

ORIGINAL ARTICLE

Patients' perceptions regarding oral anticoagulation therapy and its effect on quality of life*

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ABSTRACT

Objective: Anticoagulation clinics have improved the time spent within therapeutic range and decreased hemorrhagic complications and costs in chronic oral anticoagulation. Whether these benefits correlate to patients' quality of life (QOL) remains to be determined. The impact of patients' perceptions about anticoagulation on QOL has not been evaluated. The objective of this study was to evaluate prospectively patients' perceptions and quality of life in patients chronically anticoagulated.

Research design and methods: A cross-sectional study was designed to investigate the prevalence of positive and negative perceptions about oral anticoagulation therapy (OAT) and to identify vulnerable groups. Patients anonymously completed the SF-36 survey and a questionnaire that focused on patients' perceptions of protection from thrombotic complications or fear of haemorrhage due to the anticoagulation. We related those perceptions to the General Health SF-36 score, to the patient's characteristics, the absolute bleeding risk (i.e. intended International Normalized Ratio [INR]), duration of therapy and medical attention.

Results: One thousand patients were included and 905 questionnaires evaluated. Most patients felt protected and better since the beginning of therapy (71.5% and 61.5%, respectively). Patient characteristics associated with negative perceptions were; female sex (Odds Ratio [OR] 1.58, 95% Confidence Interval [CI] 1.06–2.36, $p = 0.01$); patients with less than 1 year of therapy (OR 2.16, 95% CI 1.34–3.48, $p = 0.006$); those not satisfied with medical attention (OR 2.86, 95% CI 1.53–5.18, $p = 0.0001$); and those that modified their lifestyle (OR 2.75, 95% CI 1.49–4.91, $p = 0.0002$). Patients with a lower bleeding risk (INR 2.0–3.0) had more negative perceptions than those with a higher risk. Patients with negative perceptions achieved the lowest score in the SF-36 survey. Haemorrhages did not affect patients' perception or QOL.

Conclusions: Patients' perceptions correlated with QOL. We were able to identify patient characteristics associated with poor QOL and thus the group of patients whose negative perceptions most warranted special attention from their clinicians.

Introduction

Chronic oral anticoagulation therapy (OAT) has dramatically decreased thromboembolic complications in atrial fibrillation (AF), mechanical heart valve prostheses

(MHVP), venous thromboembolism (VTE) and other prevalent diseases worldwide¹⁻³. Unlike other chronic therapies, OAT is not intended to improve functional capacity or alleviate symptoms but to prevent primary or secondary, arterial or venous thromboembolism.

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However, oral anticoagulant drugs have a variable therapeutic response as a result of concomitant diseases, as well as multiple drug and food interactions^{4,5}. Patients are required to be thoroughly monitored, undergo periodic blood sampling and consult before taking new medications or having surgery. Dietary restrictions or changes are often recommended in order to lower vitamin K intake. Bleeding is the most frequent and feared complication of OAT⁶⁻⁸. The benefit/risk equation of OAT (increased prevention of thromboembolism/risk of bleeding) is narrow and directly determined by the desired range of anticoagulation (International Normalized Ratio [INR]). The most thrombogenic condition is MHVP and therefore the one requiring the most intense anticoagulation treatment⁹, but with the highest risk of bleeding as a result.

Management of chronic OAT in anticoagulation clinics has improved the time spent within the therapeutic range and decreased hemorrhagic complications and costs^{10,11}. Nevertheless, whether such benefits correlate with patients' quality of life (QOL) and health status remains to be determined.

In OAT, patients undertake a treatment with no evident symptomatic benefit but with a defined risk that can influence a patient's self-perception of his or her health status and QOL. The influence of patients' perceptions on outcomes has been demonstrated in patients with coronary disease^{12,13}.

Few studies have addressed the issue of OAT and QOL¹⁴⁻¹⁶. Recently, the Duke Anticoagulation Satisfaction Scale¹⁷ was developed and preliminary validation studies were reported. To the best of our knowledge, none has related patients' perceptions regarding OAT to QOL.

Our objectives were to evaluate QOL in patients undergoing chronic OAT who were attending an anticoagulation clinic. We evaluated positive and negative perceptions regarding OAT, as well as the impact of such perceptions on QOL. In order to identify vulnerable groups, we related those perceptions to patients' characteristics and treatment characteristics, including satisfaction or dissatisfaction with medical attention.

Material and methods

The Haemostasis and Thrombosis Department, Institute of Haematological Research, National Academy of Medicine, is a referral centre for anticoagulation with a large population on OAT.

When initiating OAT, every patient receives a thorough explanation of treatment characteristics and receives a digest with all the information regarding OAT, benefits and risks. Also, a haematologist is available 24 hours a day (doctor on-call) for emergencies and requests from patients on OAT.

Patients receive the lab results and dosing from a doctor. The interval between blood sampling and dosing is 90 minutes.

Population

A cross-sectional study was conducted between September 2001 and May 2002.

Inclusion criteria were: patients that declared their willingness to participate; had signed a written consent; and that had been on oral anticoagulant drugs (i.e. warfarin or acenocoumarol), apart from aspirin, for more than 4 weeks; patients capable of reading unaided or with the help of an accompanying person; children with at least one parent.

All reasons for anticoagulation were included (i.e. AF, VTE, MHVP, mitral stenosis, coronary heart disease, among others). The desired INR for MHVP was 2.5-4.0 depending on patient and valve characteristics. The intended INR for all other diagnoses was 2.0-3.0.

Exclusion criteria were refusal to participate, less than 4 weeks on OAT and the illiterate with no accompanying person.

Surveys

Patients anonymously completed two multiple-choice questionnaires while waiting for their lab tests. Patient's anticoagulation cards were marked in order to avoid data duplication.

The questionnaires were the Spanish (Argentina) translation of the SF-36 Health-Survey (reproduced with the permission of Health Assessment Lab) and a questionnaire developed for the study. The latter was a 17 item-questionnaire developed for a broader study of patient knowledge, daily life implications and the economic burden of OAT. It also included questions regarding general epidemiological and socio-economical aspects, OAT itself (duration, indication, bleeding complications) and medical attention (in terms of contention, trust, knowledge and time devoted to patients, need for emergency calls and solution of problems by the doctor on-call). We will refer to that questionnaire as the 'specific' survey meaning it was an 'OAT specific questionnaire', not 'QOL specific'.

Initially, the specific questionnaire was evaluated in 100 patients between March and August 2001 and we obtained an answer rate of 82%. The survey used in this study was a corrected version of the former questionnaire (Cronbach's alpha coefficient: 0.8, intra-class correlation coefficient: 0.75). Based on clinical experience and literature, we proposed the perceptions of OAT that could affect QOL. Those perceptions were: (1) the feeling of protection (from thrombosis), fear (of bleeding) or no concern due to OAT; and (2)

the perception of health improvement, worsening or no change attributable to OAT.

Positive perceptions regarding OAT were 'protection from thrombosis' and 'health improvement', while 'fear of bleeding' and 'health worsening' were the negative ones.

Specific questionnaires with four or more incomplete items were excluded on the basis that this showed a lack of understanding or interest.

Considering that the SF-36 does not provide an overall QOL score but a health profile¹⁸, and allows the isolated use of the different domain scales, scores from the General Health concept were used to define 'good' and 'bad' QOL. Study population was divided into three groups according to those scores. Values in the higher percentile were considered 'good' and values within the lower percentile were defined as 'bad' QOL. The reasons for choosing the General Health score was: (1) this domain deals with the personal evaluation of health¹⁸, which was the focus of our study; (2) the characteristics of the study population, including comorbidities, are heterogeneous, determining different physical and functional status; and (3) different thrombotic disorders have different symptoms that might affect other domains of the SF-36 scale.

Statistical analysis

SPSS.10 and Epi Info 6.04 (Centre for Disease Control and Prevention [CDC], Epidemiology Program Office, Atlanta, Georgia, USA) were used for analysis. Results were expressed as mean values or percentages, as appropriate. Univariate and multivariate analysis were performed by chi square test. The odds ratio (OR) was used to estimate the strength of the association. A *p*-value < 0.05 was considered statistically significant.

Results

During the study period, there were 2201 consecutive anticoagulated patients, with 11 364 consultations. One thousand and fifty-six were new patients (i.e. less than

Table 1. Characteristics of patients (N = 905)

Patient characteristic		n	%
Sex	Female	459	50.7
	Male	439	48.5
Education	Not evaluated	7	0.8
	None	135	14.9
	Elementary school	470	51.9
	High school	184	20.3
	College-undergraduate	43	4.8
	University	60	6.6
Occupation	Other	13	1.4
	Unemployed	149	16.5
	Employee	139	15.4
	Housewife	193	21.3
	Retired	392	43.3
Time on OAT (years)	Other	32	3.5
	< 1	253	28.0
	1–5	320	35.4
	5–10	145	16.0
	> 10	147	16.2
	Not known	40	4.4

4 weeks on OAT) and were not included. The eligible population was 1145 patients. Fifty-four patients refused to participate and the remaining 91 were illiterate with no accompanying person. One thousand patients were enrolled and 1000 questionnaires were distributed. Thirty-seven questionnaires were not retrieved and 58 met exclusion criteria leaving 905 questionnaires for evaluation (response rate 90.5%).

Patients and therapy characteristics

Patient characteristics are shown in Table 1. The mean age was 61.53 ± 15.65 (range: 9–90 years). Table 2 shows the reasons for anticoagulation according to the patients. Thirty-three per cent of patients did not know the reason for anticoagulation. Patients with no education or who had only attended elementary school were more likely to ignore the reason for OAT (OR 6.86, 95% CI 4.92–9.56, *p* < 0.0001).

Four hundred and seven patients (45%) answered that they had called the doctor on-call sometime during follow-up; most (88%) found their problem adequately solved. The majority of patients (87.5%) did not

Table 2. Reasons for OAT according to the patient and intended INR for the patient diagnosis (N = 905)

Reason for anticoagulation according to the patients	n	%	INR
Unknown	299	33.0	
Mechanical heart valve prosthesis (MHVP)	164	18.1	2.5–4.0
Atrial fibrillation	125	13.8	2.0–3.0
Venous thromboembolism	104	11.5	2.0–3.0
Cardiomyopathy	73	8.1	2.0–3.0
Valvular disease	57	6.3	2.0–3.0
Coronary heart disease including unstable angina and myocardial infarction	41	4.5	2.0–3.0
Peripheral vascular disease	25	2.8	2.0–3.0
Other	17	1.9	2.0–3.0

INR = intended international normalized ratio

change their habits (diet or lifestyle) due to OAT. Two hundred and three patients (22.4%) mentioned having experienced bleeding complications during follow-up, 10% of those episodes met the criteria for major bleeding (i.e. required hospitalization, or were bleeding from the upper gastrointestinal tract). Eight per cent of patients were not satisfied with medical attention.

SF-36 scores and perceptions in the study population

The mean QOL score in the study population was 53.69 ± 23.17 . The correlation between the General Health Scale (GHS) and its component items, as well as correlations between GHS and the other Scales, were positive in direction and substantial in magnitude (data not shown). Table 3 shows the scores obtained for the eight scales.

Most patients (71.5%) felt protected from thrombosis, while 61.5% manifested to feeling better since the beginning of OAT.

QOL scores varied according to the indication for OAT ($p = 0.02$) (Figure 1). Patients with VTE had the lowest QOL score. More patients with AF than with heart valves had a bad QOL.

Negative perceptions about OAT

Table 4 shows the main factors associated with negative perceptions. Patients that felt worse since starting on OAT were also worried about bleeding complications (OR 11.72 95% CI 3.08–45.47, $p = 0.0002$).

In spite of a lower absolute risk of bleeding, patients with atrial fibrillation were more afraid of bleeding than those with heart prostheses ($p = 0.01$). Bleeding episodes, major or minor, were not associated with negative perceptions regarding OAT.

Positive perceptions

Low education level (i.e. no education or elementary school only) was associated with a feeling of improvement in health status due to OAT ($p = 0.004$). Patients that referred to an improvement in health status were also the ones that felt protected (OR 2.30 95% CI 1.67–3.17, $p < 0.00001$).

Patients that felt better and protected were satisfied with medical attention ($p = 0.0003$), called the doctor on-call more often ($p = 0.01$) and had been on OAT for more than 5 years ($p = 0.03$).

QOL group comparisons

Negative and positive perceptions in each QOL group were evaluated. Patients in the lower percentile

Table 3. SF-36 scores (N = 905)

Concepts	Mean score (SD)
Physical functioning	61.77 (25.56)
Role functioning – physical	50.01 (40.65)
Bodily pain	44.16 (9.72)
General health	53.69 (23.17)
Vitality	54.45 (22.45)
Social functioning	68.21 (26.22)
Role functioning – emotional	96.34 (51.35)
Mental health	60.95 (21.45)

SD = standard deviation

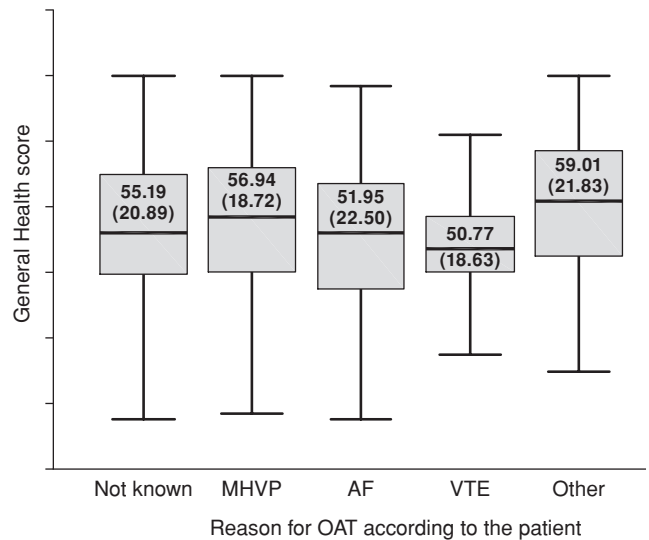


Figure 1. QOL scores according to indication for OAT (N = 905). The boxes represent mean (SD) QOL score for each indication for OAT as referred by the patients. Patients with MHVP have a significantly higher score than patients with AF or VTE ($p = 0.04$ and $p = 0.009$, respectively)

had a mean SF-36 score of 30.14 ± 8.94 while patients in the highest had a score of 82.35 ± 7.73 ($p < 0.000001$).

- Low SF-36 score (bad QOL): In this group, more patients had negative perceptions of OAT (21.5% versus 10.5% in the group with better QOL, $p = 0.008$). There were also more women ($p = 0.001$), and more patients with atrial fibrillation and venous thromboembolism in this group.
- High SF-36 score (better QOL): These patients were younger (59.1 ± 17.2 versus 61.6 ± 16.4 years, $p < 0.0001$), anticoagulated due to valvulopathy and coronary disease, among others, and consulted the doctor on-call more often (70.2% versus 53.3%).

Bleeding episodes (major and minor) were similar in both QOL groups.

Table 4. Main factors associated with negative perceptions of OAT (N = 905)

Negative perceptions	OR	95% CI	p
Female sex	1.58	1.06–2.36	0.01
< 1 year of OAT	2.16	1.34–3.48	0.006
Habit modification	2.75	1.49–4.91	0.0002
Dissatisfaction with medical attention	2.86	1.53–5.18	0.0001

Discussion

Our objectives were to evaluate the impact of patients' perceptions about the benefits and risks of OAT on QOL measured with the SF-36 scale. We related positive and negative perceptions to patient and treatment characteristics.

The instrument used to measure QOL was a validated generic survey. Patients' perceptions were evaluated through a multiple-choice questionnaire developed for the study. In order to avoid interviewer bias, patients anonymously completed both written questionnaires while waiting for the lab test results.

To the best of our knowledge, this study is the largest reported to date, including the widest spectrum of patients, indications, bleeding risks and duration of OAT. Thus, the population was representative of patients receiving chronic OAT.

A high proportion of patients ignored the reason why they were on OAT; a similar finding was reported by Arnsten *et al.*¹⁵ and Tang *et al.*¹⁹. In the series from Hong Kong¹⁹, age correlated with 'not knowing the reason for OAT' while in ours education was associated with that finding, not age or sex. The high incidence of this observation suggested to us that anticoagulation clinic staff, as well as primary care physicians, need to improve their explanations to patients regarding OAT, adapting to the needs of the individual patient.

Unlike the report by Lancaster *et al.*¹⁴, that included only patients with AF, randomized to no therapy or warfarin, to achieve a sub-therapeutic INR, we included all indications for OAT with different INR intensities, and thus different thromboembolic and bleeding risks. In the study by Lancaster *et al.*¹⁴, haemorrhagic events negatively influenced QOL. In contrast, bleeding episodes did not influence our patients' perceptions; moreover, the majority of patients considered their emergencies solved efficiently. Probably, our population was more aware of the benefits and risks than patients in the Lancaster *et al.* study.

Surprisingly, patients with a lower absolute risk of bleeding (i.e. AF and VTE) were more afraid of haemorrhage than patients with a higher risk (i.e. MHVP). Possible explanations for this paradox, also observed in other diseases^{20,21}, might be that patients with an objective higher risk are subject to a more thorough explanation; that they might have experienced severe

symptoms, and a life-threatening situation like a heart surgery, while patients with atrial fibrillation might have been completely asymptomatic.

As found in previous studies^{15,16}, most patients did not change their habits and, among those who did, there were more patients with negative perceptions and worse QOL. This observation should be taken into account when restricting a patient's diet. It is possible to instruct patients how to keep a stable vitamin K intake instead of restricting the diet.

The present study highlights the impact in QOL of specialized care and of an adequate patient-doctor relationship in chronic treatments such as OAT. Patients satisfied with medical attention had a better QOL and vice-versa.

We were not able to correlate perceptions to medical records as the questionnaires were anonymous. Blindness to patient identity is both a limitation and advantage of this investigation. It is a limitation because we cannot correlate the subjective findings with medical records, although subjective experiences do not necessarily correlate with objective medical data as demonstrated in studies of QOL in other diseases^{20,21}. Jaffary *et al.* reported that only the score for emotional function was lowest among old patients with AF and unstable control²². However, if that observation indicated a pre-morbid psychiatric condition or a response to poor stability, it requires further investigation.

However, we consider that being blind to patient identity is also an advantage since it encourages veracity and spontaneity in the questionnaire answers, and enhances credibility and validity of our observations.

The use of patients' perceptions and QOL measures in the clinical setting is still a matter of debate. However, understanding patients' preferences and perceptions might affect QOL. In particular, in chronic therapies with no symptomatic benefit, like OAT, patient perceptions have an impact on QOL. In our study, the majority of patients have a positive perception of OAT. However, we were able to identify patients prone to negative perceptions of OAT. Women, patients on OAT for less than 1 year, patients with venous thromboembolism and atrial fibrillation (in spite of their lower risk of bleeding) were the most vulnerable population. These observations have important clinical implications, since negative perceptions were associated with a poorer QOL.

Conclusion

OAT *per se* does not have a negative impact in QOL. Nevertheless, we observed that patients' perceptions about anticoagulation correlate with QOL. We could identify the group of patients susceptible to have negative perceptions and thus, that would require special attention from their doctors.

In spite of the limitations of a descriptive study, given the sample size and the representative of the population, we consider that our observations apply to patients on chronic oral anticoagulation therapy worldwide.

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