since this relationship is very complex and hard to quantify due to the many subjective factors, what matters in the end is the manner in which the patient acknowledges the requirements of this special medication. Only based on that, may we assess the patient's adherence to the treatment.

According to a study of the patients' adherence to the warfarin therapy, non-adherence ranges between 10 and 26%. [5]

The factors that influence the compliance with the anticoagulant treatment are represented by demographic and psychosocial factors [1], but also by the patient's attitude and medical information on the followed course of treatment [4, 10]. The very administering of the anticoagulant may lead to low compliance or even therapeutic failure [6].

[1] Faculty of Medicine, *Transilvania* University of Braşov.
[2] Braşov County Clinical Emergency Hospital.

In different studies, the approach of patient compliance with the chronic oral anticoagulant therapy was achieved through questionnaires [2, 4 and 9]. E.g. Martin H *et al*. used questionnaires that had been translated into 14 languages to assess the patients' expectations from the anticoagulant treatment and their degree of satisfaction, the burden of this type of treatment and the patients' perception of the efficiency and their fears about the adverse effects of the treatment [6].

Adherence to this therapy is tightly related to the effects it has over the patient's quality of life. It can be influenced by the inconvenient of having to take the medicines daily, the necessity to monitor the INR periodically, the perception of the drug efficiency, the anxiety about the possible adverse reactions and the degree of understanding of the information provided by the clinician [8].

2. Material and Methods

2.1. Design

The is a transversal, observational and prospective study that was carried out on the inpatients in the Departments of Cardiology and Internal Medicine of the Brasov County Clinical Emergency Hospital for 2 months in 2011. All the patients were assessed in the order of their admission, with no exception. That was also the randomization criterion.

In order to objectify the anticoagulated patients' stages of understanding of their home administered treatment, a questionnaire comprising 19 questions was devised (Table 1) for the patients to answer to, under the direct observation of the investigators in the study. The patients received clarifications, but their answers were not influenced (the "interview" method). The questionnaire was filled in, with the reading of the observation chart where the background disease for which the patient was under anticoagulant treatment was noted from. Nine of the questions aimed at the characteristics of the analysed group, and the remaining ten were related to the subjects' knowledge of their home administered anticoagulant treatment.

The answers to the questions about the information on the patients' home administered treatment were than recorded and quantified. Thus, each patient received a score (from 0 to 10), proportional to the level of information. The maximum score was given to those who: 1) knew about the disease that the treatment had been prescribed for; 2) knew what effect the treatment had; 3) knew the length of the treatment; 4) monitored their INR on a monthly basis; 5) only interrupted their treatment at the physician's indication; 6) knew about the risk of associating the treatment with NSAIA; 7) were aware of the counter-indication of the intramuscular injections; 8) knew what happens in the case of overdosage of the treatment; 9) knew what melena looked like; 10) warned their physicians, during the visits, about their treatment with anti-coagulants.

2.2. Statistic analysis

The statistic analysis was performed with the SPSS 17 program and it comprised some modules of univariate and multivariate analysis of the noticed parameters. Averages, medians, the analysis of data dispersion and normality, the χ^2 coefficients, Spearmen's correlation and the Student's t-distribution were used.

The normality of the distributions of the scale variables was assessed through the Shapiro-Wilk test and, where great deviations were found, the Minitab 16 software was used for the Box-Cox power

transformation and the determining of the lambda (λ) coefficient. The $\chi 2$ test was used to compare the frequency of the nominal variables in the case of the bi-categorical data. Simple ANOVA and the T test were used to compare the multi-categorical data environments, both of them associated with the Levene test for the assumption of the inequality of variances and confidence intervals of 95% (C.I. 95%) were calculated. The binomial nonparametric test was used to compare percentages. The Pearson coefficient „r" and „R^2" were used to analyse the correlations and simple regression line was drawn. The statistic relevance was set at $p < 0.05$.

The two groups of questions Table 1

Characteristics of the studied group	1	Sex
	2	Age
	3	Why is the patient hospitalized at the time of the interview (overdosing or other condition)
	4	Length of the anticoagulant treatment (in months)
	5	Was the patient ever overdosed before or at this current admission?
	6	Is he/she currently under treatment with Trombostopor Sintrom?
	7	In time, has the patient switched between the two drugs?
	8	Is he/she self-administering the treatment?
	9	Has he/she ever interrupted the treatment? Why?
Items of assessment of the patient information	1	Does the patient know what conditions he/she is taking the anticoagulant treatment for?
	2	Does he/she know the effect of the medication? What is it?
	3	At what time intervals is he/she monitoring the INR?
	4	Does he/she know how long he/she will follow this treatment (definite or indefinite term)?
	5	Does the patient know that under no circumstances must he/she stop the treatment without medical advice?
	6	Does he/she know the NSAIA pose a digestive bleeding risk?
	7	Does he/she know that theintramuscular injection is counter indicated?
	8	Does he/she know what happens in overdosing?
	9	What is melena and what does it look like?
	10	Does the patient inform other physicians about his/her treatment during different visits?

Two columns of the questionnaire included: the basic condition for the anticoagulation and the patient's score at the assessment questions.

3. Results and Discussion

3.1. Analysis of the characteristics of the studied population

126 of the patients successively admitted to the hospital during the study period were following a chronic oral anticoagulant treatment or the anticoagulant treatment was initiated during their current stay in the hospital.

The sex ratio is relatively balanced, 56 women and 70 men (44.4%, respectively 55.6%) with the average age of 65.6 (CI 95% [63.5-67.7]).

Seven of them had been admitted for overdosage (5.6%) and 119 (94.4%) for some other current pathological condition.

The frequency of the background diseases for which the patients were following the oral anticoagulant treatment is presented in Figure 1. Three were the better represented diseases: 60 patients had permanent atrial fibrillation (47.6%), 26 (20.6%) had deep vein thrombosis, and 12 of them (9.5%) cerebrovascular accident.

The average length of the anticoagulant treatment was approximately 4 years, 48 months (CI95%=[37.2-58.5]).

Only 20 (15.9%) of the 126 patients had had coumarinic overdosage antecedents or were currently hospitalized for this type of complication.

All used acenocoumarol, most of them (78.6%) under the form of Trombostop and the others (21.4%) under the form of Sintrom.

Only a fifth (19.8%) had switched from one form to the other.

In 9 of the patients (7%) the drug was administered by other persons, and the interview was addressed to those persons, whereas 117 (93%) were self-administering the treatment.

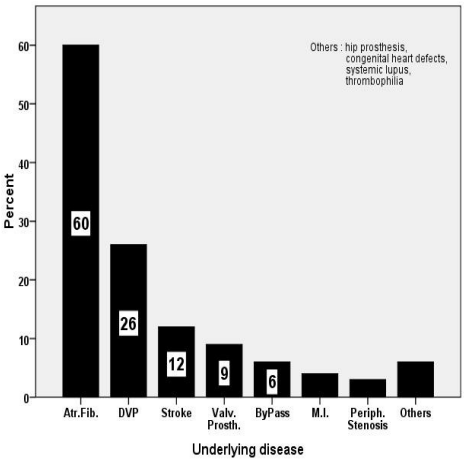

Fig. 1. *Frequency of the background diseases*

Some of the patients had interrupted the treatment temporarily, 45 (27.7%) to resume it later on. Some of them [12 (19.5%) had done so at a physician's indication, as they were to undergo a surgical intervention], but the rest of 33 (18.2%) had done so out of carelessness.

3.2. Assessment of the questions regarding the patients' information on their home administered treatment

Almost a quarter of the diseased, i.e. 28 (22.2%), didn't exactly know what disease their anticoagulant had been prescribed for. When asked whether they knew what the effect of the drug was – "blood thinning effect" – 108 (85.7%) answered positively, but only 9 (7%) knew more details about this effect. As regards the time interval when they would follow the treatment, i.e. limited or lifelong (Figure 2), 60 patients (48%) did not know how long, regardless of the diseases they suffered from. Only 5 patients (4%) answered correctly.

Of those who believed they knew many were mistaken. Thus, Figure 3 provides the results of this item based on the background disease. It can be noticed that of the entire number of the patients with fibrillation, all believed they would follow the treatment for a while, and then would stop. On the other hand, of those with DVT, 4 (15%) believed that the treatment was lifelong. All the patients with heart valve prostheses presumed that, at some point, they would stop the treatment. Also, of all the patients with CVA (stroke) and with endarteritis obliterans, none was aware of the necessity to follow this treatment for their entire lives.

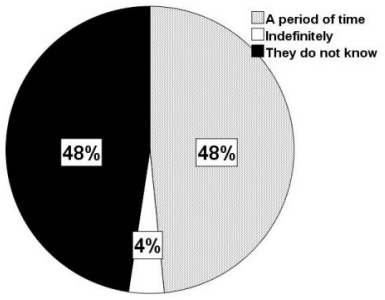

Fig. 2. *Distribution of the answering frequencies in the assessing question no. 4*

It results that an important aspect that patients should grow aware of is the length of time for which the anticoagulation needs to be secured. The fact that they should follow this treatment all their lives (where necessary) will give them a sense of responsibility in relation to their own health and will trigger an increase of the attention given to this type of medication.

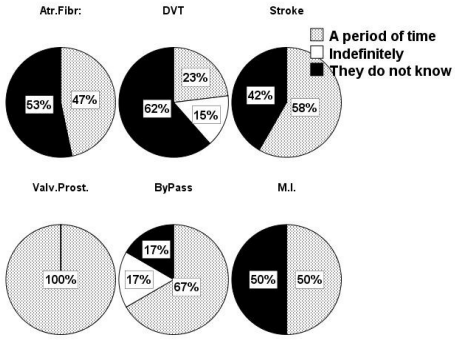

Fig. 3. *Distribution of the answering frequencies to the assessing question no. 4, based on the background disease*

As mentioned before, 45 patients had interrupted the administration of the anticoagulant temporarily, some at a physician's recommendation (for purposes of surgery), the others out of carelessness. The latter, 33 (18.2%) lost points at this item of the assessment. More than half, 72 (57%) had taken the anticoagulant and some non-steroidal anti-inflammatory agents (NSAIAs) concomitantly, whereas 100 of them (79%) claimed they knew about the risks of said association.

50 (39.7%) of the patients had not been warned about the counter-indication of intramuscular injections. 43 (34.1%) did not know what would happen in case of overdosage, even though 77 (61.1%) knew what melena looked like. It is possible that the patients do not link overdosage and melena sufficiently. This is a topic one should insist upon during the first training.

Almost all the diseased, with a single exception, thought it was absolutely necessary to warn other clinicians about their anticoagulant medication on the occasion of other visits.

3.3. Interpretation of the scores

The frequency of the patients' scores is illustrated in Figure 4. The average of the grades was 6.4 (SE±0,17 ; CI 95% [6,07–6,72]) and the median 7. We can notice a normal distribution of the grades, where approximately half of the patients got scores between 5 and 8, they being considered to have had average training. Only 7 got 9 and 10, which could be interpreted as very well. Nevertheless, it is surprising that only 15% were overdosed, despite the fact that the score was average. It is possible that the improvement of the scores by one point should significantly decrease overdosing.

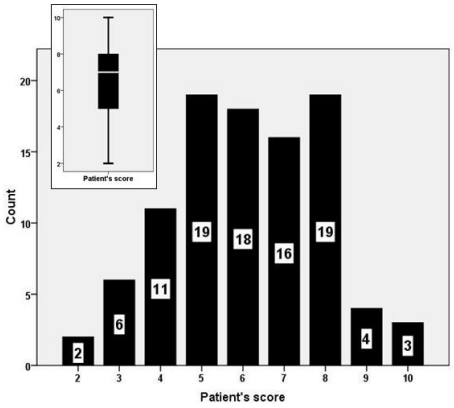

Fig. 4. *Patient score*

If the sum of all the patients' scores for each question separately (question score) is calculated, Figure 5, important differences are obtained, with a statistic significance. It can be noticed that few patients answered questions 3 and 6 correctly. Consequently, more emphasis

should be placed over the intervals when the INR needs to be repeated and over the counter-indications of anti-inflammatory agents. The scores of questions 4, 5, 8 and 9 are higher, but more attention should be given to these aspects in the discussions with the patients.

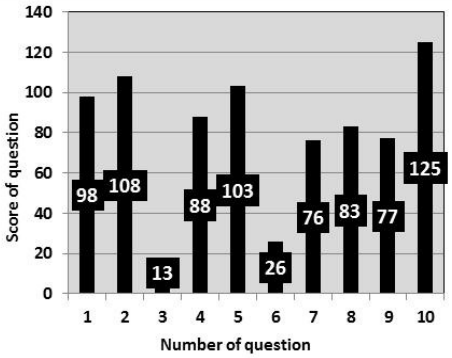

Fig. 5. *Score for each question*

ANOVA analysis of the studied parameters Table 2

Panel A	Sex	Age	Backgr. disease	Type of anticoag.	Who gives the drugs	Interr.	Score	Durat. of treat.	INR time
Overdosed	,16	,62	,41	,31	,14	**,008**	,30	,25	,07

Panel B	Sex	Age	Backgr. disease	Type of anticoag.	Who gives the drugs	Interr.	Score	Durat. of treat.	Over dosed
INR time	,52	,53	,23	,34	,40	**,001**	,025	**,054**	,07

Panel C	Sex	Age	Backgr. disease	Type of anticoag.	Who gives the drugs	Interr.	INR time	Durat. of treat.	Over dosed
Score	**,005**	,41	,57	,59	,62	,74	,83	,72	,60

The results of the ANOVA statistic analysis of the connections between different investigated parameters are synthesized in Table 2, where a significant relationship of growth ($p = 0.008$) is noticeable in the number of the overdosed patients among those who interrupted their medication (Panel A and Figure 6).

This connection might be interpreted in the light of the finding that the overdosed patients interrupted the treatment exactly for that reason, but Panel B also indicates that the time intervals between the determinations of the INR were very long ($p < 0,001$) with the same patients. Probably, this type of patients, are more likely to be not compliant to treatment. Thence results also the necessity that the physician should stress the importance of continuing the treatment as long as indicated.

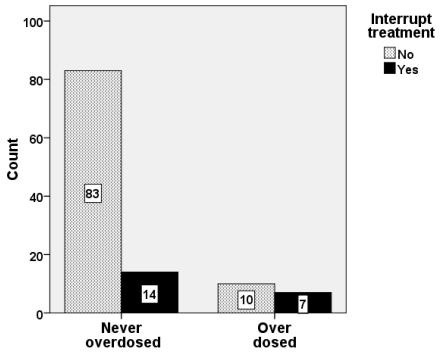

Fig. 6. *The frequency of overdosing in relation to the treatment interruptions*

In Table 2 Panel B an association may be noticed between the length of the anticoagulant treatment and the decrease of the frequency of the INR determinations. The linear regression of the two sets of data transformed to normality shows a weak, positive correlation with $R^2 = 0.19$ (Figure 7), which should be interpreted as follows : the longer the treatment lasts, the more the vigilance of INR-related follow-ups decreases. The conclusion is that the necessity to perform the INR regularly must be stressed especially in the case of the patients with a longer treatment.

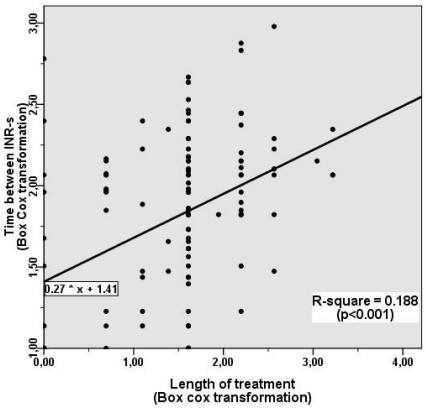

Fig. 7. *The regression line of the correlation between the length of the treatment and the frequency of the INR*

In Table 2 Panel C we may notice a higher score in female patients as opposed to male patients (p = 0,005), without having a biological explanation for that. This could be just a statistic error resulted from the structure of the studied population.

In this study there wasn't any relation between the average age and the overdosing (p = 0.61) as it was suggested in other studies, nor between the length of the treatment and the overdosing (p = 0.24), as one might have expected – a patient with a long period of treatment would present a higher number of overdoses.

But there is a correlation between the type of anti-coagulant and the overdosing. The number of overdoses was smaller with Sintrom as compared to Trombostop, even though the average duration of the treatment was significantly longer with Sintrom (Figure 8).

We would have expected that the longer the treatment period, the higher the overdosing risk should be. In the case of the result of our study, we may assume that either the Sintrom has a lower overdosing risk (which requires a new study targeted on this observation), or the overdosing occurs at the start of the treatment and immediately after (the comparison of the averages of the treatment duration shows that the overdosed patients had been under treatment for a relatively short time).

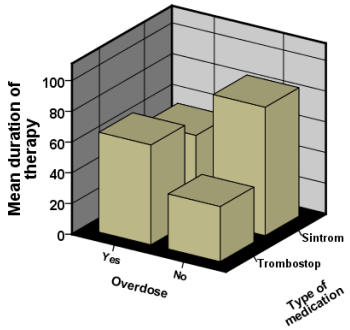

Fig. 8. *The number of overdoses in relation to the length of the treatment and the type of anticoagulant*

4. Conclusions

1. The notions the physician should lay stress upon with the anticoagulated patient: the length of the treatment, the obligation to continue the treatment, the necessity to perform the INR testing even in the patients with a long duration of the anticoagulation, and the risks associated with the use of NSAIAs.

2. Even though the score was average, only 15% of the patients were overdosed and the scores getting improved by a single point might determine a significant drop in the number of the overdosing cases.

3. There aren't any noteworthy information related differences among the patients that could be explained through the age difference, the length of the treatment, the main disease, who administers the treatment and the patients' gender.

4. More comprehensive studies are needed of the relationship between the patient and the anticoagulant medication that would comply with the psychological and social particularities of Romania's population, under the specific conditions of the healthcare system in this country. The overwhelming majority of the studies come from other cultures, with differently organized healthcare systems, and they use warfarine, an anticoagulant with a slightly different chemical formula from that of acenocoumarol, which is preponderantly used here.

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