Comparison of INR stability between self-monitoring and standard laboratory method: Preliminary results of a prospective study in 67 mechanical heart valve patients

Comparison de la stabilité de l’INR en autosurveillance et en surveillance conventionnelle au laboratoire : résultats préliminaires d’une étude prospective chez 67 porteurs de valves mécaniques

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KEYWORDS
Mechanical valves; Anticoagulant self-monitoring; Anticoagulant accidents

Summary
Introduction. — Thromboembolic accidents and haemorrhage are the main complications observed during long-term follow-up of mechanical heart valve patients. Several suggestions for improving anticoagulation quality have been made, including international normalised ratio (INR) self-monitoring.
Objectives. — We report the preliminary results of a single-centre, open, randomised study (scheduled population of 200 patients), which compares monthly laboratory monitoring...
Patients and methods. — Between May 2004 and June 2005, 67 patients with an average age of 56.6 years (± 9.6), were enrolled in the study (group A: 34 patients, group B: 33 patients). The mean follow-up was 47 weeks (± 11.5). The two groups differed only in the sex ratio (44.1 and 21.2% of women in groups A and B respectively, p = 0.0459). Mechanical heart valves were aortic in 73% of patients, mitral in 13.5%, and multiple in 13.5%. Sixty-five patients (97%) were treated with fluindione, the others with acenocoumarol. The intraclass correlation coefficient between the self- and laboratory-monitored INR was 0.75.

Results. — The time spent in the INR target range (group A: 53 ± 19%, group B: 57 ± -19%, p = 0.45) and the time spent in the INR therapeutic range, between 2 and 4.5, (group A: 86 ± 14%, group B: 91 ± 7%, p = 0.07) are longer in group B, but not significantly so. For patients outside the range, the absolute mean deviation of INR from the target or therapeutic range (range standardized between 0 and 100) is lower for the self-monitoring group (41.1 ± 39.3 and 11.27 ± 11.2) than for the control group (62.4 ± 72.6 and 39.2 ± 52.8). This difference is significant (p = 0.0004 and p = 0.0005). Eighteen adverse events were reported: 17 haemorrhages, 13 in group A (9 mild, 4 serious) and four in group B (all mild), and one sudden death in group B, two days after the patient’s discharge. No thromboembolic events were reported. Six patients (8.8 %), 3 in each group, dropped out of the study.

Conclusion. — This first study evaluating INR self-monitoring in France shows that this method leads to better stability of the INR within the target range. On the basis of these preliminary data, this appears to be related to a decrease in serious haemorrhages (11.8% serious haemorrhage cases in group A versus 0% in group B, p = 0.06, NS).

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MOTS CLÉS
Valves mécaniques ; Autocontrôle des anticoagulants ; Accidents des anticoagulants

Résumé

Objectifs. — Nous rapportons ici les résultats préliminaires d’une étude randomisée ouverte monocentrique qui compare la surveillance mensuelle au laboratoire à l’autosurveillance hebdomadaire de l’INR, avec pour objectif primaire une amélioration de la stabilité de l’INR dans la fourchette cible, et pour objectif secondaire la diminution du nombre d’évènements indésirables.

Patients et méthodes. — Entre mai 2004 et juin 2005, 67 patients, d‘âge moyen de 56,6 ans, ont été inclus dans l’étude. Le suivi moyen est de 47 semaines. La population des deux groupes ne diffère que par le sexe. Le pourcentage de prothèse aortique est de 73 %, mitrale de 13,5 %, et de prothèse multiple de 13,5 %. Soixante-cinq patients (97 %) sont traités par fluindione, les autres par acénocoumarol. Le coefficient de corrélation intraclasse entre INR en autosurveillance et INR au laboratoire a été de 0,75.

Résultats. — Le temps passé dans la fourchette d’INR cible et le temps passé dans la fourchette thérapeutique entre 2 et 4,5 sont plus longs dans le groupe B, mais de façon non significative. Pour les patients hors fourchette, l’écart moyen absolu de l’INR à la fourchette cible ou thérapeutique (fourchette ramenée entre 0 et 100) est plus bas pour le groupe autocontrôle que pour le groupe témoin. Cette différence est significative. Dix-sept hémorragies dont 13 ont été rapportées dans le groupe A et quatre dans le groupe B, et un décès par mort subite dans le groupe B deux jours après la sortie d’hospitalisation. Six patients (8,8 %) sont sortis d’étude.

Conclusion. — Cette première étude évaluant, en France, l’autosurveillance de l’INR montre que cette technique permet une meilleure stabilité de l’INR dans la fourchette cible. Cela semble lié, sur des données préliminaires, à une diminution du taux d’hémorragies graves (11,8 % d’hémorragies graves dans le groupe A, versus 0 % dans le groupe B, p = 0,06, NS).

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**Introduction**

Mechanical valve replacement has become a widely practiced therapeutic option in the cardiac surgery department, but requires lifelong anticoagulant treatment. This essential treatment is associated with constraints, amongst which is the need of monitoring. Indeed, for prosthetic valve patients, quality of life is highly dependent on the absence of anticoagulant-related adverse events, that is, thromboembolic and hemorrhagic complications. To date in France, monitoring has centered on blood tests measuring international normalised ratio (INR) at the laboratory. For the past several years in both Europe and North America, self-monitoring systems have been used to obtain reliable and more regular INR measurements with fewer constraints for the patient. They have also led to improved anticoagulation stability.

We decided to evaluate these INR self-monitoring systems in our patients by comparing them with standard laboratory methods.

**Patients and methods**

This is a single centre, regional, prospective, randomised, open study. The primary objective was to check whether self-monitoring led to better compliance with the INR therapeutic range (INR: 2–4.5), and the secondary objective was to confirm that INR stability within the INR target range (established for each patient within the therapeutic range, at the time of discharge) reduced the incidence of thromboembolic and hemorrhagic complications. All patients undergoing single or multiple mechanical valve replacement either alone or associated with myocardial revascularisation, from May 1st 2004, in the cardiovascular surgery department at the Clermont-Ferrand university hospital centre, were invited to enrol the study. The only exclusion criteria were contra-indication to oral anticoagulants, pregnancy or inability to self-monitor. After signing the informed consent form, the patients were randomly allocated to one of two groups:

- **group A**: standard INR monitoring once a month in the laboratory;
- **group B**: home INR self-monitoring, using the CoaguChek® system once a week, combined with standard INR monitoring once a month in the laboratory.

The patients in both groups received training in anticoagulant treatment monitoring methods.

In addition, the patients in group B were trained to use the CoaguChek® system by a clinical research associate in three to six sessions spread over three days. Data collection began one week after the patient’s discharge and was continued at the rate of once a month for one year, by phone. Patients were seen at the department of cardiology during the third and 12th months. The appropriate anticoagulation level was defined by the prescribing physician in accordance with French (SFC [1]), French Health Products Safety Agency (AFFSAPS) [2]), European [3] or North American (ACC/AHA) [4] recommendations in all cases. Anticoagulant dose was adjusted by the patient’s doctor on the basis of the laboratory INR measurements for group A and on self-monitoring and laboratory INR measurements for group B.

This study was approved by an Ethic Committee (direct benefit) and is part of a regional hospital clinical research program (PHRC).

The self-monitoring systems were supplied by Saint-Jude Medical, the strips by Roche International.

At the beginning of the study, the aim was to enrol 100 patients divided equally into two groups. An extension was requested and granted by the Ethic Committee for the enrolment of a further 100 patients, 50 in group A (controls) and 50 to form group B2, who performed weekly self-monitoring using the INRatio® (Hemosens) self-monitoring system. The results of this preliminary study concern the first patients enrolled, that is groups A (controls) and B1 (self-monitoring with the CoaguChek® system).

Firstly, we checked that groups A and B were comparable using Student tests or Chi² tests depending on the variable studied.

For group B, we analysed the coherence between the laboratory INR measurements and the INRs measured the same day by self-monitoring, using an intraclass correlation coefficient.

Anticoagulation quality was analysed in the two groups on the basis of the laboratory INR measurements.

We compared the groups in terms of the mean time spent in the target range and the mean time spent in the therapeutic range using a Student test. The mean time was equal to the number of INRs within the range over the number of total INR measurements.

We then compared INR stability within the target range between the two groups (Student test): as the INR target range was different for each patient depending on the indication, it was normalized on a scale of 0 to 100, making it possible to compare INR stability in the range over time:

\[
\text{new INR} = \frac{(\text{INR} - \text{lower limit of the range})}{\text{upper limit} - \text{lower limit}} \times 100
\]

Once these new INRs were obtained, the absolute deviation from the target range was calculated for the INRs outside this range. The mean deviation was thus calculated for both groups. A similar analysis was performed irrespective of the target INR, for the therapeutic range between 2 and 4.5.

Clinical events were identified as per Edmund’s et al. definitions [5] and we compared the number of serious haemorrhages for the two groups (Fisher’s exact test). The results were analysed using SAS V8 software.

**Results**

These are the results of the intermediate analysis on the first 67 patients enrolled. The populations are similar in both groups, with the exception of the sex ratio (Table 1). Random allocation of subsequent patients to the groups should lead spontaneously to a balance between the two groups. Fluindione (Previscan®) was used in 65 patients (97%) and acenocoumarol in two patients.
Table 1  Characteristics of the two groups.

<table>
<thead>
<tr>
<th></th>
<th>Group A</th>
<th>Group B</th>
<th>p</th>
</tr>
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<tbody>
<tr>
<td>Number</td>
<td>34</td>
<td>33</td>
<td></td>
</tr>
<tr>
<td>Age (years)</td>
<td>54.9 ± 9.6</td>
<td>58.24 ± 9.7</td>
<td>0.16</td>
</tr>
<tr>
<td>Females (%)</td>
<td>44.1</td>
<td>22.2</td>
<td>0.046</td>
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<tr>
<td>Euroscore</td>
<td>4.23 ± 1.5</td>
<td>4.18 ± 1.9</td>
<td>0.90</td>
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<tr>
<td>EF at 12 months (%)</td>
<td>63.13 ± 9.2</td>
<td>59.7 ± 7.3</td>
<td>0.15</td>
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<tr>
<td>Distance from lab (km)</td>
<td>13.6 ± 20.4</td>
<td>12.6 ± 16.1</td>
<td>0.83</td>
</tr>
<tr>
<td>Duration of follow-up (weeks)</td>
<td>46.8 ± 11.6</td>
<td>46.9 ± 11.5</td>
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<table>
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<th>Type of valve (n) p = 0.31</th>
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<tr>
<td>Mitral (M)</td>
<td>5</td>
<td>4</td>
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<tr>
<td>Aortic (A)</td>
<td>22</td>
<td>27</td>
<td></td>
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<td>2 valves (A and M)</td>
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<td>2</td>
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<td>3 valves (A, M and T)</td>
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<th>Target INR p = 0.27</th>
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<tr>
<td>2–3</td>
<td>14</td>
<td>20</td>
<td></td>
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<tr>
<td>2.5–3.5</td>
<td>9</td>
<td>7</td>
<td></td>
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<tr>
<td>3–4.5</td>
<td>11</td>
<td>6</td>
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<th>Treatment with aspirin (n)</th>
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<tr>
<td>Discharge from reanimation</td>
<td>31</td>
<td>27</td>
<td>0.47</td>
</tr>
<tr>
<td>Long-term</td>
<td>6</td>
<td>12</td>
<td>0.07</td>
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</table>

Concordance
The correlation coefficient was 0.75.

Time spent in the range
The average time spent in the INR target range was not significantly different between the two groups, whether in terms of the target range (group A: 53 ± 19%, group B: 57 ± 19%, p = 0.45) or the therapeutic range: INR 2–4.5 (group A: 86 ± 14%, group B: 91 ± 7%, p = 0.07).

Stability
The difference between the two groups was not significant for each measurement, but the INR values were more stable in the self-monitoring group (mean deviation 41.1 ± 39.3) than in the control group (mean deviation: 62.4 ± 72.6), for the whole study period with p = 0.0004 (Figs. 1 and 2). A similar analysis was performed irrespective of the target INR, for a therapeutic range between 2 and 4.5: in this same way, a statistically significant difference between group A and group B was identified, with a mean deviation from the therapeutic range of 11.2 ± 11.2 for group B, versus 39.2 ± 52.8 for group A (p = 0.0005) (Figs. 3 and 4).

Clinical events
Seventeen haemorrhages were reported: 13 in group A and four in group B. In group A, these were nine mild haemorrhages and seven serious haemorrhages (epistaxis leading to hemorrhagic shock after an AVK overdose, gastrointestinal haemorrhage after AVK overdose, hematuria after AVK overdose, and anemia resulting in hospitalisation). In group B, all four haemorrhages were mild (Table 2). 11.8% of the patients in group A presented with a serious haemorrhage versus 0% in group B (non significant difference, p = 0.06).

There were no thromboembolic events.
There was one case of sudden death in group B, two days after discharge.
One patient in group A was hospitalised after an AVK overdose (INR: 13), without clinical consequences.

Study withdrawals
A total of six patients dropped out of the study, three in group A and three in group B. Of the patients in group A, one was lost to follow-up and two finally refused to be monitored at the university hospital centre. Among the group B patients, one didn’t use the system properly, one found self-monitoring too restrictive and one did not trust the system.

Discussion
Despite the continuous improvements in mechanical valves, both in terms of hydrodynamic design (double leaflet valve) and the materials used (pyrolitic carbon), thromboembolic events remain the major complication of mechanical cardiac valve replacement procedures. With Saint-Jude Medical-type aortic mechanical valves, the incidence of these complications is 12% per annum, rising to 22% for mechanical mitral valves without anticoagulant treatment [6]. All mechanical valve patients require lifelong anticoagulant treatment (type 1C+ recommendations) [3]. The disadvantages of anticoagulants are their narrow therapeutic window, their high interindividual pharmacokinetic variability and the many drug and food interactions with which they are associated [7]. Their efficacy is assessed by measuring the INR [7,8]. The INR should be measured.
at least once a month once the appropriate anticoagulant
dose has been reached, but additional measurements are
also recommended in many other circumstances: when a
medication is introduced or withdrawn and in the event of
an intercurrent disease, gastrointestinal disorders, signs of
overdose or embolic event. The quality of the sample and
speed of analysis have a major impact on the reliability of
the result. Samples should therefore be taken in the labora-
tory and patients should always attend the same laboratory.
The INR value should be sent to the patient’s physician on

**Figure 1.** INR group A (new INR, in the target range standardized on a scale of 0 to 100).

**Figure 2.** INR group B (new INR, in the target range standardized on a scale of 0 to 100).
the same day, for anticoagulant dose adjustment, on that very evening, if necessary [1,2,7].

Haemorrhage is the most common and serious complication of anticoagulant treatment, representing 13% of hospitalisations for iatrogenic effects and accounting for a total of 17,000 hospitalisations per year in France [9]. These complications can be divided into minor and major haemorrhages, the latter being life-threatening and requiring transfusion and/or hospitalisation [5]. Their incidence increases in a linear fashion when the INR is more than 3 and

Figure 3. INR group A (new INR, in the therapeutic range standardized on a scale of 0 to 100).

Figure 4. INR group B (new INR, in the therapeutic range standardized on a scale of 0 to 100).
at the start of treatment: 3% during the first month, 0.8% per month during the first year and then 0.3% per month [10].

In his review of controlled trials, Levine et al. reported fatal haemorrhage rates of 0 to 4.8%, and an incidence of major haemorrhage ranging from 2.4 to 8.1% [11].

The thromboembolic and hemorrhagic risk is affected by valve type and position, left auricle dilatation, atrial rhythm, age and comorbidity [12].

For each case and taking into account the risk-benefit ratio, European and North American recommendations have defined the best anticoagulation regimen, corresponding to the target INR [1—4]. This target INR is situated within a therapeutic range extending from an INR of 2, beneath which the thromboembolic risk is unacceptable, to 5, above which the risk of haemorrhage is too high [13]. However, more than anticoagulation level, it is the instability of this anticoagulation that is recognised in the GELIA study and by Butchart et al. as a risk factor for morbidity—mortality [14,15]. This had already been suggested by Cannegieter et al. in 1999, who declared that "we must no longer look for the best anticoagulation regimen, but improve the quality of anticoagulation on a local level" [12].

In 2003, an AFSSAPS enquiry involving 450 medical analysis laboratories and 2452 patients showed that the interval between two INR measurements was more than one month for 25% of patients, that the INR of 28.2% of patients was outside the therapeutic range (2 and 4.5) and that only 48.5% of patients had an INR within their target range [16]. Three methods may be used to analyse the time spent in the target range [7,17—19]: the percentage of INR in the range for all the patient’s measurements, the percentage of INR in the range for each measurement time and finally Rosendaal’s et al. method, which is based on a daily estimation of the INR from each INR measurement [19]. For our analysis, we chose to use the first, and simplest of these methods which is also used in the AFSSAPS study. Despite the close monitoring of our patients throughout our study, the time spent in the target range is low, only just over 50%. This may be due to the lack of centralised intervention subsequent to the INR tests, since anticoagulant dose adjustments were generally made by the patient’s practitioner. However, for the patients in group B, only 9% of the time was spent outside the therapeutic range (INR: 2—4.5), and therefore "at risk" (versus 28% in the AFSSAPS study).

Three ways of improving anticoagulation have been proposed: anticoagulation clinical care, computer software-assisted dose adjustment and self-monitoring (self-testing) or self-management (self-dosage) of the anticoagulant treatment. None of these is currently available in France in routine practice and no recommendations have yet been published. Many non-randomised studies have shown that anticoagulation can be improved by anticoagulation clinical care. Indeed in 271 patients with prosthetic valves, Cortelazzo et al. showed that the incidence of major haemorrhage decreased from 4.7 to 1% and of thromboembolic complications from 6 to 0.6% in this way [20]. Similarly, several studies have shown that patients tended to be more rapidly and better stabilised when anticoagulant dose adjustment software was used: in the APROAT study (1200 patients enrolled in 5 centres) the INR was in the target range for 71.2 % versus 68.2 % of the patients and in the first three months for 51.9% versus 48.1% of the patients [21].

Self-monitoring of anticoagulant treatment allows more frequent INR testing (which is correlated with an improvement in anticoagulation [22]), always using the same machine and allows patients to manage both their condition and treatment better, which in turn leads to better compliance with therapy. It can be coupled with dose adjustments made by the family doctor: simple self-monitoring or self-testing, or by the patients themselves, self-management or self-dosage. Three self-monitoring systems are currently available worldwide. These are the

<table>
<thead>
<tr>
<th>Patient No</th>
<th>Haemorrhage classification</th>
<th>Description of hemorrhagic event</th>
<th>INR at time of event</th>
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<td>Group A</td>
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<tr>
<td>19</td>
<td>Serious</td>
<td>Anemia — hospitalisation</td>
<td>5.57</td>
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<tr>
<td></td>
<td>Mild</td>
<td>Gynecological haemorrhage</td>
<td>7.25</td>
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<tr>
<td>14</td>
<td>Mild</td>
<td>Ferrprive anemia — melena</td>
<td>4.42</td>
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<tr>
<td>1</td>
<td>Mild</td>
<td>Hematoma with cruralgia (fall)</td>
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</tr>
<tr>
<td>6</td>
<td>Mild</td>
<td>Bleeding gums</td>
<td>3.62</td>
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<td></td>
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<td></td>
<td>2.38</td>
</tr>
<tr>
<td>9</td>
<td>Serious</td>
<td>Epistaxis with hemorrhagic shock</td>
<td>6.63</td>
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<td>35</td>
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<td>Gastrointestinal haemorrhage</td>
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<td>Bleeding gums</td>
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<td>40</td>
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<td>46</td>
<td>Mild</td>
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<td>Group B</td>
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<tr>
<td>62</td>
<td>Mild</td>
<td>Sub-conjunctival haemorrhage</td>
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<td>57</td>
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<td>2.4</td>
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<td>37</td>
<td>Mild</td>
<td>Hematuria under antibiotics</td>
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<td>2.8</td>
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CoaguChek® (Roche International), the Protime monitor (ITC), and the INRatio® (Hemosens), which have recently been made available in France through AAZ. These systems can measure the INR from a drop of capillary blood obtained by pricking the finger. The reliability of each system has been demonstrated through clinical trials comparing the results obtained with the apparatus and those of standard laboratory measurement [23], or the results obtained with two different self-monitoring machines [24]. The self-monitoring system most commonly studied in these trials is the CoaguChek®. A meta-analysis of 14 studies including 3049 patients taking anticoagulants for various reasons and monitored for two months to two years, showed a significant reduction in the incidence of thromboembolic events with a relative risk of 0.45 for the self-monitoring patients and 0.27 for the self-managing patients. The relative risk of mortality in the two groups was 0.61 and 0.37 respectively and the relative risk of haemorrhage was 0.65 and 0.93. Neither this meta-analysis nor a more recent randomised trial clearly indicates that self-monitoring is better than self-management, or vice versa [25, 26].

One hundred thousand patients in Germany have already been enrolled in self-monitoring or self-management protocol. Recommendations have been issued regarding how these methods should be used: patients must have the manual dexterity and visual acuity required to perform self-monitoring correctly. If the patients themselves are unable to self-monitor, the test can be done by a family member or a friend. The patient or this other person must have been trained to use the self-monitoring system [27]. The tests are to be performed once a week, which is considered to be a suitable interval [28]. In the Early Self-Controlled Anticoagulation Trial (ESCAT) study in 600 mechanical valve patients, the study drop-out rate was 8% [29]. It is much higher in Heneghan’s et al. meta-analysis, in which 22% of the patients enrolled in the self-monitoring protocol proved to be unable to comply with protocol requirements [25]. In our cohort, the study drop-out rate is 8.8%, independent of monitoring type.

While these preliminary data do not show a significant difference in favour of self-monitoring, we can see that anticoagulation stability seems to be enhanced and this has been correlated, as reported in the GELIA study [14] and by Butchart et al. [15], with a clinical benefit, since no serious haemorrhages were observed in the self-monitoring group.

Quality of life was not analysed in this study, but it is certain that self-monitoring dispenses with difficulties associated with transport to the laboratory and the blood sampling procedure itself.

Conclusion

This is the first French study of INR self-monitoring. It confirms that self-monitoring is correlated with better anticoagulation, both from a quantitative (time spent in the target range, although this difference was not significant) and qualitative (stability, $p = 0.0004$) perspective. On the basis of these preliminary data, it also appears to be linked to a reduction in clinical events.

Acknowledgements

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References


