



Regular Article

Warfarin treatment quality is consistently high in both anticoagulation clinics and primary care setting in Sweden



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ABSTRACT

Background: Warfarin treatment in Sweden holds a high standard with time in therapeutic range (TTR) over 75%. Internationally, specialized anticoagulation clinics (ACC) have shown higher TTR compared to primary health care centres (PHCC).

Objectives: To compare warfarin treatment quality in Sweden for ACC versus PHCC, thereby clarifying whether centralization is for the better.

Patients/methods: In total 77,058 patients corresponding to 217,058 treatment years with warfarin in the Swedish national quality register Auricula from 1. Jan 2006 to 31. Dec 2011. Information regarding TTR was calculated from Auricula, while patient characteristics and complications were retrieved from the Swedish National Patient Register.

Results: Of the 100,554 treatment periods examined, 78.7% were monitored at ACC. Mean TTR for INR 2–3 for all patients irrespective of intended target range was 76.5% with an annual risk of bleeding or thrombotic events of 2.24% and 2.66%, respectively. TTR was significantly higher in PHCC compared to ACC (79.6% vs. 75.7%, $p < 0.001$), with no significant difference in overall risk of complications. Treatment periods for atrial fibrillation, except intended direct current conversion, showed similar results between ACC and PHCC without significant difference in annual risk of bleeding (2.50% vs. 2.51%) or thrombosis (3.09% vs. 3.16%). After propensity score matching there was still no significant difference in complication risk found.

Conclusions: Warfarin treatment quality is consistently high in both ACC and PHCC when monitored through Auricula in Sweden, both measured as TTR and as risk of complications. In this setting, centralized warfarin monitoring is not likely to improve the results.

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Introduction

In Sweden about 2% of the population are treated with warfarin [1, 2]. Warfarin treatment is highly efficient, preventing death or recurrent pulmonary embolism (PE) in every second PE patient [3]. The most common indication for warfarin treatment is primary or secondary prevention of ischemic stroke in patients with atrial fibrillation (AF) [1,4,5]. For patients with AF with one or more risk factors for stroke (heart failure, hypertension, diabetes, age over 75 years, prior stroke), the annual risk of a stroke is between 2 and 18%. Treatment with oral anticoagulants can reduce the risk of stroke by 2/3 [6].

At the same time, treatment with oral anticoagulants confers a significant risk of severe bleeding [6]. In recent years warfarin has topped the Medical Products Agencies list of products linked to serious side effects in Sweden [7]. This despite the fact that repeated studies have shown that the warfarin treatment quality in Swedish centres is of a very high standard [8–10].

Warfarin dosing requires an experienced staff and a well-structured organization to function optimally. The quality of the treatment can be measured either directly by the frequency of bleeding and thromboembolic events, or indirectly by measuring to what proportion of the treatment time the patients were in the planned therapeutic range, "Time in Therapeutic Range", TTR [11]. A high TTR has been shown to correlate with a low risk of bleeding or thromboembolic events [12–14], but also other factors like health care organization are likely to influence the patient's outcome.

TTR is a simple quality measurement which in computer-based dosing systems can be directly reported back to each participating centre, while the clinical outcomes like frequencies of bleeding, thromboembolic events or death are more difficult to retrieve and requires a

Abbreviations: ACC, Anticoagulation Clinics; AF, Atrial Fibrillation; DC, Direct Current; INR, International Normalised Ratio; PHCC, Primary Health Care Centers; TTR, Time in Therapeutic Range; TIA, Transient Ischemic Attack.

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Table 1

Background characteristics of patients with a hospital visit recorded in the Swedish National Patient Register prior to warfarin treatment start regardless of indication. Subdivided in those monitored at anticoagulation clinics (ACC) and primary health care centers (PHCC), respectively. Presented as number of treatment periods, n (%).

	Total n = 72267	ACC n = 56924	PHCC n = 15343
Age, years (SD)	70.5 (11.9)	69.8 (12.0)	73.4 (10.8)
Female	29721 (41.1)	23012 (40.4)	6709 (43.7)
Hypertension	35949 (49.7)	28262 (49.6)	7687 (50.1)
Cardiac failure	18996 (26.3)	15069 (26.5)	3927 (25.6)
Diabetes	11397 (15.8)	8828 (15.5)	2569 (16.7)
Myocardial infarction	10499 (14.5)	8301 (14.6)	2198 (14.3)
Renal failure	2723 (3.8)	2211 (3.9)	512 (3.3)
Chronic pulmonary disease	6018 (8.3)	4803 (8.4)	1215 (7.9)
Dementia	548 (0.8)	398 (0.7)	150 (1.0)
Alcohol abuse	1529 (2.1)	1292 (2.3)	237 (1.5)
Major bleeding	5040 (7.0)	3810 (6.7)	1230 (8.0)
Gastrointestinal bleeding	2253 (3.1)	1747 (3.1)	506 (3.3)
Intracranial bleeding	878 (1.2)	653 (1.1)	225 (1.5)
Vascular disease	17075 (23.6)	13559 (23.8)	3516 (22.9)
Stroke	10832 (15.0)	7943 (14.0)	2889 (18.8)
TIA	4696 (6.5)	3423 (6.0)	1273 (8.3)

longer follow-up. Previous studies of quality differences in warfarin treatment between anticoagulation clinics (ACC) and primary health care centers (PHCC) expressed in clinical outcome like frequencies of complications are few worldwide, but one performed in northern Sweden has shown no significant differences in bleeding frequency with 4.1 % per treatment year for ACC and 3.9 % for PHCC [8].

The aim of this study is to compare the warfarin treatment quality in ACC and PHCC in Sweden, expressed as TTR and frequency of complications, to evaluate whether the centralization of these patients is for the better.

Material and Methods

Auricula

Auricula is a Swedish national quality register for AF and oral anticoagulation, which since 2008 is funded by the Swedish Association of Local Authorities and Regions. The register started in 2006, and now includes over 110,000 patients from 224 participating centers nationwide, both ACC as well as PHCC. Approximately 50% of all patients on warfarin in Sweden are included in Auricula. Participation in Auricula is mostly within whole regions with no apparent selection bias. Over 5,000,000 INR samples are registered. Provided that the patients have not declined to participate, data from the everyday clinical practice in the anticoagulation centers is recorded and transferred to the quality register automatically once every 24 hours. Auricula also provides a clinical decision tool, aiding in the dosage of warfarin using a dosing algorithm [15]. If certain criteria are met, the algorithm can give a dose suggestion that can be accepted or manually changed. Dosing with Auricula results in higher TTR than manual dosing [16].

Swedish National Patient Register

The Swedish National Patient Register (NPR) contains information about hospital admissions as well as visits in outpatient clinics in Sweden for all patients with a Swedish personal identity number [17]. The register was launched in 1964, but complete coverage began in 1987. Currently, more than 99% of all somatic and psychiatric hospital discharges are registered in the NPR. Information in this register includes dates for admission and discharge, ICD10 codes for primary and secondary diagnoses as well as surgical procedures, age and sex category.

Methods

All patients on warfarin treatment in Auricula from 1. Jan 2006 to 31. Dec 2011 were matched with the NPR. In total 77,423 patients corresponding 217,804 treatment years within 100,952 treatment periods were retrieved. Patients with age below 18 years, or with unknown age were excluded to avoid bias; the remaining patients with altogether 100,554 treatment periods were included and followed until treatment cessation, death or end of study period at 31. Dec 2011. Treatment indication for warfarin and date of treatment cessation were collected from Auricula. Outcome was measured as TTR for INR range 2–3 irrespective of intended target range, as well as actual frequencies of major bleeding and thromboembolic events per treatment year, retrieved by using ICD10 codes from NPR (see Appendix A). Major bleeding was defined according to the International Society of Thrombosis and Haemostasis (ISTH) criteria except for Hb reduction of 20 g/l or transfusion of at least 2 units of blood of which there was no information in the NPR. Thus intracranial, gastrointestinal or other bleeds requiring in-hospital care were counted as major bleeding [18,19]. Thromboembolic events were defined as clinically verified stroke/thromboembolism/TIA, venous thromboembolism or myocardial infarction. Only the first complication of every subtype was included for each treatment period to reduce the risk of over-registering. For the same reason, only the main diagnosis from the NPR was used for cerebral haemorrhage or infarction as well as venous thromboembolism, while both primary and secondary diagnoses were used to define other bleeding complications, myocardial infarctions or baseline characteristics (Appendix A). For venous thromboembolism as well as cerebral infarction, follow up contacts soon after the index event is common and might cause double-reporting. To avoid this, a blanking period of two weeks was applied for ICD-codes identical to the index event in these patients. We excluded 21,152 patients who had not visited a hospital prior to starting warfarin from the propensity score matching, due to lack of information regarding baseline characteristics. These patients could have been managed solely in the primary care setting, thus not included in the NPR, and still have their warfarin treatment monitored at an ACC. However, if these patients should suffer a complication during their treatment like those presented here, a hospital visit and registration in NPR of that complication is mandatory.

Propensity Score Matching

To make the two groups ACC and PHCC as similar as possible with regard to comorbidities and differences in age and sex, we performed a propensity score matching based on baseline characteristics with potential influence on warfarin treatment quality as presented in Table 4. We successfully performed 2:1 nearest neighbour matching of 20,765 treatment periods in ACC with 10,498 treatment periods in PHCC.

Statistical Methods

Data were analysed using SPSS Statistics (Version 21; SPSS Inc., IBM Corporation, NY, USA), and R version 3.0.0, R Foundation for Statistical

Table 2

Indications for warfarin treatment, subdivided in those monitored at anticoagulation clinics (ACC) and primary health care centers (PHCC), respectively. Presented as number of treatment periods, n (%).

	Total n = 100554	ACC n = 79107	PHCC n = 21447
Atrial fibrillation	68758 (68.4)	52822 (66.8)	5936 (74.3)
DC conversion	12253 (12.2)	11113 (14.0)	1140 (5.3)
Heart valve disease	8700 (8.7)	7538 (9.5)	1162 (5.4)
INR 2.5–3.5	599 (0.6)	503 (0.6)	96 (0.4)
Venous thromboembolism	24448 (20.3)	16907 (21.4)	3541 (16.5)
Other indication	7332 (7.3)	5422 (6.9)	1909 (8.9)

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