Anticoagulation control in Sweden: reports of time in therapeutic range, major bleeding, and thrombo-embolic complications from the national quality registry AuriculA

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Received 16 December 2010; revised 4 March 2011; accepted 25 March 2011; online publish-ahead-of-print 26 May 2011

Aims
In anticoagulation treatment with warfarin, the risk of thrombo-embolic events must be weighed against the risk of bleeding. Time in therapeutic range (TTR) is an important tool to assess the quality of anticoagulation treatment, and has been shown to correlate with less bleeding and thrombo-embolic complications. AuriculA, the Swedish national quality registry for atrial fibrillation and anticoagulation, is used for follow-up and dosage control of warfarin. This is the first report of TTR in AuriculA and, in a subgroup of two centres, bleeding and thrombo-embolic complications during 2008.

Methods and results
Prothrombin complex (International normalized ratio) values from 18 391 patients in 67 different centres were analysed. The mean (SD) age was 70 (12) years. The main indications for warfarin treatment were: atrial fibrillation (64%), venous thromboembolism (19%), and heart valve dysfunction (13%). Time in therapeutic range for all patients was 76.2%. The mean weekly dose of warfarin decreased with age and TTR increased with age. In 4273 patients from two centres in AuriculA, the frequency of major bleedings and venous/arterial thrombo-embolism were 2.6 and 1.7% and for atrial fibrillation, 2.6 and 1.4%, per treatment year, respectively. A correlation between age and the risk of major bleeding (P < 0.001), but not thrombo-embolic complications (P = 0.147), was seen.

Conclusion
Compared with prospective randomized trials of warfarin treatment, TTR in the AuriculA population was higher. Complications were low, probably due to the organization of anticoagulation treatment in Sweden. Use of the AuriculA dosing programme could have contributed to the results by keeping dosing regimens consistent over all centres.

Keywords
Oral anticoagulation • Warfarin • TTR • INR • Atrial fibrillation • Thrombosis

Introduction
Approximately 150 000 patients in Sweden are treated with warfarin, corresponding to 1.5% of the population.1 Atrial fibrillation is the most common and rapidly growing treatment indication, and in this population, warfarin treatment has been shown to reduce the risk for embolic stroke by two-thirds.2 At the same time, warfarin treatment confers a substantial risk of bleeding, and the reduction in thrombo-embolic events must be carefully weighed against the risk of bleeding for each individual patient. This benefit to risk ratio is often not known for the individual patient due to too few and small studies, or limitations in patient selection where the elderly patients with multiple diagnoses do not fit in.3 Monitoring and tight control of anticoagulation treatment reduce the risk of both thrombosis and bleeding.4–6 and time in therapeutic range (TTR)7 is an important tool to assess
the quality of the anticoagulation treatment given. In the USA, anticoagulation clinics have been associated with higher TTR compared with standard community care where as in Sweden, a study comparing anticoagulation clinics with standard community care has not shown any differences in complications, indicating a potential difference between countries. However, this study did not validate TTR against the frequency of complications. The recently published multicentre RELY trial, comparing anticoagulation treatment with warfarin with two different doses of the thrombin inhibitor dabigatran in patients with atrial fibrillation, reported a TTR of 64%, which is in line with previous randomized controlled trials. Compared with warfarin, a significant decrease in thrombo-embolic events was seen with the higher 150 mg b.i.d. dose, and bleeding complications were lower with the 110 mg b.i.d. dose, favouring dabigatran treatment. In Sweden, the TTR of warfarin treatment was very high (77%), and retrospective subgroup analysis showed that when centres were separated according to TTR, a high TTR (>72.4%) correlated to a reduced risk of both thrombo-embolic complications and major bleeding.

The Swedish national quality registry for atrial fibrillation and anticoagulation (AuriculA) was founded in 2006. The registry, used for patient characteristics, follow-up, and dosage control of warfarin in patients with different indications of anticoagulation treatment, is growing rapidly and has by 31 December 2008 over 16 000 patients and more than 225 000 international normalised ratio (INR) values registered. In this paper, we report patient characteristics and TTR for the participating centres and, in a subgroup of two centres, bleeding and thrombo-embolic complications during the year 2008.

Methods

AuriculA is a Swedish national quality registry of patients with atrial fibrillation. The registry includes key patient characteristics, information on treatment, concurrent illnesses, investigations, and complications to atrial fibrillation as quality indicators. AuriculA, created in 2006 with the intent to improve anticoagulation treatment and to evaluate the benefits of modifications, also has a separate part for dosing of anticoagulation treatment regardless of indication (www.ucr.uu.se/auricula). The web-based dosing program suggests the dosage of warfarin according to an algorithm based on the last two INR results. Key outcome measures for patients on anticoagulation treatment are major bleeding according to ISTH (International Society on Thrombosis and Haemostasis) definitions and clinically verified arterial or venous thrombosis. AuriculA complies with the Declaration of Helsinki and the Ethics Committee at Uppsala University has approved research using this registry.

Data on age, sex, treatment indications, and TTR were extracted from AuriculA for patients listed during the period 1 January 2008–31 December 2008. In a subgroup analysis of two centres, the hospitals in Malmö and Sundsvall, we performed a follow-up of all patients registered in 2008 regardless of indication of anticoagulation treatment. In these two centres, we aimed to assess and verify the frequency of major bleedings, arterial and venous thrombo-embolism and relate data to the mean TTR in each patient category. Data on complications are collected prospectively in AuriculA through routine follow-up telephone calls, but to assure that no complications were missed, we reviewed the hospital records of every patient treated with warfarin in these two centres. All 18 391 patients in AuriculA were included in analysis of age, gender, and indication of treatment. The age of any patient in the AuriculA population was defined as the age of that patient at the time of the first INR test in 2008. Patients could have more than one indication of anticoagulation treatment with warfarin. Time in therapeutic range was calculated according to F.R. Roosenlaal’s algorithm with linear interpolation. Only patients with anticoagulation treatment with warfarin >1 week and target INR 2.0–3.0 were included in the analysis of TTR and as a result, 2242 patients with other target INR levels and 548 patients without enough INR results to calculate TTR were excluded. In every participating centre, the mean TTR was calculated based on the mean of the TTR of every patient in that centre during 2008 and was reported with 95% CI. All patients in all 67 centres who met the criteria above were included in all analyses. However, due to large confidence intervals, only centres with >10 patients (49/67) were listed in the graph displaying TTR/centre. Owing to the skew distributions of TTR and the mean weekly warfarin dose, the associations between them and age (as categories) were analysed using the Kruskal–Wallis test.

In a subgroup of two centres, data on 4273 patients on anticoagulation treatment with warfarin were extracted from AuriculA and complications to warfarin treatment (major bleeding and thrombo-embolic events) were verified against hospital records. Age in these patients was defined as the age of the patient at the time of the event. If a patient had more than one event, only the first in each separate category was used for statistical analysis. The TTR for every patient in the subgroup during 2008 was extracted from AuriculA and complications were converted to rates (per cent per patient-year) and reported with appropriate 95% CI for a rate. The mean TTR, of the separate indications of anticoagulation treatment in the subgroup, was based on the mean of the TTR of patients with that indication. Three thousand six hundred and nineteen patients on anticoagulation treatment with warfarin >1 week and target INR 2.0–3.0 were included in the analysis of TTR for the different indications in the subgroup. As a result, 611 patients with other target INR levels, and 43 patients without enough INR results to calculate TTR, were excluded. Complications were tested for differences in patient characteristics. Differences in age were tested using Wilcoxon’s test and differences in gender and treatment indications were tested using Pearson’s test. In patients with complications, only INR values before the event was used for statistical analysis. All statistical tests were two-sided and the P-value threshold for significance was <0.05. For statistical analyses, R version 2.10.1 (R Foundation for Statistical Computing, Vienna, Austria) and SAS version 9.2 (SAS Institute Inc., Cary, NC, USA) were used.

Results

A total of 250 142 INR values from 18 391 patients in 67 different centres were registered in AuriculA during 2008 (Figure 1). The mean time (SD) between INR samples was 23 (21) days and the mean of INR samples per patient-year during 2008 was 13.6. The main indications of treatment with warfarin were atrial fibrillation (64%), venous thrombosis (19%), and heart valve dysfunction (13%) (Table 1). The mean age (SD) of the whole population of 18 391 patients was 70 (12) years. The mean age (SD) was higher in women, 73 (12), than in men, 69 (12). In patients with a target INR of 2 after exclusion of the first week of therapy, the adjusted mean TTR (n = 15 601) was 76.2% (Figure 2). A TTR of >70% was consistent in all age groups, and a significant
correlation between TTR and increasing age \( (P < 0.001) \) was seen (Figure 3). The mean weekly dose of warfarin decreased with increasing age, from 43 mg/week in patients of age 41–50, to 24 mg/week in patients of age 81–90 (Figure 4, \( P < 0.001 \)). In the subgroup of two centres \( (n = 4273) \), the mean TTR was 74.9%, and a total of 87 bleedings and 58 thrombo-embolic events was detected during a total of 3377 treatment years (Table 2). There were 14 CNS (16%), 32 gastrointestinal (37%), and 41 other

![Figure 1](distribution_of_INR_values_n_250_142_in_18_391_patients_during_2008_18_9%_of_INR_values_were_below_INR_2_0_63%_were_above_INR_5_and_<0_01%_above_INR_8.)

**Table 1** Patient characteristics of 18 391 patients enrolled in AuriculA during the year 2008

<table>
<thead>
<tr>
<th>Indication</th>
<th>Total</th>
<th>Men</th>
<th>Women</th>
<th>Mean age (SD)</th>
<th>Mean dose (mg/week)</th>
<th>nPK/patient</th>
<th>Mean TTR (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whole AuriculA population</td>
<td>18 391</td>
<td>11 097</td>
<td>7294</td>
<td>70 (12)</td>
<td>30.9</td>
<td>13.6</td>
<td>76.2</td>
</tr>
<tr>
<td>Atrial fibrillation</td>
<td></td>
<td>64%</td>
<td>64%</td>
<td>73 (10)</td>
<td>29.2</td>
<td>13.5</td>
<td>76.5</td>
</tr>
<tr>
<td>Primary prevention</td>
<td>–89%</td>
<td>–90%</td>
<td>–87%</td>
<td>73 (10)</td>
<td>29.5</td>
<td>13.5</td>
<td>76.4</td>
</tr>
<tr>
<td>Stroke + TIA</td>
<td>–10%</td>
<td>–10%</td>
<td>–12%</td>
<td>76 (9)</td>
<td>27.7</td>
<td>13.1</td>
<td>77.6</td>
</tr>
<tr>
<td>Arterial embolism</td>
<td>–1%</td>
<td>–1%</td>
<td>–1%</td>
<td>79 (9)</td>
<td>24.1</td>
<td>13.6</td>
<td>73.2</td>
</tr>
<tr>
<td>Heart valve dysfunction</td>
<td>13%</td>
<td>15%</td>
<td>11%</td>
<td>66 (13)</td>
<td>34.4</td>
<td>15.8</td>
<td>78.2</td>
</tr>
<tr>
<td>Mechanical valve</td>
<td>–85%</td>
<td>–87%</td>
<td>–82%</td>
<td>65 (13)</td>
<td>35.7</td>
<td>16.3</td>
<td>79.9</td>
</tr>
<tr>
<td>Biological valve</td>
<td>–9%</td>
<td>–8%</td>
<td>–11%</td>
<td>73 (10)</td>
<td>25.6</td>
<td>12.7</td>
<td>69.4</td>
</tr>
<tr>
<td>Mitral stenosis</td>
<td>–3%</td>
<td>2%</td>
<td>–5%</td>
<td>74 (10)</td>
<td>26.2</td>
<td>13.0</td>
<td>77.2</td>
</tr>
<tr>
<td>Other</td>
<td>–3%</td>
<td>–3%</td>
<td>–2%</td>
<td>68 (10)</td>
<td>27.8</td>
<td>13.1</td>
<td>65.6</td>
</tr>
<tr>
<td>Venous thrombo-embolism</td>
<td>19%</td>
<td>16%</td>
<td>22%</td>
<td>67 (16)</td>
<td>33.5</td>
<td>12.6</td>
<td>73.6</td>
</tr>
<tr>
<td>Other</td>
<td>9%</td>
<td>9%</td>
<td>8%</td>
<td>67 (14)</td>
<td>31.5</td>
<td>12.1</td>
<td>77.6</td>
</tr>
<tr>
<td>DC cardioversion</td>
<td>7%</td>
<td>8%</td>
<td>5%</td>
<td>67 (10)</td>
<td>31.6</td>
<td>16.3</td>
<td>68.6</td>
</tr>
</tbody>
</table>

Patients can have more than one indication of anticoagulation treatment with warfarin. The mean age (SD) of men and women in the whole AuriculA population was 69 (12) and 73 (12) years, respectively. TTR was calculated in patients with treatment with warfarin \( \geq 1 \) week and target INR 2.0–3.0; \( n = 15 601 \).
Figure 2 Time in therapeutic range, 95% CI, in 49 different centres in AuriculA. Centres with <10 patients are not shown in the graph. Time in therapeutic range was calculated in patients on treatment with warfarin >1 week and target INR 2.0–3.0; mean time in therapeutic range (SD) 76.2% (20.8) \( n = 15 \, 601 \). The mean time in therapeutic range was 75.7% in hospital-based centres and 80.3% in primary care centres.

Figure 3 Box plot of time in therapeutic range of the AuriculA population divided into age categories; \( n = 15 \, 601 \), \( P < 0.001 \) for differences between age groups. The horizontal line indicates the median, the box covers the 25–75% percentiles, and the maximum length of each whisker is 1.5 times the interquartile (IQR) range. Points outside this range show up as outliers.
bleedings according to ISTH guidelines and a total of 47 arterial (81%) and 11 venous (19%) cases of thrombo-embolism. Patients with heart valve dysfunction presented the highest TTR (76.0%), and still a significant increase in thrombo-embolic events ($P = 0.03$) was seen compared with other indications of warfarin treatment (Table 2). Time in therapeutic range (SD) was generally lower in patients who had a bleeding event compared with patients who had not [69.4% (24.5) vs. 75.0% (20.2); $P = 0.09$]. In patients with thrombosis, results were similar with trends towards lower TTR (SD) when compared with patients without thrombosis [67.9% (27.3) vs. 74.9% (20.2); $P = 0.16$]. Patients with a bleeding event had a higher mean percentage of time, $>3.0$ INR (17.2 compared with 11.4%; $P = 0.001$), and we found a trend towards an increased mean percentage of time, $<2.0$ INR, in patients with thrombosis than in patients with no thrombosis (22.5 vs. 13.5%; $P = 0.08$).

Dividing complications into age categories (Figure 5) showed a significant increase in the incidence of major bleedings with increasing age ($P < 0.001$). However, there was no statistical difference in risk of bleeding ($P = 0.46$) or thrombosis ($P = 0.61$) between the sexes.

**Discussion**

In patients on anticoagulation therapy, a strong correlation has been shown between high TTR and a reduction in complications such as bleeding and thrombosis. In a meta-analysis of 47 studies on anticoagulation therapy in atrial fibrillation, randomized trials were shown to be superior to retrospective studies (TTR 64.9 vs. 56.4%; $P = 0.01$), and a high TTR correlated inversely to bleeding and thrombo-embolic complications. In clinical practice, TTR usually has been lower, due to less selection bias, compared with organized trials. Differences in TTR have also been shown between anticoagulation clinics and community practice. A meta-analysis of eight studies with a total of 14 participating centres and 22,237 warfarin-treated patients in the USA presented a mean TTR of 55%, where patients treated in anticoagulation clinics presented a mean TTR of 63% compared with 51% in

![Box plot of mean weekly dose of warfarin by 10-year age category; $n = 18,353$, $P < 0.001$ for differences between age groups. The horizontal line indicates the median, the box covers the 25–75% percentiles, and the maximum length of each whisker is 1.5 times the inter-quartile range. Points outside this range show up as outliers.](https://academic.oup.com/eurheartj/article-abstract/32/18/2282/497433/2286)
patients in community practice. In Sweden, however, these differences between anticoagulation clinics and community care were not present,\(^8\) indicating different treatment regimens between countries. This, the first report from the Swedish national quality registry for anticoagulation and atrial fibrillation, AuriculA, shows that the quality of anticoagulation treatment given in the participating centres in Sweden is high. In this paper, we report a mean TTR of 76.2% in a large, unselected clinical population. If we expand the

Table 2  Complication frequency and estimated risk per patient-year in 4273 patients from the AuriculA subgroup with 95% CI in parenthesis

<table>
<thead>
<tr>
<th>Indication</th>
<th>Total (n)</th>
<th>Mean age</th>
<th>Treatment years</th>
<th>Bleeding (n)</th>
<th>Thrombosis (n)</th>
<th>Bleeding risk/ patient-year (%)</th>
<th>Thrombosis risk/ patient-year (%)</th>
<th>Mean TTR (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whole population</td>
<td>4273</td>
<td>70</td>
<td>3377</td>
<td>87</td>
<td>58</td>
<td>2.6 (2.0–3.1)</td>
<td>1.7 (1.3–2.2)</td>
<td>74.9</td>
</tr>
<tr>
<td>no. of men</td>
<td>2425</td>
<td>69</td>
<td>1906</td>
<td>46</td>
<td>31</td>
<td>2.4 (1.7–3.1)</td>
<td>1.6 (1.1–2.2)</td>
<td>74.9</td>
</tr>
<tr>
<td>no of women</td>
<td>1848</td>
<td>73</td>
<td>1471</td>
<td>41</td>
<td>27</td>
<td>2.8 (1.9–3.6)</td>
<td>1.8 (1.1–2.5)</td>
<td>74.8</td>
</tr>
<tr>
<td>Atrial fibrillation</td>
<td>2491</td>
<td>74</td>
<td>2043</td>
<td>53</td>
<td>29</td>
<td>2.6 (1.9–3.3)</td>
<td>1.4 (0.9–1.9)</td>
<td>75.8</td>
</tr>
<tr>
<td>Heart valve dysfunction</td>
<td>597</td>
<td>67</td>
<td>519</td>
<td>12</td>
<td>14</td>
<td>2.3 (1.0–3.6)</td>
<td>2.7 (1.3–4.1)*</td>
<td>76.0</td>
</tr>
<tr>
<td>Venous thrombo-embolism</td>
<td>1146</td>
<td>66</td>
<td>802</td>
<td>21</td>
<td>14</td>
<td>2.6 (1.5–3.7)</td>
<td>1.8 (0.8–2.7)</td>
<td>72.6</td>
</tr>
<tr>
<td>Other</td>
<td>267</td>
<td>65</td>
<td>213</td>
<td>4</td>
<td>2</td>
<td>1.9 (0.0–3.7)</td>
<td>0.9 (0.0–2.2)</td>
<td>74.7</td>
</tr>
</tbody>
</table>

Patients can have more than one indication of treatment.

\(^*\)A significant increase in risk for thrombosis was seen in the group consisting of patients with heart valve dysfunctions, compared with other indications of treatment; \(P = 0.03\). Mean TTR was calculated from adjusted data (patients with target INR 2.0–3.0 with \(\geq 1\) week of warfarin therapy; \(n = 3619\). Patients with the indication of DC conversion (\(n = 95\) with four bleeding and two thrombo-embolic complications) are not listed due to too few treatment years.

Figure 5  Events per patient-year by age categories in the whole AuriculA subgroup with 87 major bleedings according to ISTH definitions and 58 thrombo-embolic events. A significant correlation between age and major bleeding (\(P < 0.001\)) is seen, but no correlation between age and thrombo-embolic events (\(P = 0.147\)).
treatment range of INR to 1.8–3.2 for the coefficient of variation of the laboratory method of INR measurement as done in SPORTIF III, the mean TTR is increased to 88.4% (data not shown). The foundation of organization of anticoagulation treatment in Sweden is built on anticoagulation centres, both in primary care and in hospital-based settings, and the number of doctors involved in dosage of warfarin outside these centres are very few in Sweden. Both large urban centres and small primary care centres from different parts of Sweden were represented in AuriculA, and although there may be differences in demographics between centres, especially between hospital-based centres and primary care centres, we believe that there is not a selection bias of patients in AuriculA. Since entire regions in Sweden enrol all their patients on anticoagulation treatment in AuriculA and all anticoagulation centres report data from every patient in that centre, we believe that the population is well representative of any other clinical population on anticoagulation treatment, at the very least in Sweden. In our study, the mean TTR in hospital-based centres was 75.7%, with respect to 80.3% TTR in primary care centres. A probable cause for this difference in TTR is that primary care centres treat a somewhat healthier population, where patients with multiple co-morbidities and medications, with subsequent difficulties of INR control are overrepresented in anticoagulation clinics. These data are consistent with earlier data from Sweden, which, quite the opposite of American studies, show that primary care centres can produce high-quality anticoagulation control.

In accordance with earlier data, one would expect complications in AuriculA to be low, and our follow-up data from two centres in AuriculA (Malmö and Sundsvall) confirm this. In a subgroup of two centres in AuriculA, we identify a low risk of major bleeding and thrombo-embolic complication in patients on warfarin treatment at 2.6 and 1.7% per treatment year. In patients with atrial fibrillation, complications were 2.6 and 1.4%, respectively. These results are in line with, or in some cases even better compared with prospective randomized clinical trials of anticoagulation treatment with warfarin. However, compared with randomized trials, the AuriculA population is representative of a clinical setting with older patients, and no exclusion criteria for treatment are present. Instead, it is up to each individual clinician to assess the risk–benefit for every single patient before referring them for anticoagulation treatment. The risk of bleeding was low for all treatment indications of warfarin, but we noticed a somewhat higher frequency of thrombo-embolic events at 2.7% per patient/year in patients with heart valve dysfunction compared with 1.7% in the whole population. However, this is only one observation in a small number of patients, and we will do a follow-up on these data in future reports of AuriculA. Even though results were not significant, there was a trend towards lower (individual) TTR in patients with events compared with those without. As anticipated, patients with bleeding complications had an increased time >3.0 INR; \( P = 0.001 \).

In accordance with previous studies, our elderly AuriculA population was expected to have more major bleedings, compared with randomized controlled trials of warfarin treatment in which patients were younger, and still the risk of major bleeding was very low. As expected, we found a correlation between age and major bleeding (Wilcoxon test; \( P < 0.001 \)), but no correlation between age and thrombo-embolic events (Wilcoxon test; \( P = 0.147 \)) was seen. Age strongly correlates with the need of a lower warfarin dose to reach therapeutic INR in our study. This could be the result of less enzymatic activity in the liver, but the increased use of concurrent medication in the elderly, for example statins, probably affects the results. Although we do not have concurrent medications listed in our study, we hope that our data could assist physicians upon initiating warfarin therapy, aiming for lower doses in the elderly patients. Our data indicate that elderly patients manage their warfarin therapy at least as well or even better than younger patients and that age itself should not affect the decision to start a patient on anticoagulation therapy, given no other contraindications are present. However, in spite of the high TTR values in the elderly, the increase in rates of major bleeding with increasing age still was significant (Figure 5).

We are aware of the limitations in our study. The prevalence of cardiovascular death and death from any causes has not been studied and this, the first report from the national quality registry AuriculA, reports only data from the year 2008 and complications from two centres. Consequently, in some cases, patient numbers and treatment years were low. For example, patients with atrial fibrillation undergoing direct current (DC) cardioversion had the lowest TTR of all indications of warfarin treatment, but numbers were too low to evaluate the frequency of complications. The low TTR, presented in Table 1, is probably due to the higher fraction of individuals recently started on warfarin in this group. Given a short duration of treatment in DC cardioversion patients, the fraction of INR values out of range during the treatment period is higher in this patient category than in patients with chronic anticoagulant treatment. We have had no possibility to investigate the CHADS2 score in patients with atrial fibrillation, and no concomitant illnesses or medications have been listed. Subsequently, no evaluations, with the exception of gender and age, of risk factors for bleeding or thrombosis have been made. Therefore, no conclusion can be drawn from these data, and even though results are interesting, future reports of AuriculA will be needed to see whether these trends are reproducible, in which we hope data on the CHADS2 score will be available.

However, as stated earlier, we believe that the AuriculA population is representative of a clinical setting, at least in Sweden, and that the TTR seen in this study reflects an organization that seems to be in good control of anticoagulation treatment with warfarin. Our data also support earlier data that TTR is an excellent prognostic marker of the quality of anticoagulation treatment given in a clinical setting. Future reports of AuriculA will however be needed to see whether the trends reported in this study are reproducible. Awaiting the upcoming era of new oral anticoagulation therapy, our data give support for the need of an improved organization of specialized anticoagulation centres and treatment regimens in centres with low levels of TTR. The question whether anticoagulation therapy with warfarin in centres with high levels of TTR will be comparable to other oral anticoagulation treatments is however still to be answered. Central registries comparing complication frequencies between different oral anticoagulation treatments in a clinical setting will be needed to give further information of any differences in clinical benefits.
Acknowledgements

The authors would like to thank Göran Pegert, Persa Ferrari, Camilla Nilsson, and Pernilla Naumann for their substantial contribution in the work of gathering data on bleeding and thrombo-embolic complications.

Funding

This study was supported by Bergers Stiftelse and funds from the Skåne University Hospital, Malmö.

Conflict of interest: none declared.

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