

SUPPLEMENTARY DATA

Text 1 of the supplementary data.

ICD-10 codes of exclusion criteria

Mitral valve disease: I05, I08, I34, and Q23.

Specific management of prosthetic valves: T82, Z95.2, Z95.3, Z95.4, and Z95.8.

Text 2 of the supplementary data.

Deviations from the protocol

The tool was implemented on December 15, 2017, and data collected between January 2018 and January 2019 were analyzed. Of the 287 potential primary care centers to be included in 2015, 325 were included in 2017 that shared the same primary care electronic medical records. In addition, of the 171 472 potential atrial fibrillation patients in 2015, only 112 887 met the criteria for confirmed atrial fibrillation and could be studied.

The following variables were studied:

1. Primary variables:

(1) Incidence of admissions and patients admitted for arterial thromboembolic events (ie, ischemic stroke, transient ischemic attack, and stroke of undetermined etiology).

Dalmau Llorca M R, et al. *Clinical value of a tool for managing oral anticoagulation in nonvalvular atrial fibrillation in primary health care. Randomized clinical trial. Rev Esp Cardiol. 2023*

(2) Incidence of admissions and patients admitted for hemorrhagic events (ie, intracranial, traumatic cranial, epidural, traumatic subarachnoid, traumatic subdural, and gastrointestinal hemorrhages and other noncranial and nondigestive hemorrhages).

(1) (2) Admissions for all of these reasons were studied.

(3) All-cause mortality rate: dates of death from any cause were collected, even if the cause could not be determined.

2. Secondary variables:

(1) Characteristics of the primary care health center: the quintiles of material and social deprivation of the urban centers were estimated with the MEDEA¹ (Mortality in small Spanish areas and Socioeconomic and Environmental Inequalities) index to classify urban centers by the level of deprivation of the sectors in which the health centers were classified. The MEDEA instrument classifies urban areas on a scale from 1 (low deprivation) to 5 (high deprivation). Rural health centers are not included in this classification but are grouped in a separate category for those serving a population of fewer than 10 000 inhabitants and a population density of less than 150 inhabitants/km².²

(2) It was not possible to obtain sociodemographic data from the professionals for reasons of confidentiality.

The other secondary variables were studied in accordance with the study protocol.³

Text 3 of the supplementary data.

Description of the final version of the CDS-NVAF

This tool uses the TTR based on the Rosendaal method⁴ and is visible in the anticoagulation module of patients using vitamin K antagonists for different diagnoses. The operation of the CDS-NVAF is based on the determinations of the INR and its registration dates, with the health care professional alerted about poor control via a pop-up window. The CDS-NVAF performs a synchronous calculation with the most recent determination of the INR and also allows asynchronous calculations of TTR with past periods. Anticoagulant changes were made according to the clinician's decision and based on local guidelines.

The researcher did not know whether the professional in the intervention group had viewed the TTR or if subsequent actions were derived from viewing the tool.

The diffusion of the CDS-NVAF was made by a notification on the first day of the intervention when the health care professional opened the electronic medical records. The professionals of the intervention group received the announcement and were provided with the CDS-NVAF. The notice was provided in the usual way used for news concerning the electronic medical records. The professionals who were part of the control group did not receive any of the above-described information.

REFERENCES

1. Domínguez-Berjón MF, Borrell C, Cano-Serral G, et al. [Constructing a deprivation index based on census data in large Spanish cities(the MEDEA project)]. *Gac Sanit.* 2008;22:179-187.
2. Caro-Mendivelso J, Elorza-Ricart J, Hermosilla E, et al. Associations between socioeconomic index and mortality in rural and urban small geographic areas of Catalonia, Spain: ecological study. *J Epidemiol Res.* 2015;2:80.
3. Dalmau Llorca MR, Gonçalves AQ, Forcadell Drago E, et al. A new clinical decision support tool for improving the adequacy of anticoagulant therapy and reducing the incidence of stroke in nonvalvular atrial fibrillation: a randomized clinical trial in primary care. *Medicine (Baltimore).* 2018;97:e9578.
4. Rosendaal FR, Cannegieter SC, van der Meer FJ, Briet E. A method to determine the optimal intensity of oral anticoagulant therapy. *Thromb Haemost.* 1993;69:236-239.

Table 1 of the supplementary data

Population analyzed after elimination of losses to follow-up.

	Control No. (%)	Intervention No. (%)	P
Total	25 005	19 231	
Sex			
Female	12 281 (49.11)	9790 (50.91)	< .001
Male	12 724 (50.89)	9441 (49.09)	< .001
Age, y	81.5 [11.33]	81.67 [11.34]	.058
Age, y			
<60	578 (2.31)	451 (2.35)	.816
60-69	2367 (9.47)	1851 (9.63)	.573
70-79	7714 (30.85)	5709 (29.69)	.008
≥80	14 346 (57.37)	11 220 (58.34)	.040
Time of atrial fibrillation diagnosis	6.05 [6.79]	5.89 [6.99]	.289
Time in therapeutic range	68.79 [29.57]	68.15 [29.35]	.008
Cardiovascular history			
Peripheral artery disease	1680 (6.72)	1410 (7.33)	.012
Ischemic heart disease	4608 (18.43)	3640 (18.93)	.181
Aortic atheromatosis	248 (0.99)	180 (0.94)	.552
Previous cerebrovascular event			
Ischemic stroke	4214 (16.85)	3096 (16.10)	.034
Stroke of undetermined etiology	426 (1.70)	293 (1.52)	.138
Intracranial hemorrhage	220 (0.88)	187 (0.97)	.312
Morbidity			
Diabetes mellitus	8311 (33.24)	6259 (32.55)	.125
Hypertension	20 005 (80.00)	15 512 (80.66)	.085
Heart failure	3352 (13.41)	3129 (16.27)	< .001
Kidney failure	7625 (30.49)	6027 (31.34)	.056
History of bleeding risk			
Alcohol	521 (2.08)	361 (1.88)	.124
Portal hypertension	43 (0.17)	29 (0.15)	.584
Liver failure	129 (0.52)	117 (0.61)	.195
Hemorrhages other than digestive and intracranial	6293 (25.17)	4749 (24.69)	.255
Digestive hemorrhage			
Digestive hemorrhage	2084 (8.33)	1522 (7.91)	.109
CHA₂DS₂-VASc index			
0	219 (0.88)	187 (0.97)	.291
1	1147 (4.59)	851 (4.43)	.416
2	4075 (16.30)	3030 (15.76)	.125
3	8755 (35.01)	6625 (34.45)	.217
≥4	10 809 (43.23)	8538 (44.40)	.014
HAS-BLED index			

0	245 (0.98)	195 (1.01)	.719
1	3768 (15.07)	2856 (14.85)	.524
2	8350 (33.39)	6310 (32.81)	.198
3	7667 (30.66)	5875 (30.55)	.800
≥4	4975 (19.90)	3995 (20.77)	.023
Patients attended outside of primary care center			
Home care	2846 (11.38)	2082 (10.83)	.066
Institutionalized	1375 (5.50)	1058 (5.50)	.990
Location of primary health center by urban MEDEA and rurality categories			
MEDEA 1 ^a	2726 (10.90)	2823 (14.68)	< .001
MEDEA 2 ^a	3256 (13.02)	3018 (15.69)	< .001
MEDEA 3 ^a	3823 (15.29)	2807 (14.60)	.043
MEDEA 4 ^a	4056 (16.22)	2716 (14.12)	< .001
MEDEA 5 ^a	3217 (12.87)	2769 (14.40)	< .001
Rural ^b	6238 (24.95)	3929 (20.43)	< .001
Lost	1689 (6.75)	1169 (6.08)	.004

CHA₂DS₂-VAsC, thromboembolic risk score; HAS-BLED, hemorrhagic risk scale; IQR, interquartile range; *P*, significance of Z test of proportions.

Values are expressed as No. (%) or median [IQR].

^a MEDEA is an index of material and social deprivation (1, low deprivation; 5, high deprivation) for the location of urban primary care centers attended by patients.

^b Rural refers to primary health care centers serving rural populations.

Table 2 of the supplementary data

Follow-up results during the intervention

	Control No. (%)	Intervention No. (%)	P	Effect size (95%CI)^a	Probability of superiority^b
Total	25 005	19 231			
TTR in the second semester of 2018	65.62 [29.7]	64.74 [30.02]	.020	0.067	0.340
Number of determinations of INR in 2018	16 [5]	17 [5]	.599	0.049	0.483
Controlled patients (TTR ≥ 65%)	10 778 (43.1)	7825 (40.69)	< .001	0.049 (0.047-0.051)	
Controlled patients (TTR > 70%)	8871 (35.48)	6479 (33.69)	< .001	0.038 (0.036-0.039)	
Switch to DOAC during 2018	1713 (6.85)	1825 (9.49)	< .001	-0.097 (-0.095 to 0.098)	

DOAC, direct-acting oral anticoagulant; CI, confidence interval; INR, International Normalized Ratio; IQR, interquartile range; TTR, time in therapeutic range

P: nonparametric Mann-Whitney U test and Z test were used to detect statistically significant differences between the 2 groups for continuous and categorical variables, respectively.

^a The g of Hedges was used to quantify the difference in categorical variables between groups and the size of the nonparametric effect.

^b The probability of superiority was used for continuous variables.

Values are expressed as No. (%) or median [IQR].



CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	1 and 2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	2
	2b	Specific objectives or hypotheses	3
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	3 and 4
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	4 and in additional material
Participants	4a	Eligibility criteria for participants	4
	4b	Settings and locations where the data were collected	4 and in additional material
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	4 and in additional material
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	4 and in additional material
	6b	Any changes to trial outcomes after the trial commenced, with reasons	In additional material
Sample size	7a	How sample size was determined	5
	7b	When applicable,	

		explanation of any interim analyses and stopping guidelines	
Randomisation: Sequence generation	8a	Method used to generate the random allocation sequence	4
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	4
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	4
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	4
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	4
	11b	If relevant, description of the similarity of interventions	In additional material
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	5
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	5
Results Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Figure 2, page 5
	13b	For each group, losses and exclusions after randomisation, together	Figure 2, page 5

		with reasons	
Recruitment	14a	Dates defining the periods of recruitment and follow-up	4
	14b	Why the trial ended or was stopped	
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Supplementary Text 2
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Tables 2 and 3
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Table 2
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	Figure 3
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	5
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	9 and 10
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	9
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	9

Other information

Registration	23	Registration number and name of trial registry	2
Protocol	24	Where the full trial protocol can be accessed, if available	page 2, doi: 10.1097/MD.00000000000009578. In additional material
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	1

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.