

Analysis of General and Oral Quality of Life and Satisfaction with Treatment among Anticoagulated Patients

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Abstract

Objectives: Anticoagulant drugs are essential for the prevention of arterial and venous thromboembolic diseases. The objective of the present study was to analyze health-related quality of life and satisfaction with anticoagulation treatment in relation to gender, age and duration of oral anticoagulant use.

Materials and Methods: Health-related quality of life (QL) was evaluated in a cross-sectional study with a sample of 100 patients treated with *acenocoumarol* for at least six months. QL and patient satisfaction with treatment by *acenocoumarol* were analyzed, using the OHIP-14, the SF-36 Health Survey (SF-36) and the Duke Anticoagulation Satisfaction Scale (DASS). A descriptive study was made of each variable. The Student t-test for two independent samples was applied to quantitative variables, in each case determining whether the variances were homogeneous. Statistical significance was accepted as $p \leq 0.05$.

Results: Statistically significant differences were found between men and women in the quality of life of anticoagulated patients: the OHIP-14 identified differences in psychological disability ($p=0.046$), social disability ($p=0.041$) and handicap ($p=0.029$); the SF-36 identified differences in the 'vitality' domain ($p=0.014$); the DASS found differences in the 'limitation' domain ($p=0.013$). In relation to the time patients had been in treatment with *acenocoumarol*, the SF-36 found significant differences in almost all domains.

Conclusions: Oral anticoagulation affects a number of quality of life domains among patients.

Keywords: Health-related quality of life, Oral anticoagulation, SF-36, Acenocoumarol

Introduction

Sintron® (*acenocoumarol*) is the most widely prescribed anticoagulant in Spain and is prescribed for the treatment or prevention of thrombotic complications [1-3]. The management of *acenocoumarol* is complicated by its narrow therapeutic window which necessitates regular blood monitoring to ensure the safety and efficacy of the therapy [1,2]. The international normalized ratio (INR) was developed by the World Health Organization as a means of standardizing prothrombin time results among different laboratories. It is now widely used to monitor oral anticoagulant therapy and dosage planning for patients receiving *acenocoumarol*.

Treatment with anticoagulants is indicated to treat many conditions including the prevention of systemic embolism in patients with mechanical cardiac valves, heart attack or arterial fibrillation. These are often long-term treatments, sometimes for life [4].

The level of knowledge the patient and family have regarding *acenocoumarol* therapy is indirectly proportional to their risk of complications, primarily major bleeding [3]. As major bleeding is the most serious side effect of *acenocoumarol* therapy, education programs that inform families of techniques to reduce that risk are of considerable significance [3-8]. Self-management can help to reduce the risk of severe anticoagulation-related complications. The meta-analysis published by Heneghan in 2012 on elderly patients has shown that anticoagulation self-management can reduce the risk from the main thromboembolic and hemorrhagic complications and improve control over oral anticoagulation.

There are a number of characteristics which cause dissatisfaction with and reduction of patient quality of life [4-7]. Patient anticoagulant management is complex and requires frequent analytic check-up appointments in order to monitor and regulate INR values,

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restrictions on diet and certain activities, potential preoccupation with bleeding or hematoma, interactions with other drugs. Nevertheless, anticoagulant treatment also has positive effects, such as the confidence felt in an effective treatment [9,10].

Health-related quality of life is increasingly considered as a parameter for clinical decision-making for chronic conditions. In recent years, research has led to the development of techniques for assessing the quality of life among patients receiving anticoagulant treatment [11-17]. However; research has paid little attention to the perceived impact of anticoagulation on general and oral quality of life.

Sawicki10 monitored the effects of an anticoagulant learning and self-management program for anticoagulated patients, finding that this measure improved health-related quality of life among these patients. Barcellona et al. [9] monitored general patient adherence to oral anticoagulation therapy, paying special attention to quality of life. The results showed that oral anticoagulation therapy did not place limits on patient life-styles, identifying only 11% limitation on their everyday lives.

The aim of the present study was to analyze health-related quality of life and satisfaction with oral anticoagulation treatment in relation to gender, age and duration of oral anticoagulant use.

Patients and Methods

This was a descriptive cross-sectional study of Spanish patients in treatment with acenocoumarol. A total of one hundred patients took part consecutively. Inclusion criteria were: patients older than 18 years, of both sexes, who had been undergoing anticoagulation therapy with acenocoumarol for a minimum of six months, anticoagulated for any indication and monitored in the health center where the study was conducted. The exclusion criteria were: neoplasia or severe disease; patients who were house-bound due to mobility problems; pregnant women; patients with dementias or other problems that prevented adequate data collection such as the inability to read, hear or understand Spanish; unwillingness to participate. The study was performed following principles laid down by the Declaration of Helsinki and was approved by the Ethics Committee of the University of Murcia. All patients were volunteers, provided informed consent.

All patients qualified for healthcare under the Murcia (Spain) regional healthcare system. Quality of life assessment was performed by means of two questionnaires: one that assesses general health (SF-36) and another that evaluates the impact of oral health on quality of life (OHIP-14) [18-20].

The SF-36 is a questionnaire with 36 items across eight domains: physical functioning, physical role limitations, physical pain, general medical health, vitality, social functioning, emotional role limitations and mental health. The Oral Health Impact Profile was applied in its shorter form (OHIP-14) to detect changes in oral quality of life. The questionnaire consists of 14 items that explore different aspects of oral function and quality of life. The patients were questioned about problems relating to speaking, taste perception, eating and problems with dentures. The Duke Anticoagulation Satisfaction Scale (DASS) [21] consists of 25 questions relating to: a) negative impacts of anticoagulation (limitations, hassles, burden) and b) positive impacts of anticoagulation (confidence, reassurance, satisfaction) and positive physical impacts. The overall score varies from 25

to 175. The items presenting the lowest scores indicate higher satisfaction with OAT.

Data were analyzed using the SPSS version 12.0 statistical package (SPSS® Inc., Chicago, IL, USA). A descriptive study was made of each variable. The Student t-test for two independent samples was applied to quantitative variables, in each case determining whether the variances were homogeneous. The associations between the different qualitative variables were studied using Pearson's chi-squared test. Statistical significance was accepted as $p \leq 0.05$.

Results

The sample was made up of 100 patients with an average age of 74.38 ± 11.08 (45-88), of whom 38 were men and 62 women. The reasons why patients were anticoagulated varied: 30 suffered atrial fibrillation, 40 thromboembolic disease, ten had heart valve prostheses and 20 were anticoagulated for other reasons. Patients had been in receipt of the anticoagulant drug acenocoumarol for an average time of 112.80 ± 69.77 (6-432) months.

As for quality of life and satisfaction in relation to age (younger or older than 75 years), the OHIP-14 did not find statistically significant differences between these age groups. However, the SF-36 revealed significant differences in physical function, physical role and emotional role. The DASS did not find significant differences in satisfaction between these age groups. In relation to gender, statistically significant differences between men and women were identified. The OHIP-14 found differences in social psychological disability ($p=0.046$), social disability ($p=0.041$) and handicap ($p=0.029$). The SF-36 found significant differences in the 'vitality' domain ($p=0.014$) and the

| Quality of life and anticoagulation satisfaction | <10 years (n=47) mean \pm SD* | ≥ 10 years (n=53) mean \pm SD | p-value |
|--|---------------------------------|--------------------------------------|---------|
| OHIP-14 | | | |
| Functional limitation | 0.47 \pm 1.21 | 0.57 \pm 1.46 | 0.718 |
| Physical pain | 0.94 \pm 1.62 | 0.91 \pm 1.87 | 0.931 |
| Psychological discomfort | 0.47 \pm 0.95 | 0.62 \pm 1.55 | 0.557 |
| Physical disability | 0.74 \pm 1.20 | 0.62 \pm 1.43 | 0.648 |
| Psychological disability | 0.57 \pm 1.15 | 0.75 \pm 1.58 | 0.521 |
| Social disability | 0.79 \pm 1.55 | 1.00 \pm 1.71 | 0.519 |
| Handicap | 0.70 \pm 1.60 | 1.17 \pm 1.95 | 1.198 |
| Total OHIP-14 | 4.68 \pm 7.15 | 5.64 \pm 10.06 | 0.588 |
| SF-36 | | | |
| Physical functioning | 57.97 \pm 37.17 | 35.84 \pm 38.73 | 0.005 |
| Role physical | 67.02 \pm 46.65 | 33.49 \pm 46.75 | 0.001 |
| Bodily pain | 69.57 \pm 26.05 | 58.72 \pm 26.87 | 0.044 |
| General health | 50.14 \pm 17.70 | 45.09 \pm 18.78 | 1.171 |
| Vitality | 67.55 \pm 22.43 | 56.93 \pm 22.66 | 0.021 |
| Social functioning | 79.78 \pm 26.01 | 60.61 \pm 26.44 | <0.001 |
| Role emotional | 71.59 \pm 42.79 | 42.13 \pm 49.20 | <0.001 |
| Mental health | 74.72 \pm 16.69 | 65.88 \pm 19.68 | 0.018 |
| DASS | | | |
| Limitations | 19.74 \pm 13.01 | 19.21 \pm 13.37 | 0.84 |
| Hassles and burdens | 11.79 \pm 7.19 | 11.94 \pm 8.44 | 0.921 |
| Positive psychological impacts | 36.85 \pm 8.04 | 34.06 \pm 8.95 | 0.105 |
| * SD = standard deviation | | | |

Table 1: Quality of life and anticoagulation satisfaction in relation to duration of treatment with oral anticoagulants (Student t-test).

DASS found differences in the 'limitation' domain ($p=0.013$). When the time the patient had been in anticoagulation treatment by acenocoumarol was analyzed, the SF-36 found significant differences in almost all domains (Table 1): Physical functioning ($p=0.005$), physical role ($p=0.001$) body pain ($p=0.044$), vitality ($p=0.021$), social functioning ($p=0.001$), emotional role ($p=0.001$) and mental health ($p=0.018$).

Discussion

Oral anticoagulant therapy involves frequent blood checks and dose changes to prevent thromboembolic or hemorrhagic complications. This may interfere with patients' social and working circumstances in addition to the possible stress caused by the condition necessitating this treatment [2-6].

Casais et al. [16] researched the prevalence of positive and negative perceptions of anticoagulation using a questionnaire dealing with patients' perception of thromboembolic complications and fear of hemorrhaging produced by anticoagulation. Using the SF-36, founding that patients felt more protected since the start of treatment and that the patient groups who showed negative perceptions were: women, patients in receipt of the therapy for less than one year, patients who were not satisfied with the medical attention received and patients who had modified their life-style.

In 2011, Corbi et al. [17] carried out a cross-sectional, descriptive study of 178 patients, analyzing health-related quality of life (HRQL) in relation to sex, age, time and indication for oral anticoagulant use. It was found that women, patents in old age and patients diagnosed with atrial fibrillation and patients in treatment for less than one year, produced the worst HRQL results 17. However, the present study found that patients in treatment for more than ten years showed the worst QL (according to the SF-36 domains) perhaps due to, or related to, their coping strategies and the period of adaptation undergone, as well as changes of diet, awareness and self-care.

The success of each therapy depends on how each individual perceives its benefits. Positive perceptions are related to better control of the oral anticoagulation therapy and better QL. For this reason, it was decided to use the Duke Anticoagulation Satisfaction Scale for the purposes of the present study [21,22].

One of the barriers to anticoagulation is hemorrhaging; for patients over 70 years of age, the risk of such an event is twice as high as in younger patients. In a recent study of this age group, the risk of major bleeding events was three times higher during the 90 days following the initiation of anticoagulation therapy and 2.75 times higher in patients ≥ 80 years of age, than in younger patients [23,24]. The present study compared patients aged less than 75 years with patients over 75 but the OHIP-14 did not identify statistically significant differences between these age groups. The SF-36 did find significant differences regarding physical function role, physical and emotional role. The DASS also revealed significant differences, but this might be explained by the fact that elderly patients often present coexisting illnesses with additional impacts on QL that could produce a more positive perception of the treatment [2,15].

The results of the present study concur with Almeida et al. [15], who made a study of quality of life in 72 patients in chronic anticoagulant use suffering atrial fibrillation and with mechanical

heart valves; the study produced positive quality of life results in relation to oral anticoagulant use. Among the domains assessed by the SF-36, the physical-emotional domain was the most compromised in terms of perceived QL. The DASS found that inconvenience arising from treatment (hassles, limitations, obligations) was the domain that was the most compromised. The SF-36 found that previous hemorrhagic events, co-morbidities, interactions with other drugs that increased the anticoagulant effect, low educational levels and young age groups were the factors that influenced negative perceptions of QL.

The present study had some limitations first in the size of the sample, which does not allow us to generalize to a broader population. Additionally, both the SF-36 and the OHIP-14 are generic instruments and it is possible that they do not offer much scope for identifying differences when variations are narrow, particularly among patients in old age with multiple comorbidities. However, the study represents a first step towards more detailed future research.

Conclusion

New anticoagulants are currently coming into use that offer attractive prospects for the prevention of complications, many in terms of patient quality of life (fixed dosages, no need for monitoring, predictable anticoagulant responses, low potential for interaction with other drugs). In this way, further studies of quality of life will be required for patients receiving treatment from these new drugs.

Clinical relevance

Scientific rationale for the study

Oral anticoagulant therapy involves frequent blood checks and dose changes to prevent thromboembolic or hemorrhagic complications. Oral anticoagulation affects a number of quality of life domains among patients

Principal findings

Health-related quality of life (QL) was evaluated in a cross-sectional study with a sample of 100 patients treated with *acenocoumarol* for at least six months. Among the domains assessed by the SF-36, the physical-emotional domain was the most compromised in terms of perceived QL. The DASS found that inconvenience arising from treatment (hassles, limitations, obligations) was the domain that was the most compromised.

Practical implications

- Low educational levels and young age groups were the factors that influenced negative perceptions of QL.

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Conflict of Interest

The Authors declare that there are no conflicts of interest

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