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Influence of decision-aids on oral anticoagulant prescribing among physicians: a randomized trial

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ABSTRACT

Background: Oral anticoagulants (OAC) are underused in treatment of atrial fibrillation (AF), with differences in patient and physician preferences. For risk communication, the graphic showing risks on treatment contains all the information, therefore the graphic showing risks without treatment may not be necessary. Here, our objective was to assess whether decision aids require information of risks without treatment and specifically whether presentation of 5-year stroke risk in patients with AF increases use of OACs compared with presentation of 1-year risk and whether decisions on treatment are different when physicians decide their own treatment versus that of the patient.

Design: Randomized controlled trial with 2^3 factorial design, performed at 12 university hospitals, one internal medicine course, and one national medical conference.

Results: Of 968 physicians who participated, 83.3% prescribed anticoagulation therapy. Treatment decisions were not influenced by the number of graphics or by the time frame of risk estimation, with risk differences of 0.5% (95% confidence interval, -4.0% to 5.4%) and 3.4% (-1.3% to 8.1%). However, physician-to-patient prescription rates were 5.4% (0.2%-10.6%) more frequent after seeing the 5-year risk graphic. Physician-to-self intentions to prescribe occurred less frequently, with risk difference of 15.4% (10.8%-20%).

Conclusions: Risks could be communicated using decision aids with only one graphic. Showing the risk of stroke at 5 years could increase the prescription of OACs to patients with

AF. Faced with the same risk of stroke, physicians prescribed less to themselves than to patients.

Clinical Trial registration ClinicalTrials.gov**:** NCT02746107.

Key words: anticoagulants, stroke, atrial fibrillation, shared decision making, factorial randomized trial

INTRODUCTION

Decision aids for any disease contain different graphic representations of the risks, with many having 2 informative representations: one showing the risk without treatment and the other showing the risk with treatment. Also included are numbers of patients saved by the treatment (absolute risk reduction, ARR) (Appendix 1). However, the latter graphic always contains all of the needed information, including risks without treatment; therefore, the first graphic may be redundant. After a search of Medline and Google Academic (https://scholar.google.com/) and asking experts in the field on the Shared Decision Making Network page on Facebook (https://www.facebook.com/groups/SharedDecisionMaking/), we did not find any study investigating the necessity of the graphic showing what happens without treatment.

Decision aids for antithrombotic prophylaxis in atrial fibrillation (AF) contain data and graphics communicating the risk of stroke and are based on the CHA_2DS_2-VASc score,[1] the currently recommended tool for assessment of stroke risk in AF, validated over a 1-year period.[2] Although patients at high risk are advised to seek long-term treatment, usually life-long therapy, seeing only the 1-year risk results may make patients underestimate both the long-term risks of stroke and the benefits of oral anticoagulant (OAC) treatment. These assumptions could be a cause of general antithrombotic treatment underuse.[3,4]

Preferences and motivations about OAC treatment in AF seem to differ between patients and physicians, with use of OACs even having opposing views.[5,6] In addition, studies on therapeutic decisions of physicians to self are scarce. Here, our study had 3 objectives. First, we aimed to investigate whether decision aids with only 1 graphic (only showing what happens with treatment) would provide enough information for patients and therefore show that a two-graphic representation (showing both risks with and without treatment) may not be necessary. Our second aim was to investigate whether presentation of stroke risk over a

longer period (5 years) (Appendix 2) would increase the rate of prescribing/taking OACs compared with presentation over 1 year. Finally, we aimed to investigate whether physician decisions concerning OAC therapy would be different if applied to self. To test our aims, we conducted a randomized controlled trial.

METHODS

Trial Design Overview

Between March and June 2016, we conducted a factorial (2^3) randomized controlled trial involving prospective inclusion of physicians who prescribe treatment for AF.

The randomization was made by number of graphic representations (2 vs 1), risk estimation period (1 vs 5 years), and the target of prescription (physician to virtual patient vs physician to self). The participants were also randomized on the risk score (1 to 5, with 5 possibilities). To ensure an equal distribution of all of these factors, the randomization was made on blocks of 40 decision aids and questionnaires (each decision aid had its own questionnaire).

Setting and Participants

Eligible participants were physicians participating in the National Congress of Internal Medicine (April 2016), an internal medicine course, or who worked in medical departments of university hospitals in Romania.

The inclusion criteria were physicians who prescribe OAC treatment (including cardiologists, internal medicine specialists, general practitioners, and hematologists) or those who deal with patients with stroke (neurologists) or bleeding (gastroenterologists). Exclusion criteria were physicians who never prescribe anticoagulant treatments or do not treat patients with stroke or bleeding secondary to OAC and therefore are not professionally interested in OAC treatment.

Interventions

The National Institute for Health and Care Excellence (NICE) graphics for decision aids concerning OAC in AF were used as support for our trial.[7] This decision aid uses data from the Swedish Atrial Fibrillation cohort study to estimate incidence rates for thromboembolic events.[8] Because few individuals in this cohort had a CHA_2DS_2-VASc score of 0 or greater than 5, the data were limited and the degree of uncertainty high; therefore, only the effects of the anticoagulant treatment on people with scores between 1 and 5 were illustrated in the NICE decision aid.[9] Of the 2 kinds of visual aids for graphic presentations (bars or Cates plot), we chose the latter. The numeric explanations, translated to Romanian, were given in a text box similarly to the original NICE decision aid (Appendix 1).[7]

The graphs used in this trial did not contain the CHA_2DS_2-VASc score value because we wanted the physicians to take the decision influenced by the perceived risk and treatment effect and not by the current guidelines. In addition, the visual aid showing risks over 5 years represented an estimation, that is, the 5× multiplication of the available data over 1 year.

Each participant received one of the decision aid options (2^2 factorial with comparison on a spectrum of risks from 1 to 5, with therefore 20 variants). Physicians were queried on whether they would prescribe or take OAC treatment for AF. Other information on the questionnaire were related to personal data (age and sex), history of stroke among people close to them (relatives or friends), and also professional information (time from graduation, medical/teaching grade, working in hospital or ambulatory setting, presence of a medical university in the city of residence, and the medical specialty).

Randomization regarding the target of OAC treatment was made by the questionnaires, with one-half asking physicians to decide treatment for a patient having the risk of stroke from the diagram and one-half asking physicians to imagine that they had the risk of stroke from the diagram and to decide what treatment to prescribe to self. After

receiving the explanation and seeing the diagram, physicians were asked to complete the questionnaires in about 5 minutes.

In our simulation study, there was no reference to the risk of bleeding (e.g. HAS-BLED score); therefore, treatment decisions of participating physicians had to take into account only the risk of stroke.

Outcome Measures

The measured outcome was the decision to prescribe/take OAC based on the mentioned graphics. The independent variables were the number of graphics used, the period for which the risk was estimated and communicated, and the risk of stroke (CHA_2DS_2-VASc score from 1 to 5, not explicitly named) presented on the risk graphic, as well as demographic information obtained from the questionnaire, including sex, age, academic degree, professional degree, time from graduation, speciality, place of work (hospital or ambulatory setting and whether in a city with medical university), and history of stroke among relatives or friends. The target of the prescription (patient or physician himself) was marked on the questionnaire.

Sample Size

We calculated a sample size of 948 participants for a two-sided α-error of 0.05, with 80% statistical power able to detect at least 5% difference between decisions (from 95%, our estimation of OAC prescription, to 90%). Therefore, we considered ±5% as equivalence.

Randomization

The randomization was performed on blocks of 40 to ensure an equal allocation in every group on the 4 variables; therefore, the allocation was 1:1 concerning the number of graphics, risk estimation period, and prescription target and 1:1:1:1:1 concerning the allocation on the 5 risk score groups.

The 40 different risk diagrams from each block together with the corresponding questionnaires were randomly ordered and consecutively given to physician participants at staff meetings, courses, and congress. We used a standard spread of the diagrams for all distribution locations, and we did not know in advance how the physicians would be spatially arranged. Moreover, most of the participants were unknown to us.

Statistical Analyses

Results were summarized as median and range for nonnormally distributed scales or ordinal variables or as numbers and percents for categorical variables. We looked for differences concerning the independent variables by outcome (decision to treat) in bivariate analysis (Mann-Whitney *U* test or chi-squared test, depending on variables), and we calculated risk differences with 95% confidence intervals. A logistic regression model with "decision to treat" as a dependent variable was computed, and all independent variables were introduced in a stepwise manner. The model with the independent variables retained by both the forward and the backward stepwise method was kept. A two-sided *P* value of $< .05$ was noted as statistically significant. Data analyses were performed with statistical software (Stata 11 from StataCorp LP, College Station, TX, USA, and SPSS version 20.0 from IBM Corporation, Armonk, NY, USA).

Ethics

Ethical approval was obtained from the Hospital Ethics Committee (No. 50/2016).

RESULTS

Our study started on 2 March 2016 and finished on 10 June 2016. Participants included 968 physicians: 77 participating in a course on internal medicine in a city from the north of the country, 312 participating in the National Congress of Internal Medicine, and 579 participating in staff meetings in 11 university hospitals from Bucharest and one city from the

center of the country. Figure 1 shows trial enrollment. Overall, participants' median age was 39 years and 72.9% were women.

The assignment of participants on the number of graphics, time frame of risk estimation, target of prescription, and CHA_2DS_2-VASc score, as a result of randomization, are shown in Table 1. Of 968 physicians questioned, 806 (83.3%) decided to prescribe OAC and 341 (35.4%) declared having someone close with stroke history. Most participants worked in hospitals (79.5%) and in cities with a medical university (80.6%). The representation of residents, specialists, and senior physicians was well-balanced in our sample. The internal medicine specialists were the most numerous (30.6%), followed by cardiologists (21.2%), general practitioners (12.1%), and neurologists (8.8%); 27.4% were of other specialities (Table 1).

Physicians prescribed 15.4% less (ARR) to themselves than to the patients. There was no significant difference concerning the prescription rate between decision aids having one or two graphics, with ARR of 0.5% (95% confidence interval, -4.0% to 5.4%). Similarly, the stroke risk estimation over 5 years versus 1 year did not appear to influence the treatment decision, with ARR of 3.4% (95% confidence interval, -1.3% to 8.1%). However, when analyzed by target of recommendation (physician to patient versus physician to self), the decision aid with 5-year risk presentation versus 1-year risk presentation determined a significant absolute increase of intent to prescribe of 5.4% for patients, whereas it did not influence the intent to prescribe for physicians themselves (this subgroup analysis was not prespecified). This interaction between the period of risk estimation and the target of prescription revealed by the stratified analysis (Table 1) was confirmed in the multivariable analysis (Table 3).

Diagrams that showed patients with a higher CHA_2DS_2-VASc risk score or ARR resulted in significantly more indications for prescriptions (Table 2). Higher CHA_2DS_2-VASc

risk score/ARR increased the probability of OAC prescription (chi-squared test for trend showed $P = .002$ and $P = .005$, respectively). Again, this trend was observed only for the prescription decisions for patients (chi-squared test for trend showed $P = .006$ and $P = .002$ for CHA_2DS_2-VASc risk score and ARR), whereas this trend was not found when the prescription was made for physicians themselves ($P = .058$ and $P = .109$, respectively) (Appendix 3).

Physicians with practices in academic cities prescribed more. The specialists in internal medicine and those of other specialities prescribed significantly less than cardiologists, whereas neurologists and general practitioners did not. There was no difference between physicians who prescribed OACs and remaining physicians concerning sex, age, or time from graduation. No differences in prescription rates were noted when analyzing different professional or academic degrees ($P = .148$) or between those practicing in hospitals or in outpatient settings. History of stroke among relatives or friends did not influence treatment decisions (Tables 1 and 2).

In our multivariable analyses, independent predictors of decisions to prescribe were the target of prescription (physicians prescribed 3 times less to themselves than to patients), the presence of a medical academic center, and the CHA_2DS_2-VASc risk score (physicians prescribed 2 times more frequently to patients with scores between 2 and 5 than to those with a score of 1) (Table 3). When introduced into the logistic regression model, the ARR excluded the CHA_2DS_2-VASc risk score (the prescription odds increased with 4% for every 1% of ARR) (Table 4).

DISCUSSION

Here, we showed that one visual graphic alone, the one presenting the risk with treatment, could be enough as a decision aid because it contains all of the necessary information. To our knowledge, this is the first study that investigated the hypothesis of whether having both

graphics, showing risks with and risks without therapy, affected treatment decisions. OAC treatment for the prevention of stroke in patients with nonvalvular AF was ideal for testing this hypothesis because this situation had multiple levels of risk (5 levels on the NICE decision aid).[7] However, our study included only physicians; therefore, we cannot be sure that these results could be extrapolated to individuals without higher medical or general education (for example, patients without university degrees). Although prescription rates were lower than estimated when the sample size was calculated, the upper limit of the 95% confidence interval exceeded the predefined margin of equivalence of ±5% by very little (5.4%), whereas the lower limit was not exceeded (-4%).

Our second study objective, to determine whether presenting risk of stroke over a time frame of 5 years instead of 1 year would increase prescription of OAC, was not confirmed in our study. This is surprising because the risk of stroke and the ARR determined by the OAC therapy were 5 times higher when calculated for 5 years, and, at a glance, the difference looked impressive (Appendix 2). We believe this happened for 2 reasons. First, the sample size was calculated estimating a prescription rate of 90%, and the actual prescription rate was 83% (91% for physician to patient and only 75.5% for physician to self); therefore, there was a loss of statistical power. This was reflected in the width of the confidence interval: the prescription rate could be even 8.1% higher in physicians exposed to the graphic showing 5-year risk than in those exposed to the graphic with 1-year risk. Second, the post hoc stratified analysis showed that physicians were influenced by the longer time frame only when they prescribed to patients (Table 1), and they did not consider this presented risk when the target of prescription was to self. This observation was confirmed by the fact that prescriptions significantly increased with the CHA_2DS_2-VASc score and ARR only when the physicians prescribed to the patients and not when they prescribed to themselves.

Previous studies have shown that doctors hesitate to prescribe OACs because they overestimate the risk of bleeding.[10,11] There is considerable variation regarding perceptions of stroke and bleeding risk because of uncertainties and fears of not having enough knowledge.[12] Moreover, physicians feel responsible for patient outcomes concerning stroke or bleeding with OACs, with this feeling of responsibility occurring more frequently in general practitioners than in hospital physicians due to their long-term relations with patients and their families.[5] This is the first randomized controlled trial showing that, in similar conditions, physicians are less eager to take OACs than to prescribe it to their patients. The absolute difference was important (15.4%), and, although no risk of bleeding was presented, the physicians probably had it in mind. As mentioned above, when physicians had to decide to prescribe antithrombotic therapy to themselves, they did not take into account the risk of stroke anymore. This is not the first study to show that physicians recommend different treatments for patients than they would choose for themselves, namely, to treat themselves less.[13]

There are other limitations of our study besides those mentioned above. This was a simulation study; participants did not have AF, and their decision could have been different in cases of real AF. The risk over a 5-year period, obtained by multiplication of the 1-year risk, was not validated; however, all risk scores are only estimations. In fact, the real risk over 5 years may even be larger because, as time passes, the yearly risk (CHA_2DS_2-VASc score) increases.

In conclusion, in our study, the physicians' decision regarding OAC treatment was not influenced by the number of risk graphs; the presentation of the risk over a 5-year time frame increased the intent to prescribe only when the target of the medication was the patient; when the therapy target was to self, physicians were less eager to prescribe antithrombotic treatment for AF, and their decision did not appear to be influenced by the risk of stroke.

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Competing interests

Cristian Baicus, Caterina Delcea, Alina Dima, Emilia Oprisan, and Ciprian Jurcut have no competing interests. Gheorghe Andrei Dan received speaker fees from Boehringer Ingelheim, Bayer, Pfeizer, and consultant fees from Boehringer Ingelheim.

Contributions

Cristian Baicus = study idea, study design, acquisition of data, data analysis, data interpretation, manuscript writing; Caterina Delcea = acquisition of data, data analysis, revision of manuscript; Alina Dima = acquisition of data, manuscript writing; Emilia Oprisan = data interpretation, manuscript revision; Ciprian Jurcut = acquisition of data, manuscript revision; Gheorghe Andrei Dan = data interpretation, manuscript revision. All authors finally approved the manuscript. Cristian Baicus is the guarantor of the study.

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Table 1. Participants' Characteristics: Categorical Variables

Variable		Number (%)			*P*
		All Participants (N = 968)	**Participants With Intent to Prescribe OACs(n = 806; 83.3%)**	**Risk Difference (95% confidence interval)**	
Sex					
Men		262 (27.1)	216 (82.4)	0	
Women		704 (72.9)	589 (83.7)	1.2% (-3.8% to 6.9%)	.72
Somenone close with stroke					
Yes		341 (35.4)	294 (86.2)	4.7% (-0.3% to 9.3%)	.07
No		622 (64.6)	507 (81.5)	0	
Number of figures on decision aid					
2		486 (50.2)	406 (83.5)	0.5% (-4.0% to 5.4%)	.82
1		482 (49.8)	400 (83.0)	0	
Period of risk estimation					
1 year		483 (49.9)	394 (81.6)	0	
5 years		485 (50.1)	412 (84.9)	3.4% (-1.3% to 8.1%)	.18
Target = patient	1 year	248 (51)	219 (88.3)	0	
	5 years	238 (49)	223 (93.7)	5.4% (0.2%-10.6%)	.03
Target = physician	1 year	235 (48.8)	175 (74.5)	0	
	5 years	247 (51.2)	189 (76.5)	2.1% (-5.6% to 9.7%)	.60
Target of treatment					
Patient		486 (50.2)	442 (90.9)	15.4% (10.8%-20%)	< .001
Self (physician)		482 (49.8)	364 (75.5)	0	

Place of work				
Hospital	765 (79.5)	642 (83.9)	3.2% (-2.4% to 9.8%)	.33
Ambulatory	197 (20.5)	159 (80.7)	0	
City				
With university of medicine	780 (80.6)	662 (84.9)	8.3% (2.2%-15.2%)	.009
Other	188 (19.4)	144 (76.6)	0	
Medical degree				.19*
Resident	332 (34.4)	279 (84.0)		
Specialist	199 (20.6)	167 (83.9)		
Senior physician	435 (45.0)	358 (82.4)		
CHA_2DS_2-VASC score				
1 point	195 (20.1)	146 (74.9)	0	
2 points	189 (19.5)	159 (84.1)	9.3% (1.2%-17%)	.03
3 points	195 (20.1)	164 (84.1)	9.2% (1.2%-17%)	.03
4 points	197 (20.4)	172 (87.3)	12.4% (4.7%-20.1%)	.003
5 points	192 (19.8)	165 (85.9)	11.1% (3.2%-18.8%)	.009
Medical specialty				
Cardiology	205 (21.2)	182 (88.8)	0	
Internal medicine	296 (30.6)	241 (81.4)	-7.4% (-13.4% to -0.9%)	.03
General practitioner	117 (12.1)	96 (82.1)	-6.7% (-15.5% to 1%)	.13
Neurology	85 (8.8)	73 (85.9)	-2.9% (-12.6% to 4.8%)	.62
Other	265 (27.4)	214 (80.4)	-8% (-14.3% to -1.4%)	.02

OAC, oral anticoagulation

*Analyzed as ordinal variable (Mann-Whitney *U* test)

Table 2. Participants Characteristics: Scale or Ordinal Variables

Variable	All Participants	Participants With Intent to Prescribe OACs	No OAC Treatment	*P*
Median age (range)	39 y (25-83 y)	39 y (25-78 y)	42 y (25-83 y)	.23
Median graduation year (range)	2001 (1958-2015)	2001 (1961-2015)	1999 (1958-2015)	.59
Median CHA_2DS_2-VASC score (range)	3 (1, 5)	3 (1, 5)	3 (1-5)	.003
Median absolute risk reduction (range)	5.7% (0.4%-28.5%)	5.7% (0.4%-28.5%)	2.5% (0.4%-28.5%)	< .001

OAC, oral anticoagulation

Table 3. Predictors of anticoagulant prescription: CHA_2DS_2-VASC logistic regression model*

Variable	**Odds Ratio**	**95% Confidence interval**	***P***
City (university/not)	1.78	1.18-2.68	.006
Target of prescription (physcian to patient/physician to self)	2.38	1.52-3.71	< .001
CHA_2DS_2-VASC score			.007
CHA_2DS_2-VASC 2/1	1.87	1.10-3.15	.019
CHA_2DS_2-VASC 3/1	1.81	1.07-3.04	.026
CHA_2DS_2-VASC 4/1	2.4	1.39-4.14	.002
CHA_2DS_2-VASC 5/1	2.27	1.32-3.88	.003
Interaction (period of risk estimation x target of precription)	2.13	1.10-4.11	.024

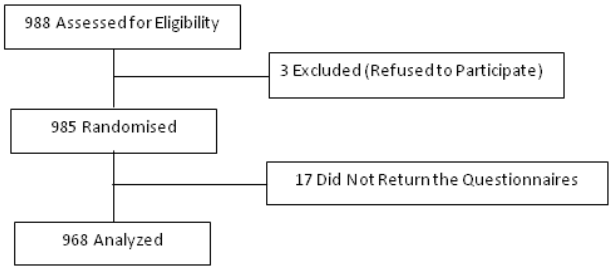
* Adjusted for age, sex, medical and academic degrees, someone close with stroke, speciality, period of risk estimation, and number of visual aids

Table 4. Predictors of anticoagulant prescription: ARR logistic regression model*

Variable	***P***	**Odds Ratio**	**95% Confidence Interval**
City (university/not)	.004	1.81	1.20-2.71
Target of prescription (physician to patient/physician to self)	< .001	3.32	2.28-4.83
ARR (%)	.001	1.04	1.01-1.06

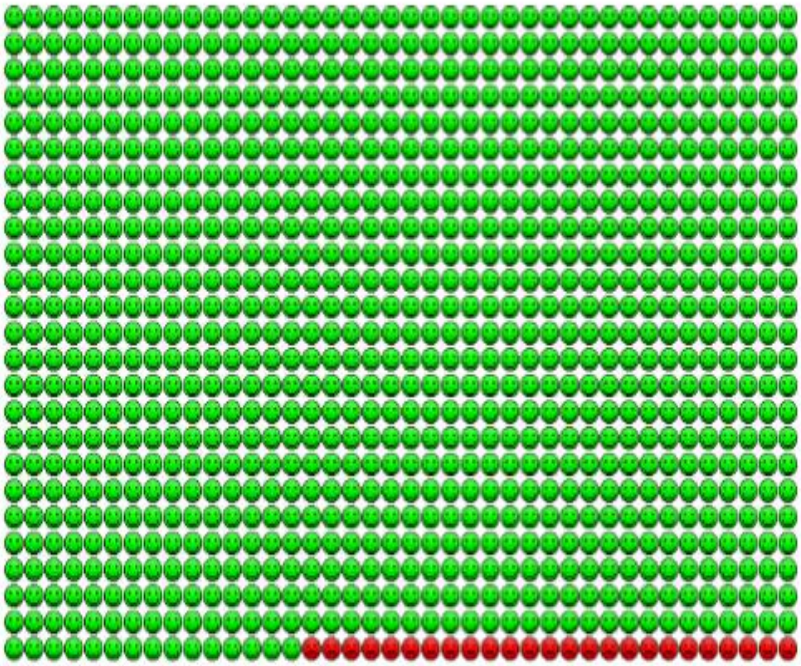
ARR, absolute risk reduction

* Adjusted for age, sex, medical, academic degrees, someone close with stroke, speciality, period of risk estimation, number of figures, and CHA_2DS_2-VASC score


988 Assessed for Eligibility
3 Excluded (Refused to Participate)
985 Randomised
17 Did Not Return the Questionnaires
968 Analyzed

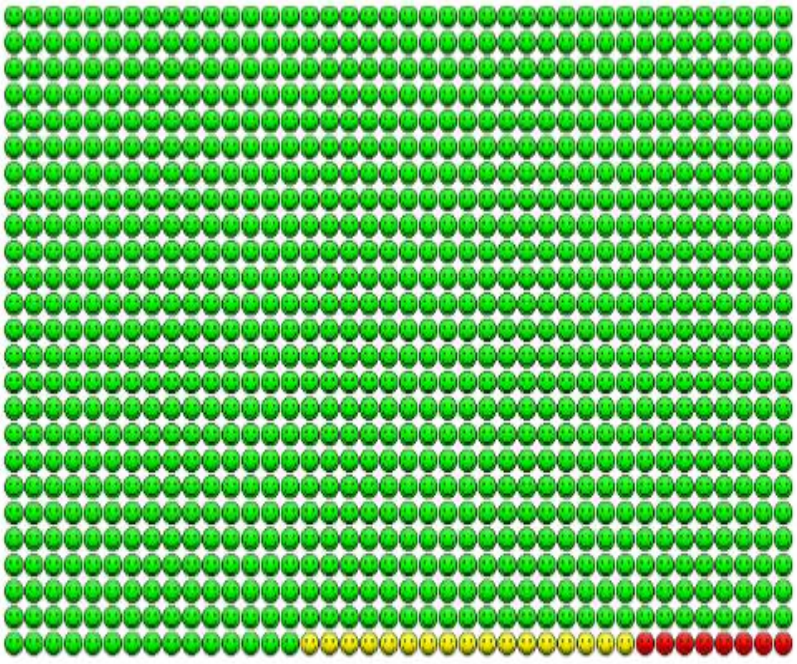
Appendix 1

Graphics used for the questionnaire 212



If 1000 people with AF and a CHA_2DS_2-VASc score of 2 take no anticoagulant, over 1 year on average:

- 975 people will not have an AF-related stroke (the green faces)
- 25 people will have an AF-related stroke (the red faces).

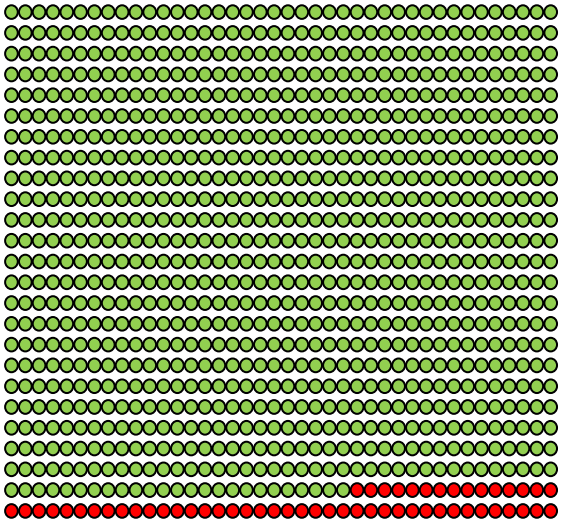


If all 1000 people take an anticoagulant, over 1 year on average:

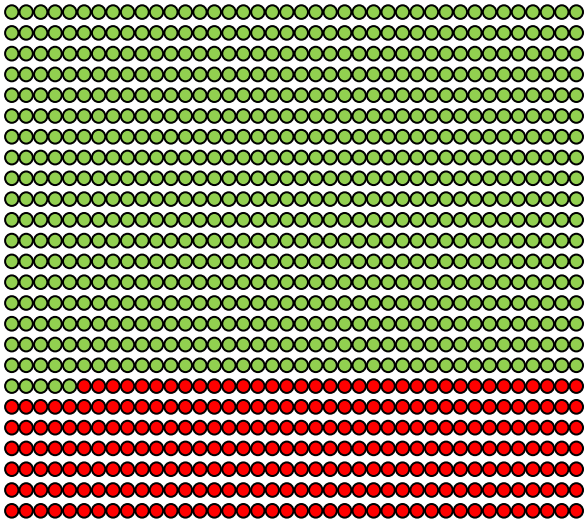
- 975 people will not have an AF-related stroke (the green faces), but would not have done anyway
- 17 people will be saved from having an AF-related stroke (the yellow faces)
- 8 people will still have an AF-related stroke (the red faces).

Appendix 2. Comparison between risk presentation on one year (left) and five years (right)*

1 year, WITHOUT treatment

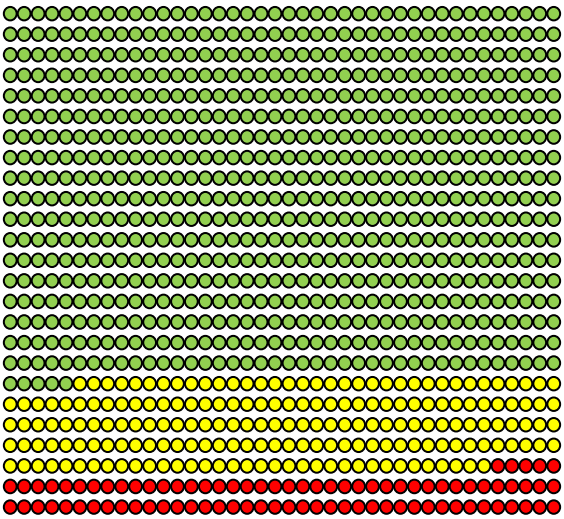


5 years, WITHOUT tratament



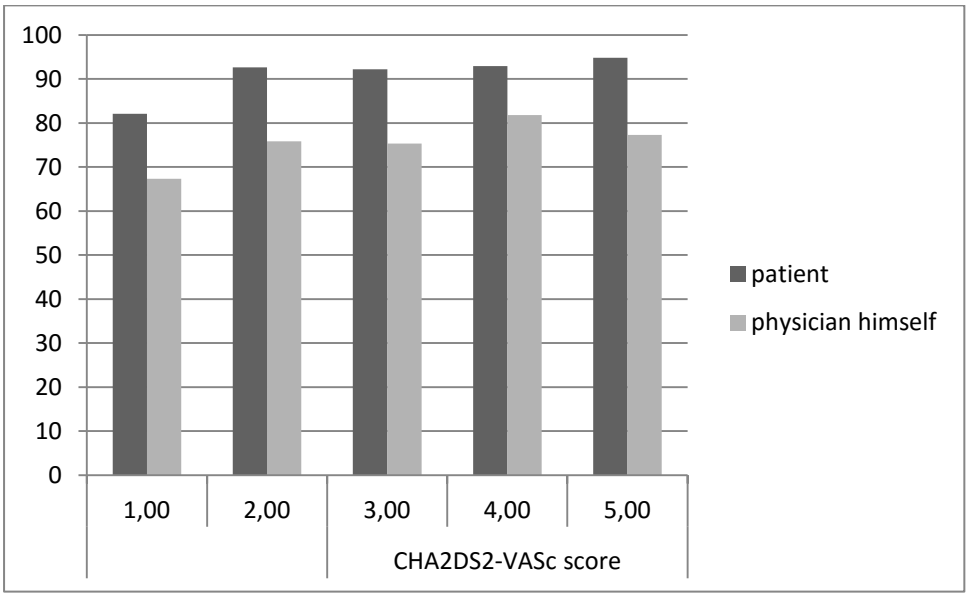
1 year, WITH tratament

5 years, WITH tratament

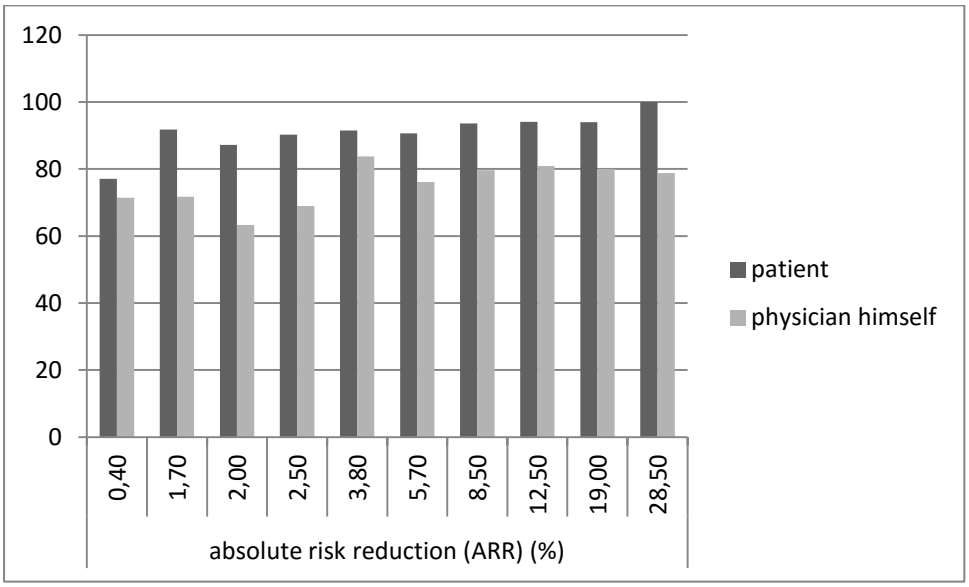


*Risk graphs coresponding to a CHA_2DS_2VASc score of 4

Appendix 3. Influence of the CHA_2DS_2-VASc score (A) and absolute risk reduction (B) on the decision to treat (stratified by the target of prescription, patient, and physician himself)



A. Chi square for trend: overall, p=0.002; patients, p=0.006; physicians themselves, p=0.058.



B. Chi square for trend: overall, p=0.005; patients, p=0.002; physicians themselves, p=0.109.
There are 10 levels of ARR, corresponding to 5 levels of risk scores x 2 timeframes (1 and 5 years).