Title

Characteristics of patients receiving district nursing assistance for anticoagulant therapy: a descriptive cohort study

Running head

Anticoagulant therapy: a descriptive cohort study

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Conflicts of interest

None declared.

Author contribution

Both authors contributed substantially to this paper.
ABSTRACT

Background: Changes between health sectors and contact with multiple professionals are indisputable conditions for many frail elderly patients in anticoagulant therapy. This constitutes a risk factor. We aimed to describe the characteristics of patients receiving district nursing assistance for their anticoagulant therapy in two Danish municipalities, with a specific focus on the complexity related to the number of professionals involved, number of hospital admissions, polypharmacy and co-morbidity.

Method: We performed a descriptive cohort study of patients receiving district nursing assistance for their oral anticoagulant therapy. Data were retrieved from municipal patient records and validated by district nurses.

Results: The cohort included 467 patients; 44.8% were men, 54.2% were women; their mean age was 81.1 years. Four out of five lived in their own home, the remaining lived in nursing homes or comparable facilities. During the inclusion period, 46.7% had no hospital admissions, whereas 10.1% had three or more admissions. Besides anticoagulant therapy, 96.6% of the patients received more than three medications. We found an increased mean age among mentally impaired individuals with more than three additional medications and for whom the indications for anticoagulant therapy was stated as unknown, compared to the total sample.

Conclusion: Danish patients in anticoagulant therapy who receive district nursing assistance related to the therapy are characterized by physical and mental frailty, polypharmacy, multiple readmissions, multiple sector shifts, and multiple health professionals involved in single patient pathways.
KEYWORDS: frail elderly; anticoagulant therapy; patient safety

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1. BACKGROUND

Changes between health sectors and contact with multiple health professionals are indisputable conditions for many frail elderly patients (1), including those in anticoagulant therapy with a vitamin K antagonist (VKA).

A distinctive feature of anticoagulant therapy is a narrow therapeutic range, requiring an extraordinary high level of professional monitoring and attention (2, 3). Studies have shown neither patient age (4) nor formal education to be associated with the quality of anticoagulant therapy (5), while an association between less time in therapeutic range (5) and polypharmacy¹ has been demonstrated. Domiciliary monitoring reduces time in therapeutic range, compared to monitoring by general practitioner (GP) or in hospital (6).

Hospital discharge is known to entail a risk of adverse drug events (ADEs), with polypharmacy, anticoagulant therapy and monitoring problems as the most frequent issues (7). Insufficient communication due to the low continuity of care that is associated with multiple sector shifts, in combination with the high number of professionals involved in the treatment, has been found to constitute a further risk factor for ADEs (8-11). A study of automated dose dispensing has shown that GPs and community pharmacies were notified of changes in drug dispensing in only 13.6% of cases (12).

¹ polypharmacy defined by the WHO as "the administration of many drugs at the same time or the administration of an excessive number of drugs". http://www.who.int/medicines/areas/rational_use/en/
Elderly and vulnerable patients in long-term anticoagulation therapy encounter many difficulties in relation to managing treatment with frequent blood testing and changes in dosage; often having to rely on their equally vulnerable spouses for support (13).

The complexity and lability of anticoagulant therapy and a fear of adverse advents may result in under-treatment, in particular of elderly patients (14), despite the strong association between anticoagulant therapy and reduced mortality (15) and the fact that the greatest risk of warfarin-related bleeding is dependency rather than age (4).

Both patient- and system-associated solutions may be needed to ensure medication safety (16). A stronger focus on socioeconomic factors, collaboration and patient education is recommended in anticoagulant treatment (17), as successful outcomes rely on the patient’s compliance, effective communication and knowledge of the patient’s home environment (18).

As a better understanding of the true level of complexity experienced by these patients is required, this study aimed to describe the characteristics of the most vulnerable group of patients receiving district nursing assistance to manage their anticoagulant therapy. We were particularly interested in mapping the complexity associated with the number of health care professionals involved, the number of hospital admissions, polypharmacy, and co-morbidity.

2. METHODS

We performed a descriptive cohort study of all patients receiving district nursing assistance for their oral anticoagulant therapy in two Danish municipalities (coded A.
and B) between December 2013 and December 2014. Data were collected retrospectively in December 2014, using web-based database software (SurveyXact.dk).

2.1 Sample
The patients resided in either of the two included municipalities and received district nursing assistance related to their anticoagulant therapy.

2.2 Variables
Analyses were performed on a large number of variables: age, gender, physical and mental ability (*impaired/not impaired*), indication for anticoagulant therapy, type of anticoagulant therapy, duration of anticoagulant therapy, frequency of monitoring, location of blood testing, management of anticoagulant therapy (hospital, GP clinic or hospital-based anticoagulant clinic), type of district assistance related to anticoagulant therapy, categories of health professional involved in anticoagulant therapy, additional pharmacotherapy, delivering pharmacy, and number of hospital admissions during the 12-month inclusion period. According to the type of district nursing assistance in relation to the therapy, we distinguished between the dispensation of medicine (counting or preparing prescribed medicine in dosage boxes) and its administration (providing and helping the patient taking the dispensed medicine).

We developed a database, which was pilot-tested on 20 patients (ten from each municipality). This resulted in minor adjustments with no material effect on the final analyses.
Data were retrieved from municipal patient records and, if necessary, validated by district nurses. Two municipal employees entered the data into the database; initial inter-rater disagreement was resolved during the pilot testing.

2.3 Analyses
The results are described by proportions and analysed by chi-square and Wilcoxon rank-sum testing using Stata, version 14 (StataCorp. 2015. Stata Statistical Software: Release 14. College Station, TX: StataCorp LP).

2.4 Ethical considerations
All participants signed an informed consent form with information on the aim of the study, the protection of privacy, and that participation was voluntary and withdrawal would have no consequences for their therapy. During entry, all data for each patient were coded by a unique number used for identification in the analyses, thus precluding identification by the researchers.

The study was approved by the Danish Data Protection Agency (no: 2008-58-0035). No further ethical approval was required according to Danish legislation.

3. RESULTS
Population and demographics
The cohort included 467 patients, 321 and 146 from municipality A and municipality B, respectively, corresponding to approximately 2.9 per thousand of each of the two populations.
Men numbered 214 (44.8%), women 253 (54.2%), their mean age was 81.1 years, SD 9.7 (80.1 years for men, SD 8.7 and 81.9 years for women, SD 10.5). Of the included patients, 80.1% were characterized by impaired physical ability, 35.6% by impaired mental ability. A total of 80.5% lived in their own home; the remainder lived in a nursing home or a comparable municipal facility, with only minor differences for the two municipalities. In the inclusion period, 46.7% had not been admitted to hospital, while 10.1% had had three or more admissions, see Table 1.

Table 1: Patient demographics by municipality

<table>
<thead>
<tr>
<th></th>
<th>Municipality A % (n)</th>
<th>Municipality B % (n)</th>
<th>Total % (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Men</td>
<td>45.2 (145)</td>
<td>47.2 (69)</td>
<td>45.8 (214)</td>
</tr>
<tr>
<td>Women</td>
<td>54.8 (176)</td>
<td>52.8 (77)</td>
<td>54.2 (253)</td>
</tr>
<tr>
<td><strong>Age (mean)</strong></td>
<td>80.2</td>
<td>83.0</td>
<td>81.1</td>
</tr>
<tr>
<td><strong>Impaired physical ability</strong></td>
<td>84.1 (270)</td>
<td>71.2 (104)</td>
<td>80.1 (374)</td>
</tr>
<tr>
<td><strong>Impaired mental ability</strong></td>
<td>34.2 (110)</td>
<td>38.4 (56)</td>
<td>35.6 (166)</td>
</tr>
<tr>
<td><strong>Hospital admissions</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>48.0 (154)</td>
<td>43.4 (64)</td>
<td>46.7 (218)</td>
</tr>
<tr>
<td>Once</td>
<td>20.9 (67)</td>
<td>30.8 (45)</td>
<td>24.0 (112)</td>
</tr>
<tr>
<td>2 or 3 times</td>
<td>20.3 (65)</td>
<td>10.3 (15)</td>
<td>17.1 (80)</td>
</tr>
<tr>
<td>More than 3 times</td>
<td>10.9 (35)</td>
<td>8.2 (12)</td>
<td>10.1 (47)</td>
</tr>
<tr>
<td>Unknown</td>
<td>-</td>
<td>6.9 (10)</td>
<td>2.4 (10)</td>
</tr>
</tbody>
</table>

* Within twelve months of data collection

**Polypharmacy**

Besides anticoagulant therapy, 96.6% of the included patients received more than three medications; 20.1% had between four and six additional medications, and 76.5% had
seven or more additional medications. These medications were prepacked (automated dose dispensation) for 13.3% of the included patients.

**Anticoagulant therapy**

By the time of inclusion, 77.3% of the patients had been in anticoagulant therapy for more than 12 months, 96.0% had been treated with warfarin, 4% with phenprocoumon (Marcoumar©). The patients had been prescribed anticoagulant therapy for a variety of indications, such as cerebral vascular disease, heart failure or vascular disease. In 14.6% of cases, the indication for anticoagulant therapy was stated as *unknown*; details are shown in Table 2.

<table>
<thead>
<tr>
<th>Indications</th>
<th>% (N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cerebral vascular disease</td>
<td>9.4 (44)</td>
</tr>
<tr>
<td>Heart failure</td>
<td>68.7 (321)</td>
</tr>
<tr>
<td>Peripheral vascular disease</td>
<td>6.2 (29)</td>
</tr>
<tr>
<td>Other*</td>
<td>3.4 (16)</td>
</tr>
<tr>
<td>Unknown</td>
<td>14.6 (68)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>102.3 (478)**</td>
</tr>
</tbody>
</table>

*Other indications include pulmonary embolism, colon cancer, blood disorder, and use of pacemaker

**Manging anticoagulant therapy**

Anticoagulant therapy requires frequent blood monitoring for control of the international normalized ratio (INR) and dosage adjustments (the daily number of tablets). For the studied group of frail elderly patients, management also included blood testing, medicine dispensing and administration of therapy.

The management of therapy was performed by GPs in 79.9% of the cases; whereas 2.4% and 16.1% were managed in the regional hospital or in its outpatient anticoagulant
clinic, respectively. In the remaining 1.7% of cases the sources stated either unknown (1.5%) or different hospital (0.2%).

The INR was monitored once every month for 45.4% of patients, every second week for 25.5%, and once a week for 4.3% of the included patients. The remaining 0.6% had a blood test at intervals shorter than one week; 13.3% were tested less frequently than every month. For 10.9% of the included patients, the frequency of blood testing was unknown.

For 67.2% of the included patients, the blood tests were taken at the GP’s clinic; the remaining tests were taken at either a hospital laboratory (4.5%), an anticoagulant clinic (13.7%), in the patient’s home (10.3%) or elsewhere (0.9%). The location was unknown in 3.4% of cases.

We found fairly large variation regarding the type of home care service (district nursing assistance) provided in connection with anticoagulant medication and the staffing of the service; details are shown in Table 3.
Table 3: Home care assistance in relation to anticoagulant medication

<table>
<thead>
<tr>
<th>Medication Dispensation</th>
<th>Municipality A % (N)</th>
<th>Municipality B % (N)</th>
<th>Total % (N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>District nurse¹</td>
<td>100 (321)</td>
<td>48 (70)</td>
<td>83.7 (391)</td>
</tr>
<tr>
<td>District nursing assistant²</td>
<td>52 (76)</td>
<td>16.3 (76)</td>
<td></td>
</tr>
<tr>
<td>Frequency of dispensation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Weekly</td>
<td>5.6 (18)</td>
<td>15.1 (22)</td>
<td>8.6 (40)</td>
</tr>
<tr>
<td>Every two weeks</td>
<td>91.0 (292)</td>
<td>82.2 (120)</td>
<td>88.2 (412)</td>
</tr>
<tr>
<td>Other</td>
<td>3.4 (11)</td>
<td>2.7 (4)</td>
<td>3.2 (15)</td>
</tr>
<tr>
<td>Administration of medicine</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The patient</td>
<td>65.7 (211)</td>
<td>53.4 (78)</td>
<td>61.9 (289)</td>
</tr>
<tr>
<td>Family/caregivers</td>
<td>6.5 (21)</td>
<td>0.7 (1)</td>
<td>4.8 (22)</td>
</tr>
<tr>
<td>District health worker³</td>
<td>27.4 (88)</td>
<td>6.9 (10)</td>
<td>21.0 (98)</td>
</tr>
<tr>
<td>District nursing assistant</td>
<td>0.3 (1)</td>
<td>37.0 (54)</td>
<td>11.8 (55)</td>
</tr>
<tr>
<td>District nurse</td>
<td></td>
<td>0.7 (1)</td>
<td>0.2 (1)</td>
</tr>
<tr>
<td>Social worker⁴</td>
<td></td>
<td>0.7 (1)</td>
<td>0.2 (1)</td>
</tr>
<tr>
<td>Unknown</td>
<td></td>
<td>0.7 (1)</td>
<td>0.2 (1)</td>
</tr>
</tbody>
</table>

¹ Bachelor-level training  
² Two-year training  
³ Nine-month training  
⁴ Bachelor-level training, with a social focus

Eleven pharmacies across the two municipalities were involved in supplying the anticoagulant medicine.

The district nursing tasks related to anticoagulant therapy included reminding patients of time for blood testing (9.2%), arranging blood tests (15.6%), accompanying patients to the blood test location (1.7%), receiving blood test results and awaiting prescription (72.8%), and receiving blood test results and contacting GP or hospital for prescription (22.7%). None (1.3%) or unknown (3.6%) was stated in the remaining cases.
In both municipalities, we found an increased mean age for those with impaired mental ability who had more than three additional medications and for whom the indication for anticoagulant therapy was stated as unknown, compared to the total sample, that is, 82.2 for municipality A (total: 80.2) and 85.9 for municipality B (total: 83.0). None of the 24 patients in this group (12 from each municipality) received help from nurses to administer their anticoagulant therapy, whereas in 62.5% (n=15) of the cases, nurses were responsible for dispensation.

Of those with impaired mental ability, 29.5% administered their own anticoagulant therapy; 62% had their anticoagulant therapy administered by a nursing assistant or health worker.

In the group whose indication for receiving anticoagulant therapy was unknown (n=68), 75% had been in anticoagulant therapy for more than 12 months, compared with 77.3% of all patients.

4. DISCUSSION AND CONCLUSION

4.1. Discussion

The patients in our study are characterized by old age, physical and mental frailty, polypharmacy and frequent admission to hospital. Many also depend on help in managing the anticoagulant therapy.

The cohort constitutes a considerable proportion of warfarin users in Denmark and may be considered representative of recipients of district nursing assistance in relation to anticoagulant therapy. A recent study of warfarin users above the age of 18 identified
105,751 users (3), equivalent to 2.3% of the adult population\(^2\). The substantial homogeneity of health care utilization across Denmark (19) justifies an estimation of the number of warfarin users in the two studied municipalities at 2,127 (Municipality A) and 911 (Municipality B), with 15-16%\(^3\) receiving home care in relation to their anticoagulant therapy.

The frequent monitoring, dosage adjustment, dispensing and administration involved in anticoagulant therapy for this group requires the services of multiple health professional groups at GP, hospital, pharmacy and municipal levels.

Although municipal health professionals were charged with dispensing and administration of the anticoagulant therapy, their knowledge of indications for treatment and dose adjustments and of clinical outcomes appeared to be insufficient.

The inclusion of the total patient cohort strengthens this study; however, the strength is weakened by the restricted documentation of data in the health records of the municipal home care services. As neither diagnoses nor INR results are documented, we are unable to report comorbidities and the quality of treatment expressed as time in therapeutic range. In a study under preparation, we focus on the cross-sectorial management of anticoagulant therapy.

\(^2\) The Danish population above the age of 18 was 4,479,374 (http://www.statistikbanken.dk/10021). Data retrieved July 2015.

\(^3\) 2.3% of the population in the two municipalities equals 2,127 and 911; the cohort sizes were 321 and 146.
4.1 Conclusion

Our study has shown that a considerable proportion of Danish patients taking anticoagulant medicines receive district nursing assistance in connection with the therapy. The patients are characterized by physical and mental frailty, polypharmacy, multiple hospital re-admissions and sector shifts. The individual patient pathway involves several health professional groups.

As the above constitute risk factors for adverse events (ADEs) we recommend that special attention is given to ensuring that relevant, sufficient and timely information is communicated across all sectors involved in the management of anticoagulant therapy.

Acknowledgements

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References


