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Convenience and satisfaction in direct oral anticoagulant–treated patients with atrial fibrillation

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Abstract

Background: Direct oral anticoagulants (DOACs) are the preferred anticoagulants for thromboprophylaxis in atrial fibrillation. We aimed to identify determinants of quality of life related to DOAC treatment to optimize DOAC treatment convenience and satisfaction.

Methods: We conducted a cross-sectional study in DOAC users. DOAC treatment–related convenience and satisfaction were measured by Perception of Anticoagulant Treatment Questionnaire. Higher scores are more favorable (range, 0-100). Patient-reported outcome measures and drug- and organization-related factors were collected. Multiple regression analyses were used to evaluate the association between these factors (ie, exposure variables) and DOAC treatment–related convenience and treatment satisfaction (ie, outcome variables).

Results: Of 1598 patients invited, 1035 responded, and 962 were included. The median convenience score was 98.1 (94.2-100.0), mean satisfaction score 66.5± 14.9. Twenty-four percent felt not well informed at the start of DOAC; 6.9% did not know who to turn to with questions. Multiple regression analyses showed that lacking sense of security, the predefined composite of receiving insufficient information at start of DOAC and/or not knowing who to turn to with questions was associated with lower convenience (regression coefficient, −1.29; 95% confidence interval [CI], −2.16 to −0.41). Bleeding, gastrointestinal complaints, and lower medication adherence were also associated with lower convenience. Missing sense of security (regression coefficient −6.59; 95% CI, −8.94 to −4.24) and bleeding without consultation were associated with lower treatment satisfaction.

Conclusions: Accessible interventions to improve DOAC care could be providing more instruction at treatment initiation and ensuring that patients know who to contact in case of problems.

KEYWORDS
anticoagulants, atrial fibrillation, medication adherence, patient reported outcome measures, quality of life

Essentials

- Direct oral anticoagulants (DOACs) are the preferred anticoagulants for thromboprophylaxis in atrial fibrillation.
- Underexposed factors associated with DOAC-related quality of life were evaluated.
- Treatment convenience and satisfaction with a DOAC were, respectively, high and fairly high.
- More instructions at initiation of a DOAC and contact information may improve anticoagulation care.

1 | INTRODUCTION

For individuals of European descent, the lifetime risk of developing atrial fibrillation (AF) is ≈25%.[1] AF increases the risk of thromboembolic stroke four to five times,[2] and therefore lifelong thromboprophylaxis is indicated for patients with additional risk factors (CHA$_2$DS$_2$-Vasc≥1).[3] For most patient groups, direct oral anticoagulants (DOACs) have gradually become the preferred anticoagulant drugs over vitamin K antagonists (VKAs). In the second half of 2019, DOACs were used by 307 000 patients in the Netherlands.[4]

The main advantages of DOACs over VKAs are no need of frequent laboratory monitoring and fewer food and drug interactions. This has made anticoagulant care less complicated and probably more convenient. Previous observational research confirmed that patients treated with DOACs scored significantly higher on treatment satisfaction than patients using VKAs.[5] On the other hand, some patients preferred International Normalized Ratio monitoring to no monitoring. The benefits were related to reassurance, routine feedback on the effect of the anticoagulants, and contact with the physician.[6] Without these, patients might experience insufficient medical support in case of side effects, bleeding complications, and/or a medical intervention. These uncertainties and other patient-related outcome measures that could lower convenience and satisfaction of DOAC use could compromise medication adherence. The latter is determinative for an effective and safe anticoagulant treatment.[7] Moreover, anticoagulant treatment not only aims to prolong life expectancy but also to improve quality of life by preventing ischemic complications such as cerebral vascular events.[8] Optimizing treatment satisfaction and convenience could lower treatment burden and in this way increase its benefit.

We hypothesized that factors as side effects, intake regimen, handling around interventions, and patient information at the start and during DOAC use might influence the patients' experienced anticoagulation care–related quality of life.

2 | METHODS

The data that support the findings of this study are available upon reasonable request.

2.1 | Study aims and design

The aim of our study was to identify possibly underexposed factors associated with DOAC-related quality of life. Therefore, in September 2018, we conducted a cross-sectional study in all patients with AF who were registered at Certe Thrombosis Service between January 1, 2014, and June 8, 2018. Without any selection, the patients were signed up for registration at the Thrombosis Service by the community pharmacists when they started a DOAC, according to a regional transmural protocol. The intention of this registry was to facilitate and monitor the annual kidney function check.

This study (University Medical Centre Groningen [UMCG] RR number 201899276) was assessed by the Medical Ethics Review Board of the UMCG, which concluded that a formal review process was not needed under Dutch law (WMO;METc2018/213). All participants provided written informed consent.

2.2 | Participants and methods

Patients were eligible to participate in our study when they used a DOAC for the indication AF and were included in the DOAC registry at Certe Thrombosis Service. There were no exclusion criteria. In September 2018 we sent all eligible patients an information letter and two questionnaires by mail. We asked that they return the questionnaires with a completed informed consent. After 1 month, nonresponders received a reminder.

2.3 | Study outcomes

We focused on patient-reported outcome measures. The primary outcome of our study was the anticoagulation-related quality of life, expressed in treatment convenience and satisfaction score. This was assessed using the validated Perception of Anticoagulant Treatment Questionnaire (PACT- Q)[9] (Supporting Information). The convenience score was based on questions about intake of the tablets/capsules, handling around interventions, dependence on others in connection with the anticoagulant treatment, and questions concerning limitations in daily life activities and physical complaints. The satisfaction score reflects on self-reliance and physical well-being with the anticoagulant treatment. The last item of the questionnaire concerns satisfaction in general. Higher scores indicate higher degree of convenience and satisfaction. The maximum score for both components is 100. The secondary outcome of our study was DOAC nonadherence.

To collect data on patient-, drug-, and organization-related factors, we used a questionnaire that was created within our clinically experienced team (Supporting Information). For the primary analyses we combined the answers of two questions ("Did the patient receive

sufficient information at the start of DOAC?" and "Did they know who to turn to with questions?") into a composite variable "sense of security." Sense of security was scored positive/present if both questions were answered yes. Furthermore, we collected patient-reported outcome measures from the previously mentioned questionnaire on bleeding and thrombotic events, type of DOAC, use of an antithrombotic in the past, and gastrointestinal complaints during DOAC use. We defined self-reported adherence if a patient indicated that they never forget the DOAC; all other options were classified as nonadherence. We have chosen this arbitrary cutoff point because we believe that the actual frequency of forgetting doses of medication is likely to be underreported by patients and therefore less informative.

The neighborhood socioeconomic status (SES) score was retrieved from the Netherlands Institute for Social Research. The SES score is based on income, education, and occupation of the inhabitants and expressed as a Z score with a normal distribution. A higher score represents a higher SES.

2.4 | Statistical analysis

Statistical analyses were performed with SPSS Statistics version 24 (IBM, Armonk, NY, USA). Continuous data were reported as means (standard deviation) for data with a normal distribution or medians (interquartile range) for nonnormal distributed data. The Students' independent samples t test or Mann Whitney U test was used to compare continuous variables, as appropriate. Categorical data were compared using the chi-square test.

Multiple regression analyses were used to evaluate the association between the patient-, drug-, and organization-related factors and Perception of Anticoagulant Treatment Questionnaire (PACT-Q) scores and self-reported DOAC nonadherence, respectively. The multiple linear regression model (ie, PACT-Q scores) were adjusted for sex, age, and SES.

A prespecified sensitivity analysis was performed, excluding the patients with an affirmative answer to the questionnaire item, "Have you stopped taking DOAC in the meantime?". Post hoc imputation was performed to substitute missing data. The missing items on the PACT-Q questionnaire were replaced by the mean of nonmissing items, stratified by dimension (ie, treatment satisfaction and convenience), as recommended in the PACT-Q manual.[10] Only the missing

items within a ≥50% completed dimension were replaced. Thereafter, multivariate imputation by chained equations was performed to impute the patient-, drug-, and organization-related variables. With an iteration number of 10, five imputed data sets were generated in which the pooled results were used to estimate regression parameters. The data were assumed to be missing at random, based on the intermittent pattern of the missing values. Differences between the original and imputed data set were evaluated. For all statistical analyses, P values <.05 were considered statistically significant.

3 | RESULTS

3.1 | Patient flow and characteristics

The flow of participants is outlined in Figure 1. One thousand thirty-five patients responded to our invitation (65%). From this group we had to exclude 73 patients for various reasons as shown in Figure 1. We included 962 patients.

The patient characteristics are summarized in Table 1. Fifty-seven percent were men. The mean age was 72.6 years (±9.7). The SES scores ranged from −3.71 to 2.59. Responders were comparable with nonresponders regarding sex, age, and SES (Supporting Information).

The most often used DOAC was dabigatran, the first approved DOAC in the Netherlands. Before start of a DOAC, 41.2% of the patients used VKA and/or had antiplatelet therapy (APT). Sixty-nine patients (7.3%) had discontinued their DOAC before completing the questionnaires. Eighty patients (8.4%) reported a bleeding during DOAC use. Gastrointestinal complaints were reported by 12% of the patients. Twenty-four percent of all patients felt not well informed, and 6.9% of all patients did not know who to turn to with questions. In our study population, 21.6% of all patients reported nonadherence; this was the same with naïve DOAC users (22.5%) as with patients who used VKAs and/or had APT before (20.5%) (P = .46).

3.2 | Primary Outcome

Table 2. shows which patient-, drug-, and organization-related factors were associated with convenience. The analysis was based on 796 patients because of missing values for the other patients.
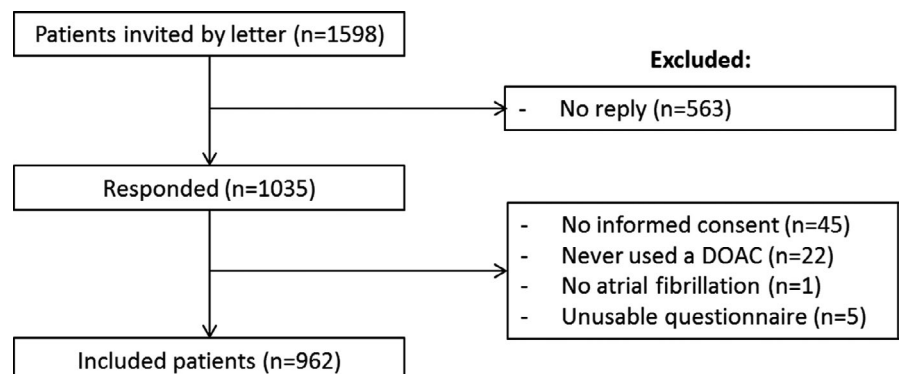
FIGURE 1 Patient flowchart. DOAC, direct oral anticoagulant

Patients invited by letter (n=1598)

Excluded:
- No reply (n=563)

Responded (n=1035)

- No informed consent (n=45)
- Never used a DOAC (n=22)
- No atrial fibrillation (n=1)
- Unusable questionnaire (n=5)

Included patients (n=962)

TABLE 1 Patient characteristics

	DOAC use (n = 962)	Data available
Male sex, n (%)	547 (56.9)	n = 962
Age, y, mean ± SD	72.6 ± 9.7	n = 962
SES,[a] median (IQR)	−0.8 (−1.5 to 0.3)	n = 953
DOAC type, n (%)		n = 962
Dabigatran	384 (39.9)	
Rivaroxaban	160 (16.6)	
Apixaban	350 (36.4)	
Edoxaban	23 (2.4)	
Multiple (serial)	36 (3.7)	
Unknown	9 (0.9)	
Antithrombotic use before DOAC, n (%)	379 (41.2)	n = 921
VKA	176 (19.1)	
APT	188 (20.4)	
VKA +APT	15 (1.6)	
Stopped DOAC, n (%)	69 (7.3)	n = 939
Bleeding during DOAC, n (%)	80 (8.4)	n = 954
Without intervention	30 (3.1)	
With evaluation by physician	35 (37)	
With hospitalization	15 (1.6)	
Thrombotic event, n (%)	21 (2.2)	n = 953
Gastrointestinal complaints, n (%)	112 (12.0)	n = 936
Sense of security present, n (%)	700 (74.5)	n = 940
Well informed	716 (76.0)	n = 942
Know who to turn to	886 (93.1)	n = 952
Forget to take DOAC never, n (%)	747 (78.4)	n = 953
Convenience, median (IQR)	98.1 (94.2-100.0)	n = 866
Satisfaction, mean ± SD	66.7 ± 15.1	n = 879

Abbreviations: APT, antiplatelet therapy; DOAC, direct oral anticoagulant; IQR, interquartile range; SD, standard deviation; SES, socioeconomic status; VKA, vitamin K antagonist.

[a]According to the Netherlands Institute for Social Research.

The differences between the included and excluded patients in the analysis are available in the Supporting Information. The median convenience score was high at 98.1 interquartile range, 94.2-100) (Table 1). If patients had a negative sense of security and/or were evaluated by a physician because of bleeding, this was associated with a significantly lower convenience score.

We saw also a lower convenience score in patients with gastrointestinal side effects and in nonadherent patients. All other factors had no significant correlation with treatment convenience. After imputation, by which 146 additional patients could be included in the analysis, the remaining number of excluded patients was only 20. The results after imputation were highly comparable with the main analysis. Only the association of previous use of a VKA and/or APT became significant but had the same point estimate (Supporting Information).

TABLE 2 Factors associated with the PACT-Q Convenience score

Factor	RC (95% CI)	P value
Convenience (constant)	96.58 (95.25 to 97.91)	
Negative sense of security	−1.29 (−2.16 to −0.41)	.004
Bleeding		
No bleeding	Reference	
Without consultation	−0.40 (−2.67 to 1.86)	.73
With evaluation by physician	−3.43 (−5.49 to −1.37)	.001
With hospitalization	−0.39 (−3.32 to 2.54)	.80
Thrombotic event	1.05 (−1.70 to 3.80)	.45
Gastrointestinal side effects	−1.92 (−3.07 to −0.76)	.001
Previous use of VKA and/or APT	−0.76 (−1.52 to 0.01)	.053
DOAC frequency		
Once daily	Reference	
Twice daily	−0.20 (−1.17 to 0.77)	.69
DOAC nonadherence	−1.42 (−2.32, −0.51)	.002
Intervention at dentist		
No intervention	Reference	
Intervention with DOAC adjustment	−1.39 (−3.06 to 0.28)	.10
Intervention without DOAC adjustment	−0.44 (−1.29 to 0.40)	0.31

Abbreviations: APT, antiplatelet therapy; CI, confidence interval; DOAC, direct oral anticoagulant; PACT-Q, Perception of Anticoagulant Treatment Questionnaire; RC, regression coefficient; VKA, vitamin K antagonist.

n = 796, R square =0.090, analysis adjusted for sex, age, and socioeconomic status.

Table 3 shows the results of the multiple regression analysis of satisfaction (806 patients included in the analysis). The characteristics of the included and excluded patients are available in the Supporting Information. The mean satisfaction score was fairly high, at 66.5 ± 14.9 (Table 1). We found a clear decrease of satisfaction with a negative sense of security. Patients who experienced a bleeding without consultation also had a significantly lower satisfaction score. After imputation, by which 131 additional patients could be included in the analysis, DOAC use twice daily had the same point estimate, but became significant. The other results were not substantially different (Supporting Information).

For both convenience and satisfaction, the sensitivity analyses, excluding the patients who stopped DOACs before completing the questionnaire, did not yield substantially different results.

3.3 | Secondary outcome

Figure 2 shows the correlation (765 patients included in the analysis) between nonadherence; convenience; satisfaction; and patient, drug-, and organization-related factors. The differences

TABLE 3 Factors associated with the PACT-Q Treatment Satisfaction score

Factor	RC (95% CI)	P value
Treatment satisfaction (constant)	67.13 (63.58 to 70.68)	
Negative sense of security	−6.59 (−8.94, −4.24)	<.001
Bleeding		
No bleeding	Reference	
Without consultation	−6.44 (−12.41 to −0.46)	.04
With evaluation by physician	−1.54 (−7.00 to 3.92)	.58
With hospitalization	−3.37 (−11.28 to 4.53)	.40
Thrombotic event	1.70 (−5.27 to 8.66)	.63
Gastrointestinal side effects	−1.98 (−5.03 to 1.07)	.20
Previous use of VKA or APT	−0.09 (−2.15 to 1.97)	.93
DOAC frequency		
Once daily	Reference	
Twice daily	2.14 (−0.45 to 4.72)	.11
DOAC nonadherence	−1.94 (−4.36 to 0.49)	.12
Intervention at dentist		
No intervention	Reference	
With DOAC adjustment	−1.64 (−6.13 to 2.86)	.48
Without DOAC adjustment	0.60 (−1.66 to 2.86)	.60

APT, antiplatelet therapy; CI, confidence interval; DOAC, direct oral anticoagulant; PACT-Q, Perception of Anticoagulant Treatment Questionnaire; RC, regression coefficient; VKA, vitamin K antagonist. n = 806, R square =0.068, analysis adjusted for, sex, age, and socioeconomic status.

between the included and excluded patients are available in the Supporting Information. Patients who knew who to turn to for questions reported to be significantly more adherent. Also, higher convenience and age >67 years were associated with adherence. A twice-daily regimen and higher SES were associated with reporting nonadherence. Patients who underwent a dental intervention without a necessary DOAC adjustment reported to be significantly more nonadherent than patients without an intervention. Men reported more often to be nonadherent than women. After imputation, by which an additional 172 patients could be included in the analysis, the results were not substantially different (Supporting Information).

4 | DISCUSSION

Most participants indicated a high convenience and a fairly high satisfaction score with their DOAC treatment. However, we found several patient-, drug-, and organization-related factors that were associated with lower scores. A negative sense of security was associated with lower treatment convenience and even stronger with lower satisfaction. Also, a bleeding with evaluation by a physician, gastrointestinal side effects, and DOAC nonadherence were associated with lower convenience. In addition, a bleeding without

consultation was associated with lower satisfaction. Although there is no consensus about a cutoff for a clinical relevant improvement or decline, it is possible to determine this on the basis of calculating absolute risk differences. By means of this calculation a decline of five or more points was set as a relevant decline, as suggested by van Miert et al.[11] When applying this method for the convenience score, no individual factors were associated with a relevant decline. However, the variables "negative sense of security" and "bleeding without consultation" were associated with a relevant lower treatment satisfaction score.

We found a number of associations between DOAC nonadherence on the one hand and convenience; satisfaction; and patient-, drug-, and organization-related factors on the other hand. Use of a DOAC with twice-daily administration was correlated to nonadherence, as was a higher SES score. In contrast, higher convenience, knowing who to turn to with questions, and age >67 years were associated with better adherence.

We used patient-reported outcome measures to focus on different aspects of anticoagulation treatment in relation to convenience, satisfaction, and nonadherence to DOAC treatment trying to find determinants of anticoagulant care–related quality of life. Patient reported outcome measures are useful tools and are increasingly being used to obtain data on patients' perceptions of their received health care.[12] The outcomes of treatment convenience and satisfaction in our study were very similar to the results of an observational study of Benzimra et al,[5] who also used the PACT-Q questionnaires. In our study, a bleeding was correlated to lower treatment convenience and satisfaction. Others have shown that bleeding impacts quality of life negatively.[13] Although the measuring methods do not quite match with our methods, it seems that especially the clinically relevant nonmajor and minor bleeds have a long-lasting impact on quality of life. The occurrence of gastrointestinal complaints in our study was similar to the findings in the ReLy study, in which the safety and efficacy of dabigatran and warfarin were compared in patients with AF.[14] These symptoms were associated with a decrease in treatment convenience, and although this is quite plausible, to our knowledge this was never published before.

After the introduction of DOACs, much concern arose about medication nonadherence. Because of the short half-lives of DOACs, nonadherence can quickly result in subtherapeutic anticoagulant levels and increase the risk of thromboembolic events.[15] The determinants associated with nonadherence in our study partly agree with the questionnaire results of Toorop et al,[16] namely, a younger age and a twice-daily dosing regimen. The correlation between knowing who to turn to with questions and nonadherence has not been investigated elsewhere.

Our study had no restrictive inclusion and exclusion criteria, so the setting can be considered as real life and therefore representative for daily clinical practice. The sample size was large, and the response rate of our questionnaires was high (65%). Responders were comparable with nonresponders regarding sex, age, and SES. Unfortunately, we are not further informed about the
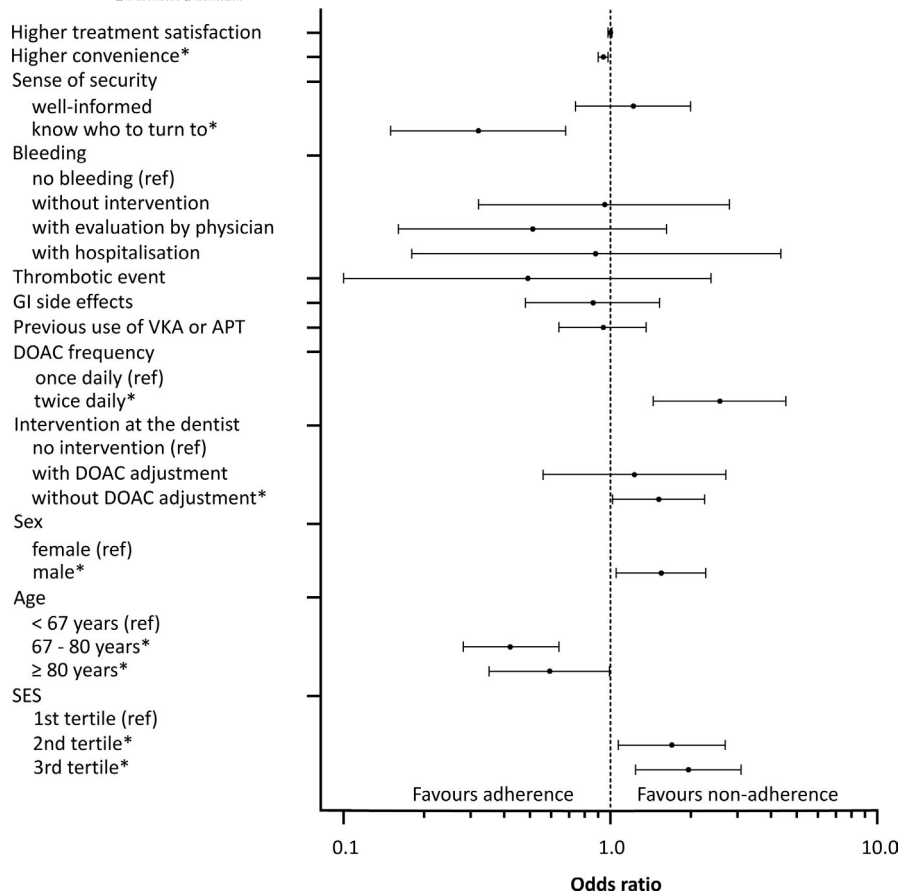
FIGURE 2 Factors associated with self-reported DOAC nonadherence. APT, antiplatelet therapy; DOAC, direct oral anticoagulant; GI, gastrointestinal; ref, reference; VKA, vitamin K antagonist

nonresponders, and it is possible that patients who had already stopped their DOAC were underrepresented in our sample. For this reason, persistence was not an outcome in our study. Because of different definitions for nonadherence in the literature our work is only partially comparable to previous studies. Moreover, we realize that self-reported adherence may be overestimated because of socially desirable answers. As validated questionnaires and definitions were lacking for variables that we were interested in, we had to use a new, as yet not validated, questionnaire.

Our study identified a number of determinants correlated to the patients' experienced quality of life related to DOAC treatment. Most of these are fixed, but others might be influenceable. The latter can help health care providers to improve the quality of anticoagulation care. An obvious solution could be providing information cards and access information, possibly in a broader educational context of a management coagulation service for all patients on DOAC therapy. Explanation of the risks of non-adherence can also receive attention in an Anticoagulation Monitoring Service.[17] Specific medication intake instructions and/or comedication can possibly relieve gastrointestinal complaints and improve convenience, but also DOAC rotation can be considered. Maybe the choice of a once-daily instead of a twice-daily medication regimen can contribute to improvement of adherence. Further research is required.

Furthermore, fixed factors are important because they can be used to focus more on certain subgroups of patients. However, we realize that the identified determinants in our analyses explain only a small part of the patients' treatment convenience and satisfaction, as the R square is relatively low.

5 | CONCLUSION

Based on our findings, several factors are associated with DOAC-related quality of life. Improving the information at treatment initiation and providing contact information that can be used in case of problems might be accessible factors for improvement of treatment convenience and satisfaction.

AUTHOR CONTRIBUTIONS

All authors were involved in the design of the study. MP-W collected the data and was responsible for data handling. TE supported the statistical analysis. AMBdV-B stimulated the community pharmacists to sign up the patients for registration. MP-W prepared the manuscript. All authors discussed the results, revised the manuscript critically, and approved submission of the manuscript.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available upon reasonable request. K. Thedinga (k.thedinga@umcg.nl) will serve as an additional point contact for data access.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

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