Implementation of SintromacWeb®, a new internet-based tool for oral anticoagulation therapy telecontrol: Study on system consistency and patient satisfaction

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Summary
Most computer- or internet-assisted systems for oral anticoagulation therapy (OAT) telemanagement have limitations when it comes to implementation within a healthcare center. It was the objective of this study to evaluate convenience and patient satisfaction with the use of SintromacWeb®, a new OAT telecontrol system, compared with the conventional control. SintromacWeb® consists of a point-of-care device for patient international normalized ratio (INR) self-testing and software that allows internet mediated interaction with physicians. Patients initiated the use of SintromacWeb® and were followed up during a three-month period. A score-based questionnaire was completed in three controlled visits, and data were subsequently analysed. A total of 102 patients were enrolled. At first visit, 55.7% of the patients had their INR within normal range, and 64.9% at the final visit. Internal consistency of the questionnaire was good (Cronbach’s α: 0.79). Scores in the questionnaire were independent of patient’s age, education level, working status and INR value. The most valued features of SintromacWeb® were: fewer visits to the hospital; simplicity and convenience of the system, and time administration for control tasks (86.7%, 82.7% and 77.6% of very satisfied patients, respectively). Also, patients showed indifference or were dissatisfied with the conventional system. At the final visit, 99% of patients declared that they were satisfied with their OAT control. Moreover, all patients continued using SintromacWeb® after completion of the study. In conclusion, SintromacWeb® telecontrol is a new model for management of anticoagulated patients. It was highly accepted and can be used by all patients regardless of their sociodemographic characteristics.

Keywords
Oral anticoagulation therapy, SintromacWeb, telecontrol, internet

Introduction
The number of patients receiving oral anticoagulation therapy (OAT) as a treatment for venous or arterial thromboembolic disease has significantly increased (1, 2). Long-term management of OAT is costly, requires considerable expenditure of human resources and has a significant impact on patient quality of life. The anticoagulation range associated with OAT is narrow, so there is a considerable risk of thrombo-haemorrhagic episodes (3). To prevent these events, regular, frequent and careful control of the anticoagulation level is necessary. This often means that patients must pay frequent visits to a hospital and/or their primary care center.

Prothrombin time is the commonly used test to monitor accuracy of OAT. However, there is a significant patient variability in the prothrombin time results as a response to OAT (4). The use of the INR (International Normalised Ratio) as a standard measure for reporting the results of blood coagulation tests permitted the development of effective recommendations for monitoring patient OAT (5, 6). With these concerns in mind, the development of small and portable point-of-care medical (POC) devices and computer-assisted technologies have led to new strategies for patient OAT self-monitoring and self-adjustment of the dose (7–13). A number of clinical trials and pharmaco-economic studies indicate that self-management of INR can be feasible, safe, cost effective and beneficial in maintaining therapeutic anticoagulation (8, 14–19). However, data must still be managed by a healthcare professional communicating test results to the patient, which can be done by phone.

Development of telemedicine and telehealth tools represents a step ahead in OAT self-management. Follow-up of anticoagulated patients at home, which includes monitoring, communication of results and dose adjustments, has a direct positive correlation with patient satisfaction and comfort (20–22). Moreover, recent medical technologies are taking advantage of global communication provided by use of the internet (23, 24). However, there are still several shortcomings affecting both self-management and telecontrol.
systems. They are often applicable only in patients who are specially selected and trained (25–27). Furthermore, most systems have been designed for limited usage, with restrictions for further implementation in a hospital or healthcare network. Feasible and reliable OAT telecontrol tools overcoming these limitations are desirable.

The new OAT telecontrol system SintromacWeb® was put into practice in our hospital. The objectives of setting an anticoagulation management system for patients at home included preserving efficiency and monitoring quality as well as improving the quality of life for chronically treated patients. In the present study, a questionnaire was prepared and validated with particular emphasis on evaluating patient satisfaction with the SintromacWeb® system compared with conventional OAT control, as well as an assessment of reliability and consistency with the telecontrol system. Our results indicate that OAT control with SintromacWeb® was highly satisfactory and strongly valued by patients.

Material and methods

Aim and study design

This prospective study followed the implementation of our hospital’s adoption and use of the SintromacWeb®, a new Internet accessed system for telecontrol at home for anticoagulated patients.

The study was designed with two objectives: first, to evaluate patient satisfaction with SintromacWeb® system compared with conventional OAT control system; and second, to determine both the reliability and consistency of SintromacWeb® as a wide reaching tool to be used by patients receiving OAT.

To accomplish these objectives, a cohort of patients undergoing OAT was recruited and their conventional OAT control schedule was switched to the new SintromacWeb® telecontrol system. Patient satisfaction levels with both conventional and telecontrol systems were assessed in a three month follow up study through analysis of answers obtained from a questionnaire tailored for this purpose. Furthermore, the possible link between patient satisfaction based upon the type of OAT control system and socio-demographic or clinical characteristics was also analysed.

The study was conducted in accordance with the Declaration of Helsinki and approved by the Ethics Committee for Clinical Investigation by the Hospital La Fe in Valencia, Spain. Written informed consent was obtained from all patients prior to their participation in the study.

Study population

Main inclusion criteria for the study were patients aged 18 or older, under conventional OAT treatment for at least three months with the expectation to start OAT telecontrol through the SintromacWeb® tool, and with adequate technical facilities at home (computer and connection to the internet) to run the SintromacWeb® online telecontrol tool. Main exclusion criteria included patients who did not follow the visit schedule, were currently a participant in a clinical trial at the beginning of the study and failed to complete the questionnaire at scheduled visits.

OAT telecontrol system description

The SintromacWeb® system for OAT telecontrol at home consists of two key elements: a POC device for patients INR self-testing, and software that allows online interaction with physicians.

The POC device used was the HemoSense INRatio® (Medical Inverness Medical Innovations, Inc., Waltham, MA, USA), which is a state-of-the-art and simple to use monitoring system for INR home testing (8, 28). Furthermore, INRatio® is capable of receiving the prothrombin time and INR results in less than a minute by using a small blood drop. A test strip is inserted into the INRatio® monitor and a sample of fresh whole blood (15 μl), received from a finger prick, and is applied to the test strip. Blood is drawn into the test area by capillary action where it mixes with coagulation inducing reagents. The monitor performs the test and determines whether the controls are within pre-set limits.

SintromacWeb® is a new-generation, internet-based software developed by Grifols (Barcelona, Spain) to allow OAT patients to communicate comfortably with their doctors online, at home or wherever an internet access point is available. The SintromacWeb® site is hosted by the same server as the Hospital La Fe website, and is accessed through the hospital portal. Patients are provided with a user name and password, which allows them to enter into their personal area. The current medication schedule can be viewed and, according to the self-testing program, INR results are introduced and sent to the healthcare center. As a result, the haematologist can connect to the system, analyse the data, and introduce a new medication schedule for the patient. After the doctor has updated the schedule, an email is sent to the patient informing him/her that the treatment recommendations are available in his/her personal area of SintromacWeb®. Moreover, if technical difficulties arise, telephone contact with a hospital is always available.

Before independently using the INRatio® device and the SintromacWeb® software, patients were trained in three 1-hour (h) sessions, in groups of 10–15 patients.

Methods and information collected

Those patients that were undergoing OAT on a regular basis were recruited from the Hospital La Fe in Valencia and the enrollment period lasted two months (February-March, 2008), after which recruited patients initiated the study and were followed up for a three-month period. Patients were required to participate in three visits according to the following schedule: first visit at the beginning of the study, intermediate visit after one month, and last visit at the end of the three-month period. Information related to pa-
tient characteristics and patient satisfaction with OAT control sys-
tems were completed in a sequential basis: prior to patients using
the OAT telecontrol with SintromacWeb® (first visit), satisfaction
with conventional OAT control system was assessed; upon the sec-
ond visit, satisfaction with both conventional and SintromacWeb®
system was assessed; and at final visit, when patients were familiar
with the use of SintromacWeb® telecontrol, satisfaction with Sin-
 tromacWeb® was assessed. Moreover, in addition to the question-
naire, without distinguishing between conventional or telecontrol,
a single question regarding patient satisfaction was also requested
at every visit. ► Table 1 summarises these data.

Patient socio-demographic data included: age, sex, education
level, working status and family environment. Historical clinical
data included name of the current pathology requiring OAT, date
of onset (year/month), anticoagulant type, starting date for cur-
rent OAT therapy (year/month), and if any concomitant diseases
were present. Clinical data related to the ongoing study included
last INR value at time of visit, within normal or abnormal range,
and weekly OAT dosage prescribed. System management data con-
sisted of those related to the use of SintromacWeb® tool, which in-
cluded: frequency of use, time of day for usage, total time invested
in performing the telecontrol process, and time elapsed between
patient sending the information and receiving the results back
from a medical professional. The variables that were considered
were: less than 6 h, 6–12 h, 12–24 h and greater than 24 h.

Satisfaction questionnaire

The patient satisfaction questionnaire was prepared by a group of
specialists within the Clinical Hemostasis Department. It was vali-
dated by a pilot study previously performed on five randomly se-
lected patients undergoing OAT (29). Patients were asked to evalu-
ate the comprehensibility of a preliminary test version of the ques-
tionnaire, which included 11 questions about their satisfaction
with OAT control, regarding system management as well as its ef-
effect on personal, professional and social quality of life. Criticisms
raised by the patients regarding the questionnaire were analysed by
the specialists, resulting in modification, substitution or elimin-
ation in order to enhance clarity. The improved questionnaire con-
tained 10 questions and was used for the present study.

Each questionnaire measured patient satisfaction with conven-
tional OAT control and SintromacWeb® OAT telecontrol. Quest-
ions were ranked on a scale from 1 (very unsatisfied) to 5 (very sat-
isfied), then were further standardised to a score of 1–100 to facili-
tate mathematical interpretation within a statistical framework.
Questions were intended to identify patient satisfaction with the
following features of the OAT control system: 1) simplicity and
convenience; 2) time schedule for control tasks; 3) accessibility and
time invested in control tasks; 4) time for receipt of results; 5) level
of treatment control achieved; 6) cooperation of doctors and am-
bulatory care staff; 7) control system in general; 8) professional life
limitations; 9) family life limitations; and 10) social life limitations
due to visits to the healthcare center.

Table 1: Collection of information at each visit.

<table>
<thead>
<tr>
<th>Patient’s information</th>
<th>First visit</th>
<th>Intermediate visit</th>
<th>Last visit</th>
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<tbody>
<tr>
<td>Sociodemographical data</td>
<td>X</td>
<td></td>
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<tr>
<td>Clinical data - Historical</td>
<td>X</td>
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<tr>
<td>Clinical data - Ongoing study</td>
<td>X X X</td>
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<tr>
<td>System implementation data</td>
<td>X X</td>
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<table>
<thead>
<tr>
<th>Satisfaction assessment</th>
<th>First visit</th>
<th>Intermediate visit</th>
<th>Last visit</th>
</tr>
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<tbody>
<tr>
<td>Conventional system control questionnaire</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>SintromacWeb® system telecontrol questionnaire</td>
<td>X</td>
<td>X</td>
<td></td>
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<tr>
<td>Single question on current overall OAT control</td>
<td>X X X</td>
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The additional single question on patient satisfaction on cur-
rent overall OAT was requested at every visit (see Table 1), and was
also ranked on a scale of 1 to 5.

Statistical analysis

Population sample size was calculated in order to estimate patient
satisfaction with SintromacWeb® tool with accuracy 20.2 standard
deviations of score, and with a significance level of 0.05. According
to these conditions, the minimum number of patients required for
the study was 97. This sample size also allowed the evaluation of
patient satisfaction with other variables, with a Pearson correlation
coefficient ≥0.3, a significance level of 0.05 and a statistical power
of 0.8.

The patient satisfaction questionnaire was analysed according
to the following procedures: feasibility, reliability, cross sectional
validity and longitudinal validity.

Feasibility was calculated as the percentage of patients who gave
a valid answer to every question in the questionnaire, as well as the
number and percentage of non-answered questions. Ceiling effect
and floor effect (rating the top and the bottom, respectively) were
also calculated.

Reliability (reproducibility of the results) was analysed in terms
of internal consistency by means of Cronbach’s ω in the total pa-
tient population sample at the intermediate visit, and in terms of
inter-rater reliability by means of the intra-class correlation coef-
ficient (ICC) with patients who did not change their satisfaction
score between the intermediate and final visit. A reliability of 0.70
or higher was required.

Cross sectional validation (construct validity) study was con-
ducted at the intermediate visit. First, the factor structure of the
questionnaire was demonstrated by principal components with
Varimax rotation factor analysis. Sampling adequacy was tested by
Kaiser-Meyer-Olkin measures and Bartlett’s test of sphericity. De-
pending on characteristics of the variables studied, scores observed
in the conventional OAT control questionnaire and the Sintromac-

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Web® OAT telecontrol in relation to socio-demographic, clinical and system management variables were compared by using the Mann-Whitney U test, Kruskal-Wallis test, chi-square test or Spearman’s rank correlation coefficient. Scores observed with the conventional OAT control and the SintromacWeb® OAT telecontrol, were compared by using Student’s t-test, and Spearman’s rank correlation whereby a coefficient was calculated. Comparison with the overall OAT control satisfaction question was completed by use of the Kruskal-Wallis test.

Longitudinal validation (sensitivity to change) study compared the scores observed with the conventional OAT control questionnaire at the first visit with those observed at the intermediate visit, and compared the scores observed in the SintromacWeb® OAT telecontrol questionnaire at the intermediate visit with those observed at the final visit. Differences in the scores were categorised in three groups according to whether satisfaction improved, remained unchanged or worsened (i.e. positive change, no change and negative change). Effect size was calculated for each category and for the total, considering a weak effect size if value was <0.2, moderate if value was between 0.2 and 0.5, and strong if value was >0.5.

Finally, an additional study analysing the evolution of scores and change of patient satisfaction following successive visits was performed in addition to an analysis of features associated with favoring the SintromacWeb® telecontrol system. A linear regression model was constructed with score values at the intermediate visit as the dependent variable and associated socio-demographic or clinical features as the independent variable. Those features showing p<0.2 in the bivariate analysis were included in the model and a backward method was used for the selection of variables.

Unless otherwise stated, values were based on mean ± standard deviation (SD). In all comparisons, statistical significance was set at p≤0.05. The statistical program SPSS v.15.0.1 for Windows was used for calculation and analyses.

Results

Population characteristics

A total of 102 patients who met the inclusion criteria were enrolled, and 98 patients were evaluated. Four patients were excluded from the study due to failure to complete the questionnaire upon the first or intermediate visit. Two patients failed to complete the study due to death and two as a result of a medical decision. Figure 1 shows the flow of subjects through the study and data available for analysis.

Fifty-five patients were men and 43 patients were women. Average age was 62.5 ± 16.4 years, median age was 61 years and range was 18 to 90 years. More socio-demographic characteristics of patients are summarised in Table 2.

Clinical data

Most patients (96.9%) presented a concomitant disease during the study, with an average of 2.5 ± 1.5 diseases per patient. Most preva-
lent concomitant diseases were arterial hypertension (67.3%), dyslipidaemia (36.7%), diabetes mellitus and other endocrine disorders (30.6%), and other cardiovascular diseases (28.6%). A number of other disorders showed prevalence under 18.0%.

The most common OAT requiring pathology presented by patients was atrial fibrillation (48.0%), followed by cardiac valve prosthesis (30.6%), stroke (16.3%), deep-vein thrombosis (13.3%), cardiac valvulopathy (12.2%), ischaemic cardiomyopathy (9.2%) and pulmonary thromboembolism (5.1%). A number of other pathologies showed percentages under 5.0%. The average time of pathology onset and starting OAT treatment was $5.9 \pm 5.2$ years.

The most commonly used anticoagulant was acenocoumarol (94.9% of patients, average weekly dose $18.3 \pm 8.1$ mg), while the remaining 5.1% of patients were treated with warfarin (average weekly dose $34.6 \pm 1.5$ mg). Fifty-two percent of patients were prescribed an increased anticoagulant dose between the first and intermediate visit, 24.5% maintained the same dose and 23.5% were prescribed a dosage decrease. Between the intermediate and final visit, 39.4% of patients were prescribed an increased dose, 29.8% experienced an unchanged dose and 30.9% were prescribed a decreased dose. No statistical differences between acenocoumarol and warfarin treatments were observed.

Average INR value at first visit was $2.8 \pm 0.8$, with 55.7% of patients within normal range. At the intermediate and final visit, INR values were $2.5 \pm 0.7$ and $2.8 \pm 0.7$, respectively, and percentages of patients in the normality range were 63.3% and 64.9%, respectively. Differences were, however, not statistically significant.

### Feasibility study

Ninety-eight percent of patients completed the questionnaire correctly. The remaining 2% answered two questions, numbers 7 and 10, incorrectly. No patient scored at the bottom in any question (floor effect) whereas 24.5% of questions were scored at the top (ceiling effect).

### Reliability study

Cronbach’s $\alpha$ value of the questionnaire was 0.79 on average; indicating a good internal consistency. Table 3 reflects detailed values of Cronbach’s $\alpha$ for the conventional and SintromacWeb® system. Inter-rater reliability for the SintromacWeb® system questionnaire between intermediate and final visit was moderate for global satisfaction (ICC=0.55). Values of ICC for control system management satisfaction and personal life quality satisfaction were 0.21 and 0.64, respectively.

### Cross-sectional validation study

Factorial analysis demonstrated that the questionnaire was structured by two factors. The first factor accounted for 36.1% of the total variance (48.0%) and was associated with OAT control system management satisfaction (questions 1–7), while the second factor accounted for 11.9% of the total variance and was associated with quality of life (questions 8–10). Further analysis of the relationship between the questionnaire scores and patient characteristics took into account the existence of two factors: “satisfaction with system management” and “satisfaction with personal life quality,” combined with “global satisfaction”.

Scores in conventional OAT control questionnaire were independent of patient’s age, education level, working status, type of pathology, years of pathology evolution and INR value. No statistically significant correlation was observed. However, those patients under treatment with warfarin consistently scored lower...
Scores in SintromacWeb® telecontrol system questionnaire were independent of patient's age, education level, working status, years of pathology evolution, type of anticoagulant used and INR value. However, patients presenting pulmonary thromboembolism scored significantly higher in the system management satisfaction and in the global satisfaction, compared with patients with other pathologies (average scores over 98 vs. a range 89.2–95.0, respectively; \( p = 0.02 \)).

At the intermediate visit, average scores observed in the SintromacWeb® telecontrol system questionnaire were always over 90%, which is significantly higher than those observed in the conventional control system questionnaire, which ranged 42.6–61.2 (\( p = 0.01 \); Fig. 2). The correlation, however, was not statistically significant.

Patients who used the SintromacWeb® telecontrol system more than once a week were slightly less satisfied than those who used the system once a week or less. However, results were not statistically significant (scores ranging 88.5–89.6 vs. 90.5–95.4, respectively).

Higher scores in global satisfaction with SintromacWeb® telecontrol system showed statistically significant correlation with shorter time invested in performing the telecontrol process (\( p = 0.019 \), as well as with shorter time in receiving feedback from medical staff (\( p = 0.026 \); Fig. 3). Two patients revealed that they had not received proper training on how to use SintromacWeb® tool and analysis revealed that higher scores were also significantly correlated with training (\( p = 0.024 \)). A higher frequency of use of the SintromacWeb® tool was scored lower in patient satisfaction, although the difference was not statistically significant.

A comparison of the questionnaire scores with the satisfaction degree declared in the single question about overall OAT control is
shown in Figure 4. In both the conventional system at the first visit (Fig. 4A) and SintromacWeb® system at last visit (Fig. 4B), scores in the questionnaire were significantly correlated with the satisfaction declared in the overall OAT control question (p<0.01). Scores observed with the conventional system were consistently lower than those observed with SintromacWeb® system, although differences were not significant.

Longitudinal validation study

In the conventional system questionnaire, changes in the score were neither associated with changes in the dose prescription, nor with changes in the normal value of INR. In contrast, the SintromacWeb® system questionnaire results concluded that patients who changed their prescription dose were less satisfied (lower score), whereas patients who continued with their regular dose were more satisfied with system management and in global quality of life (p<0.05; Fig. 5). Furthermore, there were significant statistical differences in scores related to changes in the INR values (p<0.02). Thus, patients who at the conclusion of the study presented an INR value within the normal range scored 1.9 ± 6.6 higher in system management satisfaction and 1.8 ± 6.7 higher in global satisfaction. However, those patients whose INR value was out of the normal range scored 3.9 ± 10.4 lower in system management satisfaction and 2.1 ± 10.1 lower in global satisfaction.

Changes in satisfaction level with the SintromacWeb® system were not associated with changes in frequency of use; changes in time invested in performing the controlled task, or with changes in
time until feedback was received. Effect size for patients who improved their overall satisfaction level between intermediate and final visit was moderate (0.48), with an average difference in scores of 4.1 ± 6.2. Overall effect size was weak (0.1).

**Evolution of patient satisfaction**

Figure 6 summarises the evolution of average scores observed between the first and the intermediate visit in the conventional system and between the intermediate and the final visit in the SintromacWeb® system. Scores in the conventional system showed a decreasing trend in all factors. Although statistically non-significant (p=0.054) there was greater satisfaction with controlled system management. In addition, scores in the SintromacWeb® system showed a non-significant increase in satisfaction with quality of personal life.

The evolution of satisfaction with the overall OAT control is shown in Figure 7, in which a progressive increase in the percentage of satisfied patients can be seen across the three visits, almost reaching total patient satisfaction at the final visit with 98.7% of patients being rather satisfied or very satisfied. The same values at first and intermediate visits were 71.9% and 94.3%, respectively.
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Figure 7: Evolution of overall satisfaction with the OAT control system from first to last visit.

Features favouring the SintromacWeb® telecontrol system

A linear regression model was not constructed due to lack of association between scores in the satisfaction questionnaire and the possible socio-demographic and clinical features associated (p≥2 in the bivariant analysis). Nevertheless, in a total assessment, the most notable features of SintromacWeb® system were: fewer visits to a healthcare center and social life improvement (86.7% of patients very satisfied), simplicity and convenience of the system (82.7% of patients very satisfied) and time administration for controlled tasks (77.6% of patients very satisfied). No patient declared to be very dissatisfied in any question asked. By contrast, patients showed indifference or were dissatisfied with the conventional system. More than half of the population was dissatisfied with frequent visits to a healthcare center and with the limitations of family and professional life. Cooperation of doctors and ambulatory care staff was the best valued feature of the conventional system.

Discussion

The growth of clinical indications for OAT in conjunction with the development of acceptable and reproducible INR determination tests in capillary blood (30, 31), have resulted in progressive migration of patients from established centralised hospital care to primary care centers (32, 33) as well as in new care models such as self-monitoring and self-management. Studies on these models ultimately transfer patient risk and responsibility for treatment, and most of them are focused on monitoring anticoagulation levels achieved by limited cohorts of patients through restricted use control systems (34–38). In contrast, our study was built on the evaluation of reliability and patient satisfaction with an OAT telecontrol system (SintromacWeb®) that was already implemented and is currently operative in the Hospital La Fe (Valencia, Spain). Clearly, the results illustrate and emphasise the usefulness and favorable reception of SintromacWeb® system, in comparison to the conventional OAT control.

Use of the questionnaire was a crucial tool in achieving our objectives, and state-of-the-art statistical procedures to confirm its validity were thoughtfully carried out. Other questionnaires aimed at evaluating the patient’s opinion on different aspects of anticoagulant therapy have been developed (39–42) and even validated (43), with substantial differences among them. Most are focused on assessing patient satisfaction with treatment (low-molecular-weight heparin or OAT) using heterogeneous questionnaires (number of items ranging from 3 to 40). In contrast, our questionnaire was specially designed to assess patient satisfaction with the use of an internet-based tool for OAT telecontrol. Moreover, it is important to point out that patients in our study were not selected with a bias to achieve a favourable outcome. Our results indicated that the questionnaire was feasible and was correctly completed by almost all patients. A strong feature of the questionnaire was its good internal consistency (average Cronbach’s value of 0.79). This is in contrast to other studies which reported questionnaires with lower consistencies, on average (41–43). Additionally, factorial analysis revealed that satisfaction issues in the questionnaire could be grouped by two factors: one associated with OAT control system management and another associated with personal quality of life. This was considered an additional positive feature for questionn-
naire consistency. Inter-rater reliability of the questionnaire between intermediate and final visit was moderate for global satisfaction and lower for control system management satisfaction and personal quality-of-life satisfaction. As long as inter-rater reliability defines the degree of agreement or consensus, the ratings’ low values of ICC can be attributable to the homogeneity of the sample.

More importantly, scores in both conventional and SintromacWeb® system questionnaire did not correlate with patient’s age, education level, working status, type of pathology, years of pathology evolution, type of anticoagulant used and INR value. Therefore, we can assume that our analysis can be applicable with a high degree of confidence to the whole patient population undergoing OAT. In contrast, other studies have found that a patient’s perception was associated with their education level (42). Linear regression model confirmed that scores in the questionnaire were independent of the socio-demographic and clinical features possibly favoring the SintromacWeb® telecontrol system. Patients presenting pulmonary thromboembolism, surprisingly scored higher in the SintromacWeb® questionnaire about satisfaction with the OAT control system management as well as in global satisfaction. Notwithstanding, this result cannot be considered conclusive due to the fact that the patients were trained subjects who frequently received expedient feedback from medical staff, which were two features associated with high satisfaction scores and independent of the pathology suffered.

Patients positively valued signs indicative of good performance of SintromacWeb® system (i.e. short time invested in performing the control process and short time in receiving feedback from medical staff). Therefore, being previously trained on proper use of the telecontrol system increased patient satisfaction. Moreover, expectations on the system’s capabilities could explain why those patients who received a dose alteration prescription program during the study, and those whose INR value was out of the normal range at the end of the study, showed a lower satisfaction level with the SintromacWeb® system. A plausible explanation is that patients wrongly associated the worsening of their health evolution to inconvenience of OAT telecontrol system, instead of a medical decision which was obviously independent of the control system employed. In general, the questionnaire showed a high sensitivity to change in those patients who reduced their satisfaction level between intermediate and final visit, and moderate sensitivity to those who increased their satisfaction. Since global effect size was small, a study with a larger population would probably help to increase global sensitivity to change.

Over 80% of the patients indicated that the most valued features of the SintromacWeb® system were the improved social life, mainly attributed to reduced travel to a healthcare center, as well as simplicity and convenience of the system. Other studies have also reported that OAT telemanagement indicates a marked improvement in quality of life (22, 44, 45). However, significant loss of patients or no further implementation of the systems tested are flaws commonly found in studies assessing OAT self-management and telemanagement strategies (24, 33–38). This suggests that models are presented in which practical benefit remains to be established. By contrast, in our study, no voluntary withdrawals were registered and patients continued using the SintromacWeb® tool after completion of the study. In fact, SintromacWeb® was implemented and is actively working in the Hospital La Fe in Valencia, with full satisfaction for patients and physicians. In addition, it is believed that use and access to the hospital portal website was a key element that explained the patient’s high acceptance of this tool. The success of the system has been so well received that the number of patients under management is continuously increasing and consideration to expand use of telecontrol to other pathologies is under consideration.

In summary, our results demonstrate that the questionnaire was a valid tool, feasible and sensitive enough to assess both the reliability and consistency of the SintromacWeb® OAT telecontrol system, in terms of patient satisfaction. SintromacWeb® was proven to be highly accepted by patients undergoing OAT and considered useful to perform self-control through the internet regardless of the patient’s socio-demographic characteristics.

References


