Research Article

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Patients' perceptions with dabigatran in patients with atrial fibrillation previously treated with vitamin K antagonists

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Aim: To analyze the perception of anticoagulation with dabigatran in patients with nonvalvular atrial fibrillation previously treated with vitamin K antagonists over a 6-month period. **Materials & methods:** This is a prospective, noninterventional, noncontrolled, multicenter study. To assess patients' perceptions, PACT-Q2 questionnaire was completed. **Results:** Six hundred and fifty nine patients (73.1 ± 9.4 years, CHA_2DS_2-VASc 3.6 ± 1.6) were included. At baseline, the convenience and satisfaction scores were 60.9 ± 24.9 and 49.9 ± 17.7, respectively. The scores significantly increased along the study. Convenience score was higher in males and in patients with low–moderate thromboembolic risk. Satisfaction score was higher in females. Only 8.0% of patients discontinued dabigatran (3.7% due to side effects). **Conclusion:** Convenience and satisfaction scores for nonvalvular atrial fibrillation patients treated with dabigatran at 6 months were significantly better than with previous vitamin K antagonists.

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Keywords: atrial fibrillation • dabigatran • PACT-Q2 questionnaire • satisfaction • treatment convenience

Anticoagulation is mandatory in most patients with nonvalvular atrial fibrillation (NVAF) to prevent stroke and systemic embolism [1,2]. For decades, vitamin K antagonists (VKA) have been used for this purpose, but their well-known limitations (e.g., routine coagulation monitoring, food and drug–drug interactions) [3,4], together with gaps in the knowledge about AF treatment, have led to unacceptably high rates of nonanticoagulated patients [5]. By contrast, direct oral anticoagulants (DOACs) are associated with lower rates of stroke and bleeding and fewer daily restrictions than VKA [6], as they have a lineal anticoagulant effect, lower risk of interactions and are easier to prescribe [3,4,7]. These factors, among others, have the potential to positively impact on quality of life (QoL) and patients' perception about anticoagulant treatment, leading to higher anticoagulation rates and better adherence [8–14]. As a result, decisions about the choice of anticoagulation therapy and dosage selection should be based on physician and patient factors that include not only prescribing information, but also patients' and physicians' perceptions. However, the influence of patients' perceptions on anticoagulant treatment has not been well studied [15,16].

Dabigatran is a direct thrombin inhibitor approved for the prevention of stroke and systemic embolism in patients with NVAF stroke prevention in atrial fibrillation (SPAF) with one or more risk factors. In the RE-LY trial, compared with warfarin, dabigatran 150 mg twice daily significantly reduced the risk of stroke or systemic

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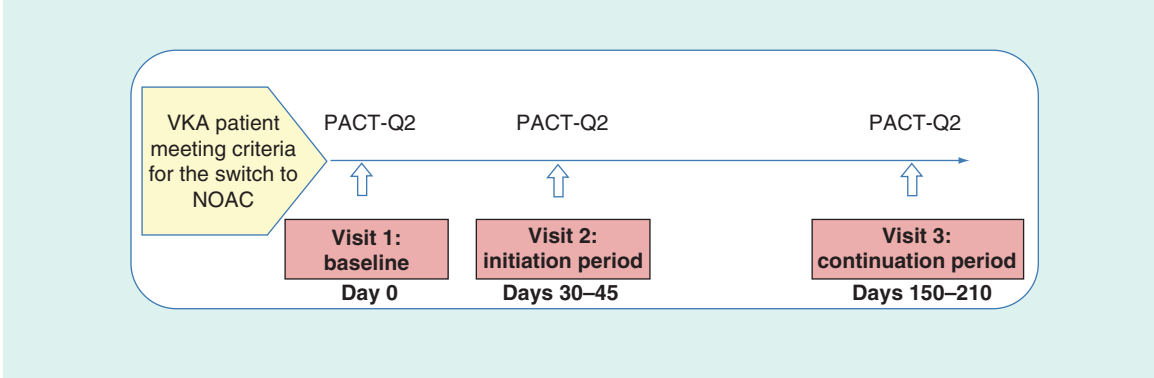

Figure 1. Design of the study.
NOAC: Nonvitamin K antagonist oral anticoagulant; VKA: Vitamin K antagonist.

embolism, with similar rates of major bleeding but a lower risk of intracranial hemorrhage; dabigatran 110 mg twice daily reduced the risk of major and intracranial bleeding with similar rates of stroke or systemic embolism [17]. In the RE-LY trial, health-related QoL remained stable after 1 year of treatment among patients without cerebrovascular or bleeding outcomes, independently of the assigned therapy [18]. However, in nonselected 'real-life' patients, these results could be different. Notably, currently available data on perception of treatment, specifically with dabigatran, in clinical practice are very scarce [8].

The aim of this study was to analyze the perception of anticoagulation with a current VKA therapy and the subsequent initiation of treatment with dabigatran over a 6-month period in patients with NVAF.

Materials & methods

This was a prospective, noninterventional, noncontrolled, national, multicenter and observational study. The inclusion criteria were: patients of both sexes, ≥18 years of age with a diagnosis of NVAF, with at least 6 months of continuous VKA treatment for stroke prevention prior to baseline assessment; that switched to dabigatran according to the Summary of Product Characteristics, the therapeutic positioning report from Spanish competent authorities and visa from each autonomous community [19]; and that provided written informed consent prior to participation. The inclusion of the patient in the study was not related with the decision of dabigatran's prescription. Dabigatran's prescription was based on the Health authorities' recommendations in the positioning report of DOACs [19]. Patients with contraindications for the use of dabigatran or VKA, receiving dabigatran or VKA for any reason other than stroke prevention in NVAF, or participating in any clinical trial of an investigational medicinal product or medical device, were excluded from the study. The study was approved by the Clinical Research Ethics Committee of the University Hospital La Paz, Madrid, Spain, on 12 January 2016 and the Spanish Health Authorities were notified accordingly. The study was conducted in Spain by 93 physicians at 73 sites from four autonomous communities (Catalonia, Galicia, Andalusia and Basque Country), and consecutively included patients who met the inclusion/exclusion criteria. The recruitment period started on 28 June 2016 and concluded on 10 October 2018. Selected participating sites included cardiologists and a few other specialists (internists, hematologists and general practitioners) reflecting current clinical practice of anticoagulation in NVAF in Spain.

The primary objective of the study was to describe patients' perceptions of their treatment for NVAF using the PACT-Q2 questionnaire at three time points: during the baseline period (after the indication for dabigatran), after approximately 1 month and during the continuation period. The secondary objective of the study was to characterize the clinical profile of patients taking dabigatran in Spain.

Patients were monitored for a period of 6 months and data were collected at three time points according to usual clinical practice at each site: after the indication for dabigatran (visit 1: this visit reflected the patient's treatment perception with VKA); 30–45 days after starting treatment with dabigatran (visit 2: to capture the patient's treatment perception with dabigatran during the initial period); and 150–210 days after starting treatment with dabigatran (visit 3: to reflect the patients' treatment perception with dabigatran during the continuation period; Figure 1). Notably, collection of data was managed only during routine outpatient clinic visits because no visits could be conducted out of daily practice for study purposes in the time windows. Visits were performed

face-to-face at the study site as the patient had to complete the self-administered questionnaire in accordance with PACT-Q instructions (validated Spanish version of the PACT-Q2) at each visit [20,21].

At baseline (visit 1), demographic data (age, gender, race, autonomous community), physical examination (BMI, heart rate, blood pressure), cardiovascular risk factors (hypertension, diabetes), vascular disease (cardiac disease, ischemic stroke, renal insufficiency, peripheral artery disease, thromboembolisms), thromboembolic (CHA_2DS_2-VASc score) and bleeding (HAS-BLED score) risk, were recorded in a specific electronic case report form. The duration of previous treatment with VKA, reasons for switching to dabigatran and the dosage of dabigatran, were also recorded.

Patients completed the PACT-Q2 questionnaire at the three specified time points: at baseline (visit 1), initial period (visit 2) and continuation period (visit 3) [20,21]. PACT-Q2 is a self-administered questionnaire, including 20 questions grouped into two domains: convenience and satisfaction. The PACT-Q2 questionnaire was made up of two domains (Supplementary Material):

- Convenience (items B1–B11 and C1–C2): this domain was calculated by adding the inverted scores (six-item score) for each of the 13 items and converting them to a scale ranging from 0 to 100.
- Satisfaction with the anticoagulant treatment (items D1–D7): this domain was calculated by adding the scores for each of the seven items and converting them to a scale ranging from 0 to 100.
- The higher the score, the higher the convenience/satisfaction.

In addition, all serious and nonserious adverse events occurring during the study from signing the informed consent form through the observational phase and up to 30 days after, were collected. Changes in the dosage of dabigatran or discontinuation, and associated reasons, were also recorded.

Statistical methods

Categorical variables were described by their absolute (n) and relative frequencies (%). Continuous variables were described using the mean and standard deviation. For comparisons between visits for quantitative variables, nonparametric tests (Wilcoxon signed-rank test) were used, according to the characteristics of the specific variables (no normal distribution, confirmed by Shapiro–Wilk test). For comparisons of quantitative variables between patient groups, nonparametric tests (Mann–Whitney U-test and Kruskal–Wallis test) were also used, according to the number of groups to be compared. Linear regression models with adjustment were used to study the effect of the covariables on the final score for the primary end point (the description of patients' perceptions of their anticoagulant treatment for SPAF, using the PACT-Q2 questionnaire). Missing data or lost values were not imputed to avoid information bias (except for the PACT-Q2 questionnaire, where rules of scoring had been applied). Missing data for important variables were controlled by filters when collecting data from the electronic case report form. A level of statistical significance of 0.05 was applied in all statistical tests. Data were analyzed statistically using the SAS statistical package, version 9.4.

Results

A total of 671 patients were enrolled initially. As 12 patients (1.8%) were excluded because they did not fulfill the selection criteria (patients who were not switching to dabigatran, not treated continuously with VKAs for stroke prophylaxis for at least 6 months prior to the baseline visit or not diagnosed with NVAF), 659 patients (98.2%) were finally analyzed. Additionally, as follow-up data were lacking for another six patients, 653 patients (97.3%) were considered for the safety analysis.

Demographic and clinical characteristics of the study population at baseline are reported in Table 1. Mean age was 73.1 ± 9.4 years, 58.3% males. Cardiovascular risk factors and vascular disease were common (arterial hypertension 53.3%; ischemic heart disease: 20.6%). A total of 89.7 and 30.5% of patients had a high thromboembolic and high bleeding risk, respectively. The most commonly used previous VKA treatment was acenocoumarol (94.8%), with a mean duration of 48.0 ± 47.0 months. Approximately three out of four patients switched to dabigatran due to poor international normalized ratio control. In the majority (63.0%) of patients, the initial prescribed dabigatran dosage was 150 mg twice daily, with the remaining patients (37.0%) receiving dabigatran 110 mg twice daily.

Regarding the primary study end point, baseline PACT-Q2 scores increased significantly ($p < 0.0001$) after visit 2 and visit 3 in both the convenience and satisfaction domains with dabigatran (Table 2 & Figure 2). Complete data

Table 1. Clinical characteristics of the study population at baseline (n = 659).

Variable	Value
Biodemographic data	
Age (years) – ≤65 years, n (%) – >65 years, n (%)	73.1 ± 9.4 132 (20.0) 527 (80.0)
Sex (men), n (%)	384 (58.3)
Race – Caucasian – Latin American – North African	 638 (9.8) 19 (2.9) 2 (0.3)
Distribution of patients by autonomous community – Andalusia – Catalonia – Galicia – Basque country	 223 (33.8) 220 (33.4) 128 (19.4) 88 (13.4)
Physical examination	
BMI (kg/m^2)	28.4 ± 4.2–
Heart rate (bpm)	74.0 ± 13.5
Systolic blood pressure (mmHg)	134.5 ± 16.3
Diastolic blood pressure (mmHg)	78.4 ± 10.9
Cardiovascular risk factors	
Arterial hypertension, n (%)	351 (53.3)
Diabetes mellitus, n (%)	159 (24.1)
Vascular disease	
Ischemic heart disease or heart failure, n (%)	136 (20.6)
Ischemic stroke, n (%)	88 (13.4)
– Creatinine clearance <50 ml/min, n (%) – Creatinine clearance (Cockcroft–Gault) (ml/min)	47 (7.3) 73.9 ± 22.7
Peripheral arterial disease, n (%)	19 (2.9)
Thromboembolisms, n (%)	17 (2.6)
Thromboembolic and bleeding risk	
CHA_2DS_2-VASc scale score – Low risk (score 0 in males/1 in females), n (%) – Moderate risk (score 1 in males/2 in females), n (%) – High risk (score ≥2 in males/≥3 in females), n (%)	3.6 ± 1.6 8 (1.2) 60 (9.1) 591 (89.7)
HAS-BLED – Low risk (score 0), n (%) – Moderate risk (score 1–2), n (%) – High risk (score ≥3), n (%)	2.1 ± 1.0 23 (3.5) 435 (66.0) 201 (30.5)
Anticoagulant treatment	
Previous VKA treatment – Acenocoumarol, n (%) – Duration (months) – Warfarin, n (%) –Duration (months)	 625 (94.8) 48.0 ± 47.0 34 (5.2) 44.1 ± 37.2
Reasons for switching from VKA to dabigatran, n (%)† – Poor INR control – Patient's decision – Lack of access to conventional INR management – Suffering from severe arterial thromboembolic episodes despite good INR control – Others	 484 (73.4) 137 (20.8) 45 (6.8) 29 (4.4) 39 (5.9)
Prescribed dabigatran dose, n (%) – 150 mg b.i.d. – 110 mg b.i.d.	 415 (63.0) 244 (37.0)

†A single patient might have simultaneously specified more than one reason.
b.i.d.: Twice daily; INR: International normalized ratio; VKA: Vitamin K antagonist.

Table 2. PACT-Q2 questionnaire scores for the convenience and satisfaction domains.

Domains	Visit 1 (baseline)	Visit 2	Visit 3	p-value$_{V1-2}$	p-value$_{V1-3}$	p-value$_{V2-3}$
Convenience	60.9 ± 24.9	80.9 ± 17.0	84.2 ± 15.2	<0.0001	<0.0001	<0.0001
Satisfaction	49.9 ± 17.7	69.1 ± 14.1	72.8 ± 14.8	<0.0001	<0.0001	<0.0001

Data shown are mean ± standard deviation.

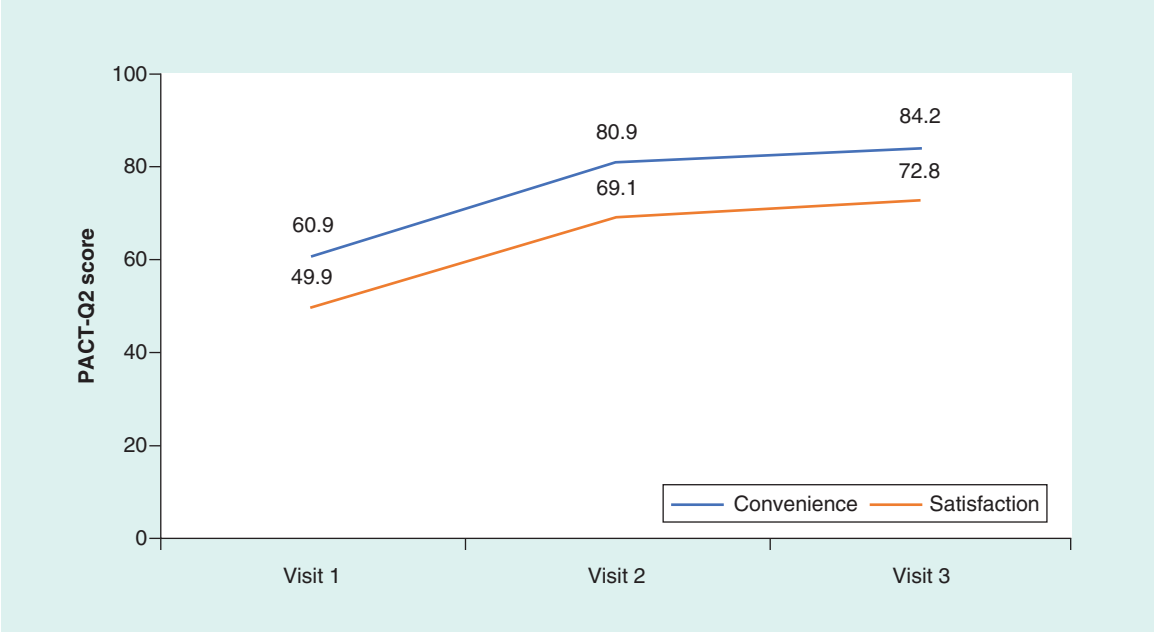

Figure 2. Changes in PACT-Q2 questionnaire scores for the convenience and satisfaction domains during the study.
$p < 0.0001$ in all the comparisons between visits.

regarding PACT-Q2 scores during the study are reported in the Supplementary Material (Supplementary Tables 1–3).

Patients' perceptions of treatment, based on PACT-Q2 scores for the two domains, were analyzed in the three visits, according to different clinical characteristics (Table 3). Regarding all evaluated variables, statistically significant differences were observed for gender and thromboembolic risk. Thus, at visit 1, males showed significantly higher scores with previous VKA treatment than females in both PACT-Q2 domains. At visit 3, after 6 months of dabigatran, treatment was more convenient for males, but females showed more satisfaction with dabigatran. For both VKA and dabigatran, treatment convenience score was higher in patients with lower thromboembolic risk, but no differences were found in treatment satisfaction scores (Table 3).

Additionally, a linear regression model with adjustment for all of the covariables included in Table 3 was used to assess their effect on PACT-Q2 scores during the final assessment at visit 3 (Table 4). According to the multivariate analysis, gender and thromboembolic risk had some effect on convenience score. The convenience score was higher in males (p = 0.0244) and in patients with low–moderate thromboembolic risk (p = 0.0001). On the other hand, satisfaction score was higher in females than in males (p = 0.0048).

Overall, only 53 patients (8.0%) discontinued dabigatran during the follow-up and almost all patients continued with the same dosage prescribed at visit 1 (99% continued with the same dose at visit 2, and 98.5% at visit 3). In the few patients (n = 12) who reduced their dabigatran dose, the reason was mainly due to the high risk of bleeding, or for moderate renal failure, and, in the few patients (n = 3) who increased the dabigatran dose, the reason was mainly to achieve greater efficacy.

Only 69 patients (10.6%) reported 82 adverse events, with 6.1% (n = 5) being considered serious adverse drug reactions and four were related to the study treatment (0.6% of the total safety sample). Most of these reactions were of gastrointestinal origin, with dyspepsia being the most frequent (2.3% of patients), followed by rectal hemorrhage (0.9%), hematuria (0.5%) and upper abdominal pain (0.5%). Twenty-four patients (3.7%) discontinued study

Table 3. PACT-Q2 questionnaire scores for the convenience and satisfaction domains during follow-up according to different clinical characteristics.

	Baseline				Visit 2				Visit 3			
Age:	**≤65 years**		**>65 years**	**p-value**	**≤65 years**		**>65 years**	**p-value**	**≤65 years**		**>65 years**	**p-value**
Convenience	63.3 ± 23.8		60.3 ± 25.2	0.20	82.3 ± 16.1		80.6 ± 17.3	0.43	85.9 ± 14.0		83.7 ± 15.4	0.21
Satisfaction	50.6 ± 17.6		49.7 ± 17.8	0.71	67.6 ± 14.8		69.5 ± 13.9	0.28	72.8 ± 14.1		72.8 ± 15.0	0.75
Gender:	**Male**		**Female**	**p-value**	**Male**		**Female**	**p-value**	**Male**		**Female**	**p-value**
Convenience	64.1 ± 23.9		56.5 ± 25.6	0.0002	81.8 ± 16.7		79.7 ± 17.4	0.14	85.3 ± 14.6		82.6 ± 15.8	0.03
Satisfaction	51.2 ± 16.5		48.1 ± 19.2	0.01	68.1 ± 13.7		70.5 ± 14.6	0.07	71.3 ± 14.9		74.8 ± 14.5	0.01
Dabigatran dose:	**110 mg**		**150 mg**	**p-value**	**110 mg**		**150 mg**	**p-value**	**110 mg**		**150 mg**	**p-value**
Convenience	60.8 ± 25.3		61.0 ± 24.7	0.86	80.5 ± 17.7		81.1 ± 16.7	0.88	84.0 ± 15.5		84.3 ± 15.0	0.99
Satisfaction	51.4 ± 16.7		49.0 ± 18.3	0.07	69.9 ± 14.3		68.6 ± 14.0	0.27	72.3 ± 14.9		73.0 ± 14.8	0.93
HAS-BLED:	**Low**	**Moderate**	**High**	**p-value**	**Low**	**Moderate**	**High**	**p-value**	**Low**	**Moderate**	**High**	**p-value**
Convenience	62.0 ± 21.2	60.4 ± 24.4	61.9 ± 26.5	0.70	76.7 ± 18.2	80.1 ± 17.6	83.2 ± 15.4	0.10	81.3 ± 15.6	84.0 ± 15.0	84.9 ± 15.6	0.42
Satisfaction	49.5 ± 16.9	49.8 ± 16.6	50.3 ± 20.2	0.73	68.2 ± 11.8	68.5 ± 14.0	70.6 ± 14.7	0.37	72.5 ± 11.0	72.6 ± 14.4	73.3 ± 16.1	0.61
CHA2DS2-VASc:	**Low**	**Moderate**	**High**	**p-value**	**Low**	**Moderate**	**High**	**p-value**	**Low**	**Moderate**	**High**	**p-value**
Convenience	73.6 ± 18.4	69.1 ± 23.2	59.9 ± 25.0	0.008	86.5 ± 9.3	85.7 ± 14.4	80.3 ± 17.3	0.08	92.3 ± 9.1	90.6 ± 9.6	83.3 ± 15.5	0.001
Satisfaction	52.7 ± 15.9	53.8 ± 16.2	49.5 ± 17.9	0.24	73.2 ± 18.6	67.7 ± 15.8	69.2 ± 13.9	0.83	79.5 ± 12.8	74.2 ± 15.1	72.5 ± 14.8	0.44

Data shown are mean ± standard deviation.

Table 4. Linear regression model: scores for the convenience and satisfaction domains of the PACT-Q2 questionnaire at Visit 3.

Convenience				
Variable	**LS Means**	**95% CI LS Means**	**F**	**p-value**
Patient gender				
Females	85.3	82.9–87.8	5.09	0.0244
Males	88.2	86.0–90.4		
Thromboembolic risk (CHA_2DS_2-VASc)				
High	82.9	81.6–84.3	14.86	0.0001
Low–moderate	90.6	86.9–94.3		
Satisfaction				
Variable	**LS Means**	**95% CI LS Means**	**F**	**p-value**
Patient gender				
Females	74.8	72.9–76.7	8.00	0.0048
Males	71.3	69.7–72.9		

F: F-value; LS: Least squares mean; p: p-value (ANOVA F-statistic).

treatment due to these adverse reactions and eight patients (1.2%) died during the study, one of them because of gastrointestinal bleeding.

Discussion

This prospective, noninterventional study, performed in a wide sample of NVAF patients, showed that treatment with dabigatran was associated with better satisfaction and convenience than VKA. In addition, dabigatran showed good tolerability in most patients, with low rates of discontinuation. In order to avoid bias and improve data quality, consecutive enrollment was performed. Moreover, patient-reported outcomes were assessed using validated scales within a limited period of time and remote monitoring calls were made to verify the collected study data.

In our study, mean age was 73 years, comorbidities were frequent, nearly 90% of patients had a high thromboembolic risk and less than a third of patients had a high bleeding risk. These clinical characteristics are concordant with previous studies that have analyzed the clinical profile of patients taking DOACs in Spain [22,23]. Although it has been reported that, initially, prescription of DOACs was mainly performed in low-risk patients [10], nowadays DOACs are prescribed in the overall NVAF population [22,23]. In the RE-LY trial, although mean age was 72 years, only a third of patients had a $CHADS_2 \geq 3$ [17]. Therefore, studies performed in 'real-life' patients are necessary to complete information that is obtained from clinical trials, as the latter do not always reflect daily clinical practice [24].

In our study, at baseline, all patients were taking VKA during at least 6 months (mean duration 48 months). Of note, dabigatran was prescribed according to usual clinical practice, based on the Health Authorities' recommendations [19]. The main reason for switching to dabigatran was poor international normalized ratio control (three-quarters of patients). This is in accordance with 'real-world' data, whereas approximately 40–50% of patients who are treated chronically with VKA exhibit insufficient anticoagulation control [25,26].

Although achieving the best efficacy (reduced thromboembolic complications) and safety (low bleeding rates) profile is mandatory when choosing an oral anticoagulant, studies have shown that patients' preferences within convenience and satisfaction criteria should also be considered as they could result in higher adherence [27–29].

At baseline, the convenience domain score was 61, and the satisfaction domain score was approximately 50, indicating that patients' perceptions about convenience and satisfaction with VKA therapy was only moderate in patients treated chronically with these drugs. This is not surprising as treatment with VKA is associated with many limitations [3,4]. In contrast, a recent study performed in AF patients taking VKA showed that satisfaction with treatment during the last year was high [16]. On the other hand, some studies have shown that impairment of QoL associated with VKA therapy occurs mainly during the first few months, with the negative impact on QoL decreasing over time [16,30]. However, these differences could be related to the fact that patients who remain on VKA are usually those with higher treatment satisfaction levels or those who adapt well to lifestyle limitations imposed by long-term anticoagulation. Otherwise, patients with lower satisfaction levels have a greater probability of discontinuing medication and may not be included in such studies [16,30].

Our study showed that patients' perceptions of dabigatran treatment increased progressively in both domains, convenience and satisfaction, over time. This is likely related to the fact that dabigatran has fewer practical limitations and does not require frequent anticoagulation monitoring [3,4]. A number of studies have shown that switching from VKA to DOACs is associated with improved QoL and less treatment burden. However, most of these studies were limited to short follow-up periods [13,31–33]. Our work showed that patients' perceptions of dabigatran treatment improved progressively during the initial period and also during the continuation period. Although no differences in health-related QoL were observed between warfarin and dabigatran after 1 year of treatment in the RE-LY trial [18], a study performed in routine clinical practice showed that, in NVAF patients with high thromboembolic risk, adherence, satisfaction and QoL were higher for patients treated with dabigatran compared with VKA [8]. Our study showed improvements in convenience and satisfaction when switching from VKA to dabigatran, with continued improvement over time. The differences between 'real-life' and RE-LY trial data could reflect the fact that, in clinical trials, patients have a lower risk and a stricter follow-up that may reduce differences in the patients' perception of anticoagulant treatment. Furthermore, in 'real-life' studies, entry criteria are much less restrictive than those for a randomized clinical trial, which may allow enrollment of a broader patient population in real-life studies.

On the other hand, our study showed that the convenience score was higher in patients with low–moderate thromboembolic risk (vs high thromboembolic risk). It has been identified that knowledge gaps exist in patients taking oral anticoagulants, particularly patients taking DOACs [34]. In addition, patients' knowledge has a direct impact on the use of oral anticoagulants and the global management of AF [35]. As a result, it is necessary to improve patients' knowledge about anticoagulation through education in order to reduce these gaps, although recent evidence not support this assumption [36]. Poor adherence to anticoagulant medication is associated with higher rates of thromboembolic and bleeding complications and greater healthcare costs [37–39]. Although follow-up was limited to 6 months in our study, only 8% (<4% due to adverse events) of patients discontinued treatment with dabigatran, in line with previous studies [8]. However, it is likely that a longer follow-up period could be associated with lower adherence to dabigatran [40,41]. Consequently, more efforts are required to ensure adequate medication compliance to reduce the risk of thromboembolic and bleeding complications [42,43].

Finally, although our study was not designed to assess the efficacy and safety of dabigatran, the safety results were very positive, with a very low risk of side effects. These data, together with data from other studies [44–46], suggest that in 'real-world' patients, the tolerability of dabigatran is very good, and that it can be prescribed safely.

This study has some limitations. Due to the design of the study, there was no control group. As a result, we could only assess the impact of switching from VKA to dabigatran but were unable to assess whether patients' perceptions regarding VKA change over time. However, as this had been studied previously with VKA, the aim of our study was specifically to analyze how patients' perceptions change with dabigatran not only when switching from VKA, but also during a 6-month dabigatran treatment period, using a sample size that was powered sufficiently to address the primary study end point. Additionally, as noted earlier, particular caution was taken to reduce the risk of bias, at the site and patient levels. According to the inclusion criteria, patients were switched to dabigatran before being included in the study. As a result, those patients that were not willing to change the anticoagulant therapy could not be included. However, patients were consecutively included to reduce this potential bias. In addition, a learning effect because of the repeated use of the same questionnaire at different visits could happen and could influence the interpretation of the outcomes. Finally, as this study was performed in Spain, the conclusions can only be applied to patients with the same clinical profile and, very importantly, within a similar healthcare system.

In conclusion, the present study, which was conducted in a large sample of patients with high thromboembolic risk, showed that switching from VKA to dabigatran is associated with improvements in patients' perceptions regarding anticoagulant treatment and, notably, that this improvement increases over time. Secondarily, the study also showed that, after a 6-month period, dabigatran was associated with high medication adherence, and a low risk of side effects.

Supplementary data

To view the supplementary data that accompany this paper please visit the journal website at: www.futuremedicine.com/doi/suppl/10.2217/cer-2020-0001

Author contributions

V Barrios, C Escobar, JJ Gómez-Doblas and E Donado contributed to the conception and design of the manuscript. J Fernández-Dueñas, R Romero Garrido, J Pindado Rodríguez, J Umarán Sánchez and E Arellano-Rodrigo contributed to the data collection. V Barrios, C Escobar, JJ Gómez-Doblas and E Donado contributed to the analysis and interpretation of data. All authors have participated in writing, reviewing and/or revising the manuscript and have approved its submission.

Financial & competing interests disclosure

V Barrios has received honoraria for oral presentations and consultancy fees from: Bayer, BMS/Pfizer, Boehringer Ingelheim and Daiichi Sankyo. C Escobar has received honoraria for oral presentations and consultancy fees from: Bayer, BMS/Pfizer, Boehringer Ingelheim and Daiichi Sankyo. E Arellano-Rodrigo declared no conflict of interest. E Donado is employee of Boehringer Ingelheim Spain. JJ Gómez-Doblas has received honoraria for oral presentations and consultancy fees from Bayer, BMS/Pfizer, Boehringer Ingelheim and Daiichi Sankyo. The authors have no other relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript apart from those disclosed.

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Ethical conduct of research

The authors state that they have obtained appropriate institutional review board approval or have followed the principles outlined in the Declaration of Helsinki for all human or animal experimental investigations. In addition, for investigations involving human subjects, informed consent has been obtained from the participants involved.

Summary points

Background

- Currently available data on perception of treatment, specifically with dabigatran, in clinical practice are very scarce.
- The aim of this study was to analyze the perception of anticoagulation therapy with dabigatran in patients with nonvalvular atrial fibrillation previously treated with vitamin K antagonists over a 6-month period.

Materials & methods

- This is a prospective, noninterventional, national, multicenter, observational study.
- To assess patients' perceptions on anticoagulation therapy, patients completed the PACT-Q2 questionnaire at three time points according to usual clinical practice: at baseline (visit 1), initial period (visit 2: 30–45 days after starting dabigatran) and continuation period (visit 3: 150–210 days after starting dabigatran).

Results

- A total of 659 patients (73.1 $\pm$ 9.4 years, CHA_2DS_2-VASc 3.6 $\pm$ 1.6; HAS-BLED 2.1 $\pm$ 1.0) were included.
- During the study, the convenience and satisfaction scores significantly improved along the study.
- In multivariate analysis, the convenience score was higher in males and in patients with low–moderate thromboembolic risk, whereas the satisfaction score was higher in females than in males.
- Only 8.0% of patients discontinued dabigatran (3.7% due to side effects).

Conclusion

- Convenience and satisfaction scores for patients with nonvalvular atrial fibrillation treated with dabigatran at 6 months were significantly better than with previous vitamin K antagonists anticoagulation therapy.

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