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Mind the gap - atrial fibrillation patients and their physicians perceive risk and benefits of stroke prevention differently

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Abstract

Objective

Since more than 20 years, oral anticoagulation (OAC) is state-of-the-art therapy for atrial fibrillation (AF), the most common arrhythmia worldwide. However, little is known about the perception of AF patients and how it correlates with risk scores used by their physicians. Therefore, the objective of our study was to correlate patients' estimates of their own stroke and bleeding risk with the objectively predicted individual risk using CHA_2DS_2-VASc and HAS-BLED scores.

Design

Cross-sectional prevalence study using convenience sampling.

Settings

Nine hospitals (first, secondary and tertiary care) and one general practitioner in Austria. Patients' perception of stroke and bleeding risk was opposed to commonly used risk scoring.

Participants

Patients with newly diagnosed AF and indication for anticoagulation.

Main Outcome Measures

Comparison of subjective risk perception with CHA_2DS_2-VASc and HAS-BLED scores showing possible discrepancies between subjective and objective risk estimation. Patients' judgement of their own knowledge on AF and education were also correlated with accuracy of subjective risk appraisal.

Results

Ninety-one patients (age 73±11 years, 45% female) were included in this study. Subjective stroke and bleeding risk estimation did not correlate with risk scores (ρ=0.08, p=0.47 and ρ=0.17, p=0.15). The majority of patients (57%) underestimated the individual bleeding risk. Patients feared stroke more than bleeding (67% vs. 10%). There was no relationship between accurate perception of stroke and bleeding risks and education level (ρ=-0.06, p=0.63 and ρ=0.17, p=0.15). However, we found a correlation between the patients' judgement of their own knowledge of AF and correct assessment of individual stroke risk (ρ=0.24, p=0.02).

Conclusions

In this cross-sectional analysis of OAC-naïve AF patients, we found major differences between patients' perceptions and physicians' assessments of risks and benefits of OAC. To ensure shared decision-making and informed consent, more attention should be given to evidence-based and useful communication strategies.

Trial registration

NCT03061123

Key words

Atrial fibrillation, oral anticoagulation, questionnaire, self-assessment

Article summary

Strengths and limitations

- The design of this cross-sectional study allowed the objective assessment of the patients' risk perception immediately after initiation of anticoagulation for atrial fibrillation.
- For generalizability, primary, secondary and tertiary health care centres were included in this study.
- The low sample size is the main limitation of this study.

Introduction

Atrial fibrillation (AF) is the most common significant arrhythmia worldwide, associated with a fivefold increase in risk for stroke[1] and almost doubles of mortality.[2] In an ageing population, the number of individuals affected is projected to increase exponentially over the next decades.[3] Since the early 1990ies, oral anticoagulation (OAC) is the state-of-the-art therapy for reducing stroke and embolic events.[2] OAC is considered a long-term, often lifelong medical intervention. Therefore, clinicians and particularly patients need to have a clear understanding of the related benefits and immanent harms.[4] It serves as reasonable background for shared-decision making of patients and their doctors, one of the most important principles for patients' reliance, compliance and adherence to recommended medical strategies.[5 6]

Adequate information of patients[7] and increased health literacy[8 9] are of major importance for compliance and adherence to therapy. Patients' knowledge also affects the perception of risk for stroke, embolic events and bleeding. It has been shown that the extent of information perceived influenced patients' preferences towards or against OAC treatment the most.[10]

Clinicians use algorithms like CHA_2DS_2-VASc and HAS-BLED scores[11-13] to predict the balance of future risk for stroke and embolic events versus bleeding in an individual patient. A recent survey of the European Heart Rhythm Association proved that a considerable amount of time and resources are needed in daily clinical practice to communicate risk / benefit ratios to patients suffering from AF: Several centres have established special OAC clinics and initial visits mostly lasted 21-30 minutes.[14] However, decades after the introduction of OAC therapy, standardised and validated risk communication tools[15-17] are still missing and adherence follow-up programmes

are rare.[14] Those programmes have an important impact on effectiveness of OAC: Adherence to OAC is considered a key factor for preventing events,[18] but it is still as low as 43%.[19]

Little is known about the perception of AF patients and how it correlates with risk scores used by their physicians.[20] A potential gap between subjective and objective assessments may increase the likelihood of non-compliance to OAC in AF patients.[21] Therefore, the study was designed to correlate the subjective stroke and bleeding risk with the objectively predicted individual risks calculated by CHA_2DS_2-VASc and HAS-BLED scores.

Methods

This work is a cross-sectional prevalence study, using convenience sampling by trained doctors at 10 centres (representing primary, secondary and tertiary health care) in the province of Styria, Austria. Responsible institutional review boards approved the study (1376/2015 [BHB Graz, Austria], 28-004 ex 15/16 [Medical University of Graz, Austria]) Furthermore, the study was registered under the ClinicalTrials.gov number NCT03061123. Patients with first diagnosed and ECG-documented non-valvular AF and indication for OAC were included in the study. Exclusion criteria were pre-existing OAC therapy, valvular heart disease, history of valve surgery, denial or inability of informed consent.

This study was designed to comply with standard operating procedures of individual centres for initiation of OAC therapy. Responsible physicians carried out pre-treatment interviews, including discussion of benefits, harms and side effects of OAC. After informed consent was signed, a standardized questionnaire was handed out to all patients (supplemental figure S1).

Questionnaire

The survey was conducted using a standardized questionnaire with two parts (supplemental table S1). The patient-oriented part consisted of seven questions covering subjective perception of patients with regard to general individual risk/benefit ratios of OAC in AF, the willingness of therapy continuation even in the possible case of minor adverse effects (haematoma, minor bleeding) and the individually discerned level of information. We used 3- and 4-point verbal rating scales to comply with the patients' categorical perception of checks and balances.[22]

Physicians in charge of patients filled the second part, which included patient demographics, CHA_2DS_2-VASc and HAS-BLED scores, as well as the intended OAC therapy.

CHA_2DS_2-VASc and HAS-BLED scores were stratified into four risk categories each corresponding to the four different risk levels for stroke/embolic events and bleeding interrogated by the patient questionnaire. Risk estimations were based on published data from large population studies. Regarding CHA_2DS_2-VASc score, patients with zero points (stroke rate 0-1%/year) were considered *low risk*, one point (stroke rate 1-2%/year) *intermediate risk*, 2-4 points (stroke rate 2-7%) *high risk* and ≥ 5 points (stroke rate > 7%/year) *very high risk* cohort.[11 23 24] The corresponding categories concerning HAS-BLED score were as follows: no or one risk factor (*low risk* group, bleeding rate 0-4%/year), two risk factors (*intermediate risk* group, bleeding rate 4-6%/year), 3 or 4 risk factors (*high risk* group, bleeding rate 6-10%/year) and 5 or more risk factors (*very high risk* group, bleeding rate > 10%/year).[12 23]

For assessing the awareness of general benefit of OAC, we asked patients to estimate their appraisal of relative risk reduction (RRR) for stroke and embolic events. We defined *high* (RRR 50-74%) as accurate answer,[25] others were *low (RRR 0-24%), intermediate* (RRR 25-49%) and *very high* (RRR 75-100%). We extrapolated predicted hazard ratios (HR) of bleeding due to OAC from meta-analyses[25-28] and defined the general risk of OAC as *intermediate* (HR 1.25-1.49). Other options were *low* (HR 1.00-1.24), *high* (HR 1.50-2.00) and *very high* (HR > 2.00). Subjective scales were interpreted as “correct” if they corresponded correctly to individual objective risk groups.

Statistical analysis

Sample size calculation

Sample size calculation was performed using the freeware tool G*Power by Heinrich Heine University Düsseldorf (http://www.gpower.hhu.de). We sought to oppose the self-reported benefits and risks of OAC with an actual assessment using validated data (including CHA_2DS_2-VASc Score and HAS-BLED Score). To prove correlation ($|\rho|<0.3$) with type I error (α) of 0.05 and power ($1-\beta$) of 80%, at least 84 patients had to be included into the study.

Univariate analysis

Two-sided significance level was 0.05. Data are presented as mean±standard deviation, median (interquartile range) or count (proportion), where appropriate. Pearson's test and Spearman's rank correlation coefficient were used to correlate ordinal variables (e.g. subjective perceptions and risk scores). Correlation coefficients (i.e. $|r|$, $|\rho|$) were interpreted as follows: negligible correlation (0.0-0.3), low correlation (0.3-0.5), moderate correlation (0.5-0.8) and strong correlation (0.8-1.0).[29]

Data were analysed with IBM® SPSS® Statistics version 23 (IBM Corporation, Armonk, NY).

Results

Patient population

From September 2015 to March 2016, 91 patients (age 73±11 years, 45% female) from nine centres were included in this study (supplemental table S3). As highest educational attainment, lower secondary education (ISCED level 2, n=32, 35%) and higher secondary vocational education (ISCED level 3B n=25, 28%) were most prevalent. New oral anticoagulants (NOACs) were used most frequently (n=75, 82%). vitamin K antagonists (n=14, 15%) and low-molecular weight heparin (n=2, 2%) were given to remaining patients.

Objective risk estimation

Median CHA_2DS_2-VASc-Score was 4 (interquartile range 2-5). Therefore, we summarized most patients on high risk for stroke or embolic event (CHA_2DS_2-VASc score 2-4, stroke risk 2-7%/year, figure 1). Most common risk factors were arterial hypertension and age > 75 years (table 1). In terms of HAS-BLED score, most of patients were in low (0-1 points, bleeding risk 0–4 %) and intermediate risk groups (2 points, bleeding risk 4–6 %; figure 1).

Perception of individual risk

Many patients (n=41, 45%) interpreted risk for stroke and embolic events in atrial fibrillation *in general* as *high* to *very high* (corresponding stroke risk 2-7% and >7% per year, respectively). Bleeding risk was estimated mainly as *intermediate* (corresponding bleeding risk 4-6% per year, n=40, 44%). Patients feared stroke more than bleeding (67% vs. 10%) and only 9% would discontinue OAC therapy if minor

bleeding complications (e.g. epistaxis) would occur. Patients estimated their personal level of information as *good* or *adequate* in 41% and 34%, respectively.

Correlations

Patients estimated their risk for stroke or embolic events in concordance to the individual CHA_2DS_2-VASc score in 25 (28%) of cases, by the majority (n=52, 57%) risk was underrated. Bleeding risk was assumed accurately in 37% (n=41), but overestimated in 31 cases (34%). There were no significant correlations neither between objectively assessed and subjectively expected risk for stroke nor for bleeding (ρ=0.08, p=0.47, figure 2 and ρ<0.01, p=0.98, figure 3).

Analogies in patients' answers and CHA_2DS_2-VASc and HAS-BLED scores did not correlate to the levels of highest education (ρ=-0.06, p=0.64 and ρ=0.17, p=0.15). However, we observed a significant correlation between patients' judgement of their knowledge of AF with regard to concordant assumptions of stroke risk and CHA_2DS_2-VASc score (ρ=0.24, p=0.02, figure 4). No correlation was observed between patients' judgement of AF knowledge and concordance with subjectively assumed and objectively predicted risk for bleeding events (ρ=0.08, p=0.45).

Perception of general risk

Most patients (n=51, 56%) assumed score-predicted effectiveness of OAC in AF as *high* (corresponding stroke risk reduction 50-74%). Other answers were *very high* (RRR 75-100%; n=23, 25%), *intermediate* (RRR 25-49%; n=15, 17%) or *low* (RRR 0-24%; n=1, 1%).The estimated general risk of bleeding caused by OAC was considered by patients as *intermediate* (HR for bleeding 1.25-1.49; n=37, 41%) and

low (HR 1.00-1.24; n=30, 33%). Only 3 patients (3%) estimated the bleeding risk associated with OAC as *very high* (HR > 2.00).

Discussion

This cross-sectional questionnaire study in 91 OAC-naïve patients with non-valvular AF shows that (1) patients generally underestimated their risk of stroke, (2) they perceived their individual stroke risk to higher extent than bleeding risk and (3) there was a significant correlation between accuracy in answers and patients' judgement of their knowledge of AF.

Due to the high prevalence of AF in the western world, non-adherence to OAC in AF patients has a tremendous impact on our society. Despite the availability of adequate therapy, AF-related strokes are still estimated to cost eight billion USD annually in the United States[30 31] or over 9,000 pounds per stroke in the UK.[32] The increased severity of AF-related strokes compared to other etiologies[33] may even increase the negative effect of general embolic events on quality of life.[34] As a consequence, it is urgently necessary to ameliorate adherence to OAC therapy for AF. We proved underjudgement of stroke risk and therefore postulate better patient education as possibility to overcome this problem.

No correlation between subjective assessment and objective risk

To our knowledge, this is the first study that compares the subjective risk perception of AF patients with evidence-based risk scores used in daily clinical practice. We found no significant correlation between subjective and objective assessment of stroke or bleeding risk. Therefore, our study provides evidence that a perception gap remains after informed consent discussion before OAC initiation.

If this finding remains constant in larger trials, it has a direct impact on clinical practice. Such a perception gap is problematic at the start of a lifelong medical

intervention. It hinders not only shared decision making, but it also influences treatment compliance and adherence.

Previous studies already evaluated the levels of information in patients after initiation of OAC treatment.[20 35-39] In a survey of 711 AF patients that were on OAC for at least one year, only 7% knew the purpose of anticoagulation in AF.[38] Lane et al.[35] observed that 51% of AF patients with OAC therapy for ≥ 3 months could not name their cardiac condition. Furthermore, the knowledge could not be increased by a brief educational intervention. McCabe et al.[40] showed considerable knowledge deficits already two weeks after initial diagnosis of AF. A recent qualitative systematic review postulated the lack of patient information as one of the most important reasons for VKA underuse.[41]

Although Dantas et al.[37] demonstrated that only minimal knowledge of patients is needed to allow acceptance of OAC, doctors should seek shared decisions. This is even more important, when evidence for drug treatment is marginal,[42] which is definitely not the case in patients with high risk scores for AF.[2] However, the physician's perspective of shared decision making may not be congruent to the patient's perceptions.[43] LaHaye et al.[44] demonstrated high interpatient variability regarding individual treatment thresholds. Consequently, we propose that health literacy of patients should be enhanced before OAC initiation, especially regarding the individual risk/benefit ratio. Thus, patients may be able to participate in decision-making of therapy initiation. Patients also seem to have difficulties regarding verbal descriptions of risk.[45] Therefore, graphical information might help overcome this problem.[7 15] One promising example is an electronic prototype for the translation of Grading of Recommendations Assessment, Development and Evaluation (GRADE) summaries[46] into decision aids using interactive formats to present evidence

summaries at varying levels of detail.[17] Another possibility is the establishment of a Fact Box, which describes evidence of benefits and harms without making recommendations.[16] Further theory-driven educational interventions have been shown to increase OAC control[47] or knowledge of INR targets.[35]

Stroke is topping bleeding risk

In our study, most of the patients assumed their personal stroke risk to be the most frequent and serious complication of untreated atrial fibrillation in their setting. However, the majority (57%) underestimated their stroke risk while 41% interpreted the bleeding risk accurately. In other studies, patients were keen on avoiding stroke more than bleeding[48] and placed even more importance on stroke prevention than doctors[49] with higher tolerance of adverse bleeding events.[50] With increased duration of OAC therapy, knowledge about OAC in the indication of AF seems to deteriorate.[38]

Factors influencing correct risk estimation

We found out that the highest level of educational attainment did not correlate with analogies in risk estimation in our analysis. Our results therefore indicate that understanding of individuals' risk is not correlated with formal education levels. However, the preservation of knowledge might be correlated with better education.[40] Lip et al.[39] showed differences of AF perceptions in different ethnical groups. We could not add evidence to this factor as we included only Caucasian patients.

Patients that felt better informed had an improved understanding of their individual risks in this study. Consequently, we encourage to evaluate patients' information level repeatedly by asking how informed they felt and to take appropriate measures to enhance the patient's level of information if required.

Limitations

Our study has several limitations. Firstly, patient enrolment was not consecutive and therefore selection bias cannot be ruled out. Secondly, our sample size was not large enough for comparing differences between sites. Therefore, we cannot asses how differences in risk communication may have influenced our study results. Thirdly, we currently have no follow up data available. Therefore, we can only assume that higher levels of information might be associated with better adherence and outcomes as results of previous studies suggested. Fourthly, recent ESC guidelines do not endorse the HAS-BLED score any more as additional non-modifiable risk factors of bleeding have been established in the recent years. The HAS-BLED score is still propagated by the National Institute for Health and Clinical Excellence (NICE) guidelines.[51] Lastly, we intended to concentrate on the risk perception of individual patients and did not evaluate the general knowledge of AF and stroke prevention per se in a standardized questionnaire.[52] Due to this fact, we kept the questionnaire short and tried to minimize bias due to selection of motivated patients that may not be representative of the general AF population.[20]

Conclusion

In this cross-sectional analysis of OAC-naïve AF patients, we found major differences between patients' perceptions and physicians' assessments of risks and benefits of OAC. To ensure shared decision-making and informed consent, more attention should be given to evidence-based and useful communication strategies.

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Competing interests statement

Dr. Bauer reports personal fees from Bayer, Medtronic, Daiichi-Sankyo, Servier, personal fees from Bayer, AstraZeneca, other from Boehringer-Ingelheim, Bayer, Lilly, outside the submitted work.

Dr. Heine has nothing to disclose.

Dr. Krippl has nothing to disclose.

Dr. Reicht has nothing to disclose.

Dr. Schumacher has nothing to disclose.

Dr. Sprenger has nothing to disclose.

Dr. Stepan has nothing to disclose.

Dr. Watzinger reports personal fees from Lectures, personal fees from Consulting, outside the submitted work.

Dr. Zweiker D has nothing to disclose.

Dr. Zweiker G has nothing to disclose.

Dr. Zweiker R has nothing to disclose.

Contributorship statement

RZ, MS and NW designed the study.

RZ, KR, MS, VS, PK, NB, MH, GR, GZ, MS and NW were involved in conduction of the study and data collection.

DZ and NW performed the statistical analysis.

DZ, RZ, MS and NW wrote the manuscript.

All authors have read and approved the last version of the manuscript.

Data sharing statement

All raw data is available in the supplementary appendix.

Tables

$CHADS_2$ score	2 (1-3)
CHA_2DS_2-VASc score	4 (2-5)
Congestive heart failure	14 (15%)
Hypertension	75 (82%)
Age > 75 years	48 (53%)
Diabetes mellitus	18 (20%)
Stroke or TIA	15 (17%)
Vascular disease	27 (30%)
Age 65-75 years	25 (28%)
Female **S**ex	41 (45%)
HAS-BLED-Score	2 (1-2)
Hypertension (systolic blood pressure > 160 mmHg)	42 (46%)
Abnormal kidney / liver function	8 (9%)
Stroke	14 (15%)
Bleeding	1 (1%)
Labile INR values	1 (1%)

Elderly (age > 65 years)	72 (79%)
Drugs or alcohol (1 point) Drugs and alcohol (2 points)	16 (18%) 2 (2%)

Table 1. CHA_2DS_2-VASc and HAS-BLED Scores and individual risk factors. TIA: transient ischaemic attack; INR: international normalized ratio.

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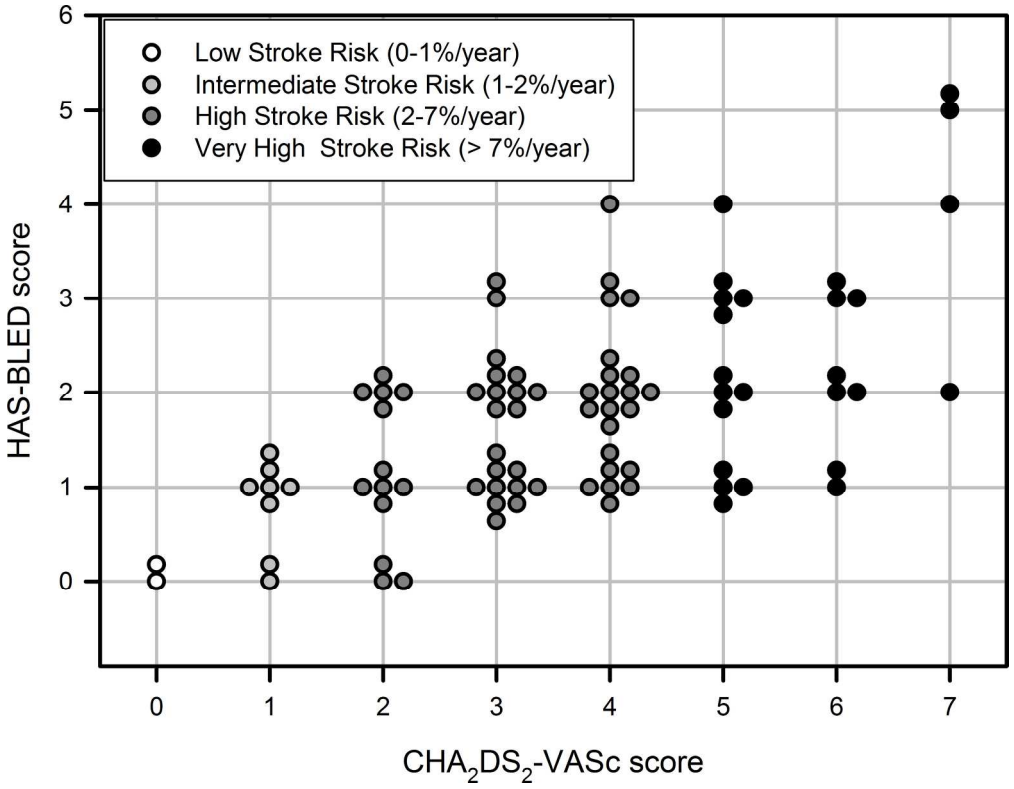

Figure 1: CHA_2DS_2-VASc and HAS-BLED scores of individual patients, including our classification into low, intermediate, high and very high stroke risk groups (stratified by CHA_2DS_2-VASc score).

107x83mm (600 x 600 DPI)

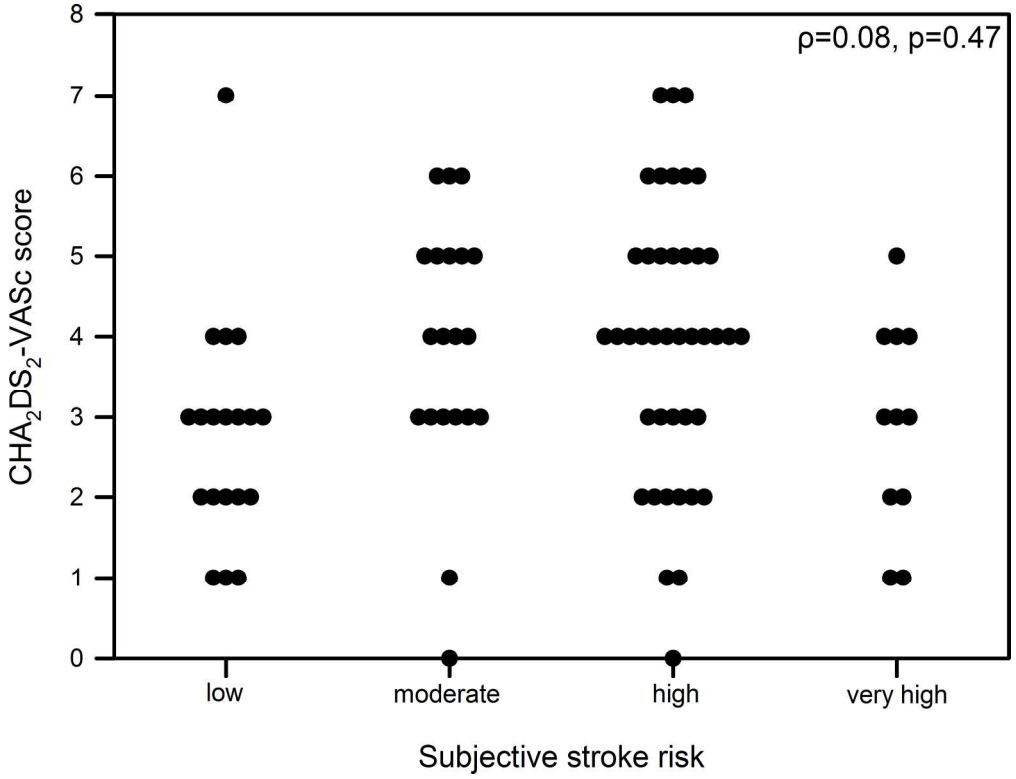

Figure 2: Correlation of CHA_2DS_2-VASc score and subjective assessed stroke risk.

107x82mm (600 x 600 DPI)

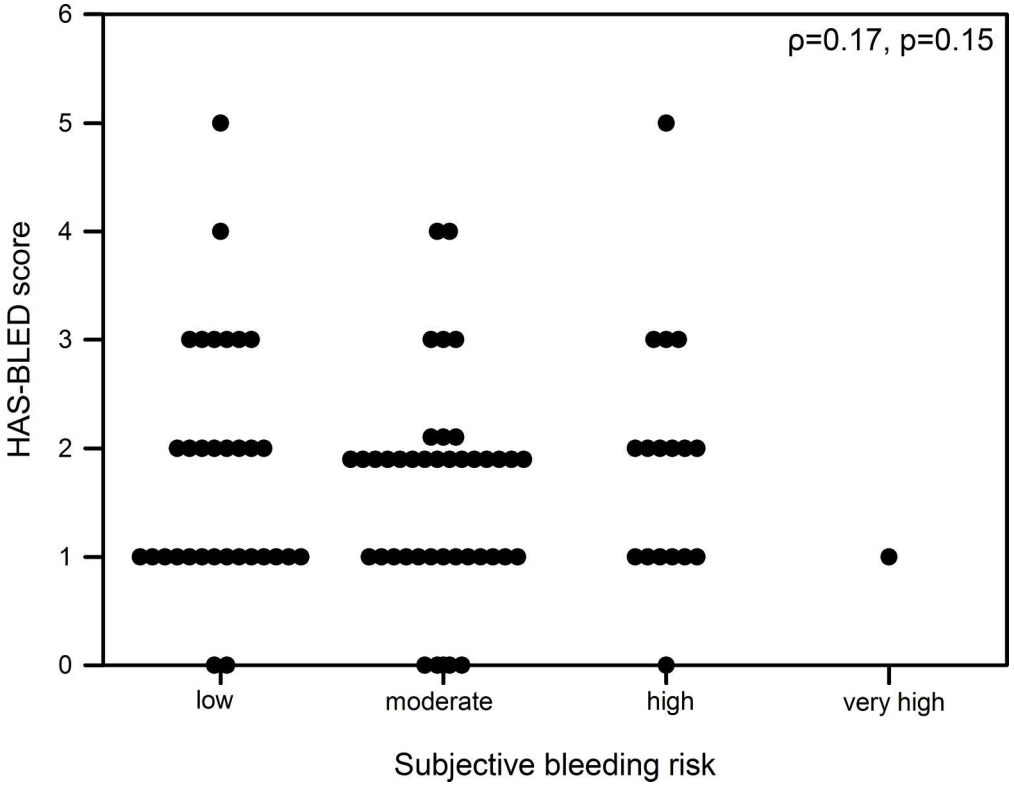

Figure 3: Correlation of HAS-BLED score and subjective assessed bleeding risk.

107x83mm (600 x 600 DPI)

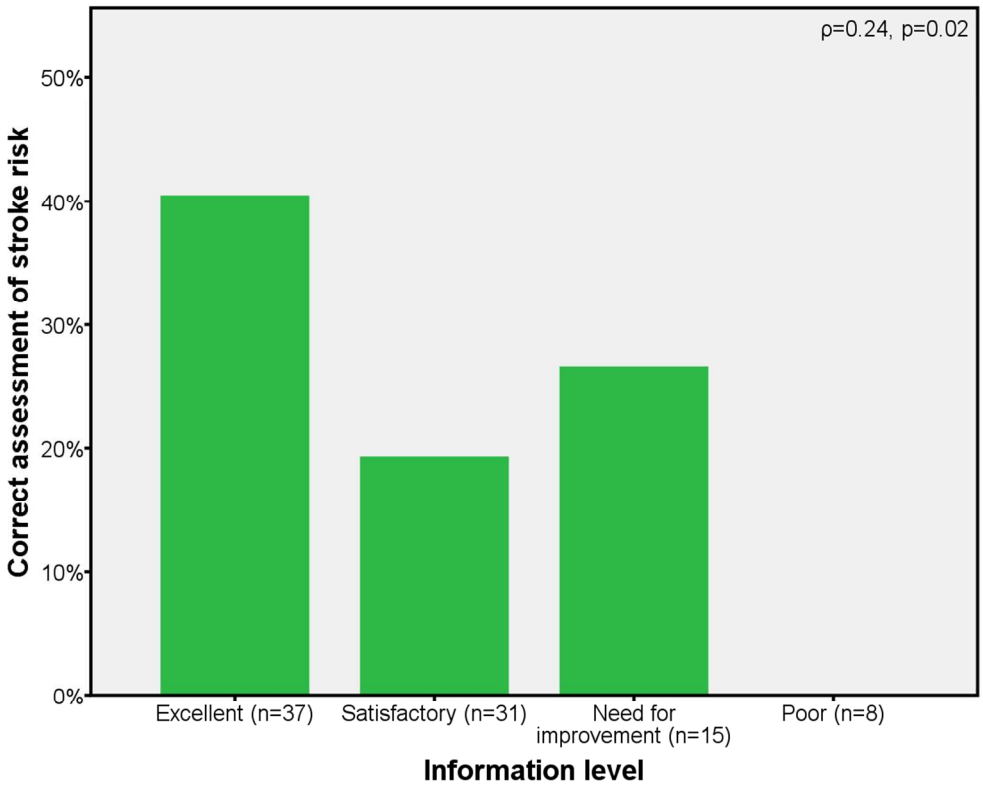

Figure 4: Amount of correct answered assessment of stroke risk in patients with different self-assessed levels of information.

437x349mm (72 x 72 DPI)

Mind the gap - atrial fibrillation patients and their physicians perceive risk and benefits of stroke prevention differently

David Zweiker[1], Robert Zweiker[1], Konstantina Roesch[1], Martin Schumacher[2], Vinzenz Stepan[3], Peter Krippl[4], Norbert Bauer[5], Martin Heine[6], Gerhard Reicht[7], Gudrun Zweiker[8], Martin Sprenger[9], Norbert Watzinger[10]*

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Supplemental material

Supplemental tables

Part I: To be completed by the patient
1) How do you judge the risk of stroke without anticoagulation? a) Low b) Intermediate c) High d) Very high
2) How do you judge the efficacy of the proposed therapy? How strong is the effect of anticoagulation to avoid a stroke? a) Low b) Intermediate c) High d) Very high
3) The bleeding risk depends on comorbidities. How to you judge the risk of severe haemorrhagic complications within one year? a) Low b) Intermediate c) High d) Very high
4) How do you judge the disadvantages of treatment? How do you think increases the risk of severe haemorrhage if you take your medication appropriately? a) Low b) Intermediate c) High d) Very high

5) Would you discontinue anticoagulation therapy if minor bleedings would occur (e.g. haematoma, epistaxis, gum bleeding) a) Yes b) No c) I don't know
6) What do you fear more: stroke or bleeding complications? a) Stroke b) Bleeding c) I don't know
7) How do judge your general level of information regarding the disease "Atrial fibrillation" and the proposed therapy? a) Good b) Okay c) Improvable d) Bad
Part II: To be completed by the physician
1) Demographics a) Age (years): b) Gender: female/male c) Education: compulsory school/apprenticeship/vocational school/grammar school/vocational school with higher entrance qualification/university of applied sciences/university of general sciences
2) Planned type of anticoagulation a) Vitamin K antagonist (VKA) b) NOAC

c) Low molecular weight heparin

d) Combination with antiplatelet

3) CHA_2DS_2-VASc score

a) C = Congestive heart failure / LV dysfunction

b) H = Hypertension

c) A_2 = Age ≥ 75 years

d) D = Diabetes mellitus

e) S_2 = Stroke/TIA/thrombo-embolism

f) V = Vascular disease

g) A = Age 65-74 years

h) S = Sex category (i.e. female sex)

4) HAS-BLED Score

a) H = Uncontrolled hypertension (systolic blood pressure > 160 mmHg)

b) A = Abnormal renal function (presence of chronic dialysis or renal transplantation or serum creatinine ≥200 mmol/L) or abnormal liver function (chronic hepatic disease [e.g. cirrhosis] or biochemical evidence of significant hepatic derangement [e.g. bilirubin 2 x upper limit of normal, in association with aspartate aminotransferase/alanine aminotransferase/alkaline phosphatase .3 x upper limit normal]) (1 point each)

c) S = Stroke

d) B = Bleeding (previous bleeding history and/or predisposition to bleeding, e.g. bleeding diathesis, anaemia)

e) L = Labile INRs (unstable/high INRs or poor time in therapeutic range [e.g. < 60%])

f) D = Drugs or alcohol (concomitant use of drugs, such as antiplatelet agents, non-steroidal anti-inflammatory drugs, or alcohol abuse) (1 point each)

Supplemental table S1. Questionnaire (English translation). LV: left ventricle; TIA: transitory ischaemic attack; INR: international normalized range

Patients per centre	
LKH Feldbach, Department of Internal Medicine	36 (40%)
Medical University of Graz, Division of Cardiology	18 (20%)
BHB Graz-Marschallgasse, Department of Internal Medicine	9 (10%)
KH Elisabethinen Graz, Department of Internal Medicine	8 (9%)
LKH Feldbach, Department of Neurology	6 (7%)
LKH Fürstenfeld, Department of Internal Medicine	5 (6%)
LKH Hartberg, Department of Internal Medicine	5 (6%)
BHB Graz-Eggenberg, Department of Internal Medicine	2 (2%)
Zweiker, MD, General Practitioner	2 (2%)
Highest completed education (ISCED level)	
Lower secondary education (2)	32 (35%)
Upper secondary vocational education (3B)	25 (28%)
Upper secondary general education (3A)	8 (9%)

Upper secondary vocational education (3C)	4 (4%)
Tertiary general education (5A)	3 (3%)
Post-secondary non-tertiary vocational education (4A)	2 (2%)
Tertiary vocational education (5A)	1 (1%)

Supplemental table S2. Demographics of included patients. ISCED: International Standard Classification of Education.

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	Information can be found in page
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	Abstract
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	Abstract
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	5-6
Objectives	3	State specific objectives, including any prespecified hypotheses	6
Methods			
Study design	4	Present key elements of study design early in the paper	7
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	7;10
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	7
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	Not applicable
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	7-8
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	7-8
Bias	9	Describe any efforts to address potential sources of bias	16
Study size	10	Explain how the study size was arrived at	9
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	8
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	9
		(*b*) Describe any methods used to examine subgroups and interactions	9
		(*c*) Explain how missing data were addressed	9
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up	9

		was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy	
		(*e*) Describe any sensitivity analyses	9
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	10
		(b) Give reasons for non-participation at each stage	10
		(c) Consider use of a flow diagram	Not applicable
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	10
		(b) Indicate number of participants with missing data for each variable of interest	10-12
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	Not applicable
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	Not applicable
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	Not applicable
		Cross-sectional study—Report numbers of outcome events or summary measures	10-12
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	10-12
		(*b*) Report category boundaries when continuous variables were categorized	10
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	Not relevant
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Not applicable
Discussion			
Key results	18	Summarise key results with reference to study objectives	13-15
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	16
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	13-15
Generalisability	21	Discuss the generalisability (external validity) of the study results	14-15
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Transparency declaration

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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Association between subjective risk perception and objective risk estimation in atrial fibrillation patients: a cross-sectional study.

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Association between subjective risk perception and objective risk estimation in atrial fibrillation patients: a cross-sectional study.

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Abstract

Objective

Oral anticoagulation (OAC) is state-of-the-art therapy for atrial fibrillation (AF), the most common arrhythmia worldwide. However, little is known about the perception of AF patients and how it correlates with risk scores used by their physicians. Therefore, we correlated patients' estimates of their own stroke and bleeding risk with the objectively predicted individual risk using CHA_2DS_2-VASc and HAS-BLED scores.

Design

Cross-sectional prevalence study using convenience sampling and telephone follow up.

Settings

Eight hospital departments and one general practitioner in Austria. Patients' perception of stroke and bleeding risk was opposed to commonly used risk scoring.

Participants

Patients with newly diagnosed AF and indication for anticoagulation.

Main Outcome Measures

Comparison of subjective risk perception with CHA_2DS_2-VASc and HAS-BLED scores showing possible discrepancies between subjective and objective risk estimation. Patients' judgement of their own knowledge on AF and education were also correlated with accuracy of subjective risk appraisal.

Results

Ninety-one patients (age 73±11 years, 45% female) were included in this study. Subjective stroke and bleeding risk estimation did not correlate with risk scores (ρ=0.08 and ρ=0.17). The majority of patients (57%) underestimated the individual stroke risk. Patients feared stroke more than bleeding (67% vs. 10%). There was no relationship between accurate perception of stroke and bleeding risks and education level. However, we found a correlation between the patients' judgement of their own knowledge of AF and correct assessment of individual stroke risk (ρ=0.24, p=0.02). During follow up, patients experienced the following events: death (n=5), stroke (n=2), bleeding (n=1). OAC discontinuation rate despite indication was 3%.

Conclusions

In this cross-sectional analysis of OAC-naïve AF patients, we found major differences between patients' perceptions and physicians' assessments of risks and benefits of OAC. To ensure shared decision-making and informed consent, more attention should be given to evidence-based and useful communication strategies.

Trial registration

NCT03061123

Key words

Atrial fibrillation, oral anticoagulation, questionnaire, self-assessment

Article summary

Strengths and limitations

- The design of this cross-sectional study allowed the objective assessment of the patients' risk perception immediately after initiation of anticoagulation for atrial fibrillation.
- For generalizability, primary, secondary and tertiary health care centres were included in this study.
- To evaluate long-time outcome, follow up was obtained via telephone.
- The study is statistically powered for the cross-sectional comparison, but the number of patients included does not allow association between baseline characteristics and events during follow up.

Introduction

Atrial fibrillation (AF) is the most common significant arrhythmia worldwide, associated with a fivefold increase in risk for stroke[1] and almost doubles the risk of mortality.[2] In an ageing population, the number of individuals affected is projected to increase exponentially over the next decades.[3] Since the early 1990´s, oral anticoagulation (OAC) is the state-of-the-art therapy for reducing stroke and embolic events.[2] OAC is considered a long-term, often lifelong medical intervention. Therefore, clinicians and particularly patients need to have a clear understanding of the related benefits and immanent harms.[4] It serves as a reasonable background for shared-decision making of patients and their doctors, one of the most important principles for patients' reliance, compliance and adherence to recommended medical strategies.[5 6]

Adequate information of patients[7] and increased health literacy[8] are of major importance for compliance and adherence to therapy. Patients' knowledge also affects the perception of risk for stroke, embolic events and bleeding. It has been shown that the extent of information perceived influenced patients' preferences towards or against OAC treatment the most.[9]

Clinicians use algorithms like CHA_2DS_2-VASc and HAS-BLED scores[10-12] to predict the balance of future risk for stroke and embolic events versus bleeding in an individual patient. A recent survey of the European Heart Rhythm Association proved that a considerable amount of time and resources are needed in daily clinical practice to communicate risk / benefit ratios to patients suffering from AF: Several centres have established special OAC clinics and initial visits mostly lasted 21-30 minutes.[13] However, decades after the introduction of OAC therapy, standardised and validated

risk communication tools[14-16] are still missing and adherence follow-up programmes are rare.[13] Those programmes have an important impact on effectiveness of OAC: Adherence to OAC is considered a key factor for preventing events,[17] but it is still as low as 43%.[18]

Little is known about the perception of AF patients and how it correlates with risk scores used by their physicians.[19] A potential gap between subjective and objective assessments may increase the likelihood of non-compliance to OAC in AF patients.[20] Therefore, the study was designed to correlate the subjective stroke and bleeding risk with the objectively predicted individual risks calculated by CHA_2DS_2-VASc and HAS-BLED scores.

Methods

This work is a cross-sectional prevalence study, using convenience sampling by trained doctors at nine centres (representing primary, secondary and tertiary health care) in the province of Styria, Austria. Responsible institutional review boards approved the study (1376/2015 [BHB Graz, Austria], 28-004 ex 15/16 [Medical University of Graz, Austria]). Furthermore, the study was registered under the ClinicalTrials.gov number NCT03061123. Patients with first diagnosed and ECG-documented non-valvular AF and indication for OAC were included in the study. Exclusion criteria were pre-existing OAC therapy, valvular heart disease, history of valve surgery, denial or inability of informed consent.

This study was designed to comply with standard operating procedures of individual centres for initiation of OAC therapy. Responsible physicians were asked to include all eligible patients. Immediately after the pre-treatment interviews, which included the discussion of benefits, harms and side effects of OAC, patients were asked to participate in the study. After informed consent was signed, a standardized questionnaire was handed out to all patients (supplemental table S1).

Questionnaire

The survey was conducted using a standardized questionnaire with two parts (supplemental table S1). The patient-oriented part consisted of seven questions covering subjective perception of patients with regard to general individual risk/benefit ratios of OAC in AF, the willingness of therapy continuation even in the possible case of minor adverse effects (haematoma, minor bleeding) and the individually discerned level of information. We used 3- and 4-point verbal rating scales to comply with the patients' categorical perception of checks and balances.[21]

Physicians in charge of patients filled the second part, which included patient demographics, CHA_2DS_2-VASc and HAS-BLED scores, as well as the intended OAC therapy.

CHA_2DS_2-VASc and HAS-BLED scores were stratified into four risk categories each corresponding to the four different risk levels for stroke/embolic events and bleeding interrogated by the patient questionnaire. Risk estimations were based on published data from large population studies. Regarding CHA_2DS_2-VASc score, patients with zero points (stroke rate 0-1%/year) were considered *low risk*, one point (stroke rate 1-2%/year) *intermediate risk*, 2-4 points (stroke rate 2-7%/year) *high risk* and ≥ 5 points (stroke rate > 7%/year) *very high risk* cohort.[10 22 23] The corresponding categories concerning HAS-BLED score were as follows: no or one risk factor (*low risk* group, bleeding rate 0-4%/year), two risk factors (*intermediate risk* group, bleeding rate 4-6%/year), 3 or 4 risk factors (*high risk* group, bleeding rate 6-10%/year) and 5 or more risk factors (*very high risk* group, bleeding rate > 10%/year).[11 22]

For assessing the awareness of general benefit of OAC, we asked patients to estimate their appraisal of relative risk reduction (RRR) for stroke and embolic events. We defined *high* (RRR 50-74%) as an accurate answer,[24] others were *low (RRR 0-24%), intermediate* (RRR 25-49%) and *very high* (RRR 75-100%). We extrapolated predicted hazard ratios (HR) of bleeding due to OAC from meta-analyses[24-27] and defined the general risk of OAC as *intermediate* (HR 1.25-1.49). Other options were *low* (HR 1.00-1.24), *high* (HR 1.50-2.00) and *very high* (HR > 2.00). Subjective scales were interpreted as “correct” if they corresponded correctly to individual objective risk groups.

Follow up

Follow up was obtained by phone calls. Patients were asked about their current status of OAC therapy and the occurrence of cardiovascular or bleeding events.

Statistical analysis

Sample size calculation was performed using the freeware tool G*Power by Heinrich Heine University Düsseldorf (http://www.gpower.hhu.de). We sought to oppose the self-reported benefits and risks of OAC with an actual assessment using validated data (including CHA_2DS_2-VASc Score and HAS-BLED Score). To prove correlation ($|\rho|<0.3$) with type I error (α) of 0.05 and power ($1-\beta$) of 80%, at least 84 patients had to be included into the study.

Two-sided significance level was 0.05. Data are presented as mean±standard deviation, median (interquartile range) or count (proportion), where appropriate. Pearson's test and Spearman's rank correlation coefficient were used to correlate ordinal variables (e.g. subjective perceptions and risk scores). Correlation coefficients (i.e. $|r|$, $|\rho|$) were interpreted as follows: negligible correlation (0.0-0.3), low correlation (0.3-0.5), moderate correlation (0.5-0.8) and strong correlation (0.8-1.0).[28]

Data were analysed with IBM® SPSS® Statistics version 23 (IBM Corporation, Armonk, NY). All raw data can be found in the supplemental file.

Results

Patient population

From September 2015 to March 2016, 91 patients (age 73±11 years, 45% female) from nine centres were included in this study (supplemental table S2). As highest educational attainment, lower secondary education (ISCED level 2, n=32, 35%) and higher secondary vocational education (ISCED level 3B n=25, 28%) were most prevalent. New oral anticoagulants (NOACs) were used most frequently (n=75, 82%). vitamin K antagonists (n=14, 15%) and low-molecular weight heparin (n=2, 2%) were given to remaining patients.

Objective risk estimation

Median CHA_2DS_2-VASc-Score was 4 (interquartile range 2-5). Therefore, we summarized most patients on high risk for stroke or embolic events (CHA_2DS_2-VASc score 2-4, stroke risk 2-7%/year, figure 1). Most common risk factors were arterial hypertension and age > 75 years (table 1). In terms of HAS-BLED score, most of patients were in low (0-1 points, bleeding risk 0–4 %) and intermediate risk groups (2 points, bleeding risk 4–6 %; figure 1).

Perception of individual risk

Many patients (n=41, 45%) interpreted risk for stroke and embolic events in atrial fibrillation as *high* (corresponding stroke risk 2-7% per year). Bleeding risk was estimated mainly as *intermediate* (corresponding bleeding risk 4-6% per year, n=40, 44%). Patients feared stroke more than bleeding (67% vs. 10%) and only 9% would discontinue OAC therapy if minor bleeding complications (e.g. epistaxis) would occur.

Patients estimated their personal level of information as *good* or *adequate* in 41% and 34%, respectively.

Correlations

Patients estimated their risk for stroke or embolic events in concordance to the individual CHA_2DS_2-VASc score in 28% (n=25) of cases, but by the majority (n=52, 57%) risk was underrated. Bleeding risk was assumed accurately in 41% (n=37), but overestimated in 31 cases (34%). There were no significant correlations neither between objectively assessed and subjectively expected risk for stroke nor for bleeding (ρ=0.08, p=0.47, figure 2 and ρ<0.01, p=0.98, figure 3).

Analogies in patients' answers and CHA_2DS_2-VASc and HAS-BLED scores did not correlate to the levels of highest education (ρ=-0.06, p=0.64 and ρ=0.17, p=0.15). However, we observed a significant correlation between patients' judgement of their knowledge of AF with regard to concordant assumptions of stroke risk and CHA_2DS_2-VASc score (ρ=0.24, p=0.02, figure 4). No correlation was observed between patients' judgement of AF knowledge and concordance with subjectively assumed and objectively predicted risk for bleeding events (ρ=0.08, p=0.45).

Perception of general risk

Most patients (n=51, 56%) assumed score-predicted effectiveness of OAC in AF as *high* (corresponding stroke risk reduction 50-74%). Other answers were *very high* (RRR 75-100%; n=23, 25%), *intermediate* (RRR 25-49%; n=15, 17%) or *low* (RRR 0-24%; n=1, 1%).The estimated general risk of bleeding caused by OAC was considered by patients as *intermediate* (HR for bleeding 1.25-1.49; n=37, 41%) and

low (HR 1.00-1.24; n=30, 33%). Only 3 patients (3%) estimated the bleeding risk associated with OAC as *very high* (HR > 2.00).

Follow up

Follow up via telephone was obtained 18±2 months after enrolment from 84 patients (92%). The remaining 7 patients were lost to follow up because of missing contact details (n=6, 7%) or denial to participate (n=1, 1%). The following events were reported during follow up: death of unknown cause (n=5, 5%), ischaemic stroke (n=2, 2%) and epistaxis requiring hospitalization (n=1, 1%). All patients with ischaemic or bleeding events were under OAC therapy and had continued it until follow up.

At time of follow up, four patients had discontinued OAC therapy intermittently (n=1, 1%) or permanently (n=3, 3%). One female patient with CHA_2DS_2-VASc score of 2 reported that OAC therapy was terminated due to successful pulmonary vein isolation without any recurrence of AF during 9 months of event recorder monitoring. Three patients (CHA_2DS_2-VASc score between 3 and 7) discontinued OAC therapy on their own; although one patient reinitiated OAC therapy after discussion with his general practitioner.

Patients, who stopped OAC therapy on their own, believed that their current condition “had no indication” for OAC therapy. Two of them had underestimated their individual stroke risk at baseline interrogation, while one had overestimated it. Two stoppers feared the risk of bleeding more than the risk for ischemic events.

Discussion

This cross-sectional questionnaire study in 91 OAC-naïve patients with non-valvular AF shows that (1) patients generally underestimated their risk of stroke, (2) they perceived their individual stroke risk to higher extent than bleeding risk and (3) there was a significant correlation between accuracy in answers and patients' judgement of their knowledge of AF. During follow up, we observed OAC discontinuation despite clear indication in 3% of patients.

Due to the high prevalence of AF in the western world, non-adherence to OAC in AF patients has a tremendous impact on our society. Despite the availability of adequate therapy, AF-related strokes are still estimated to cost eight billion USD annually in the United States[29 30] or over 9,000 GBP per stroke in the UK.[31] The increased severity of AF-related strokes compared to other etiologies[32] may even increase the negative effect of general embolic events on quality of life.[33] As a consequence, it is urgently necessary to ameliorate adherence to OAC therapy for AF. We proved underjudgement of stroke risk and therefore, postulate better patient education as a possibility to overcome this problem.

No correlation between subjective assessment and objective risk

To our knowledge, this is the first study that compares the subjective risk perception of AF patients with evidence-based risk scores used in daily clinical practice. We found no significant correlation between subjective and objective assessment of stroke or bleeding risk. Therefore, our study provides evidence that a perception gap remains after informed consent discussion before OAC initiation. Although not powered for it, we provide preliminary data on the OAC discontinuation rate one year

after OAC initiation. Two of three patients, who stopped OAC on their own, had underestimated their stroke risk at baseline.

If this finding remains constant in larger trials, it has a direct impact on clinical practice. A perception gap between subjective and objective assessment of stroke or bleeding risk is considered a major obstacle at the start of a lifelong medical intervention. It hinders not only shared decision making, but may also worsen treatment compliance and adherence.[34]

Previous studies already evaluated the levels of information in patients after initiation of OAC treatment.[19 35-39] In a survey of 711 AF patients that were on OAC for at least one year, only 7% knew the purpose of anticoagulation in AF.[38] Lane et al.[35] observed that 51% of AF patients with OAC therapy for ≥ 3 months could not name their cardiac condition. Furthermore, the knowledge could not be increased by a brief educational intervention. McCabe et al.[40] showed considerable knowledge deficits already two weeks after initial diagnosis of AF. A recent qualitative systematic review postulated the lack of patient information as one of the most important reasons for VKA underuse.[41]

Although Dantas et al.[37] demonstrated that only minimal knowledge of patients is needed to allow acceptance of OAC, doctors should seek shared decisions. This is even more important, when evidence for drug treatment is marginal,[42] which is definitely not the case in patients with high risk scores for AF.[2] However, the physician's perspective of shared decision making may not be congruent to the patient's perceptions.[43] LaHaye et al.[44] demonstrated high interpatient variability regarding individual treatment thresholds. Consequently, we propose that health literacy of patients should be enhanced before OAC initiation, especially regarding the individual risk/benefit ratio. Thus, patients may be able to participate in decision-

making of therapy initiation. Patients also seem to have difficulties regarding verbal descriptions of risk.[45] Therefore, graphical information might help overcome this problem.[7 14] One promising example is an electronic prototype for the translation of Grading of Recommendations Assessment, Development and Evaluation (GRADE) summaries[46] into decision aids using interactive formats to present evidence summaries at varying levels of detail.[16] Another possibility is the establishment of a Fact Box, which describes evidence of benefits and harms without making recommendations.[15] Further theory-driven educational interventions have been shown to increase OAC control[47] or knowledge of INR targets.[35]

Stroke risk is topping bleeding risk

In our study, most of the patients assumed their personal stroke risk to be the most frequent and serious complication of untreated atrial fibrillation in their setting. However, the majority (57%) underestimated their stroke risk while 41% interpreted their bleeding risk accurately. In other studies, patients were keen on avoiding stroke more than bleeding[48] and placed even more importance on stroke prevention than doctors[49] with higher tolerance of adverse bleeding events.[50] Nevertheless, with increased duration of OAC therapy, knowledge about OAC in the indication of AF seems to deteriorate.[38]

Factors influencing correct risk estimation

We found out that the highest level of educational attainment did not correlate with analogies in risk estimation in our analysis. Our results therefore indicate that understanding of individuals' risk is not correlated with formal education levels. However, the preservation of knowledge might be correlated with better education.[40]

Lip et al.[39] showed differences of AF perceptions in different ethnical groups. We could not add evidence to this factor as we included only Caucasian patients.

Patients that felt better informed had an improved understanding of their individual risks in this study. Consequently, we encourage to evaluate patients' information level repeatedly by asking how informed they felt and to take appropriate measures to enhance the patient's level of information if required.

Limitations

Our study has several limitations. Firstly, due to the absence of a screening log, consecutive patient enrolment cannot be guaranteed. Secondly, the study was powered for cross sectional analysis, but not for associations association between baseline parameters and OAC adherence or events at follow up. Therefore, we can only speculate that higher levels of information might be associated with better adherence and outcomes as results of previous studies suggested. Thirdly, we did not evaluate other bleeding risk scores, such as ATRIA[51] or ORBIT,[52] into the analysis. Lastly, we intended to concentrate on the risk perception of individual patients and did not evaluate the general knowledge of AF and stroke prevention per se in a standardized questionnaire.[53] Due to this fact, we kept the questionnaire short and tried to minimize bias due to selection of motivated patients that may not be representative of the general AF population.[19]

Conclusion

In this cross-sectional analysis of OAC-naïve AF patients, we found major differences between patients' perceptions and physicians' assessments of risks and benefits of

OAC. To ensure shared decision-making and informed consent, more attention should be given to evidence-based and useful communication strategies.

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Competing interests statement

Dr. Bauer reports personal fees from Bayer, Medtronic, Daiichi-Sankyo, Servier, personal fees from Bayer, AstraZeneca, other from Boehringer-Ingelheim, Bayer, Lilly outside the submitted work.

Dr. Heine has nothing to disclose.

Dr. Krippl has nothing to disclose.

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Ms. Winkler has nothing to disclose.

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Contributorship statement

RZ, MS and NW designed the study.

RZ, EW, KR, MS, VS, PK, NB, MH, GR, GZ, MS and NW were involved in conduction of the study and data collection.

DZ and NW performed the statistical analysis.

DZ, RZ, MS and NW wrote the manuscript.

All authors have read and approved the last version of the manuscript.

Data sharing statement

All raw data is available in the supplementary appendix.

Tables

$CHADS_2$ score	2 (1-3)
CHA_2DS_2-VASc score	4 (2-5)
CHA_2DS_2-VASc score ≥ 2	81 (89%)
Congestive heart failure	14 (15%)
Hypertension (diagnosis of arterial hypertension)	75 (82%)
Age > 75 years	48 (53%)
Diabetes mellitus	18 (20%)
Stroke or TIA	15 (17%)
Vascular disease	27 (30%)
Age 65-75 years	25 (28%)
Female **S**ex	41 (45%)
HAS-BLED score	2 (1-2)
HAS-BLED score ≥ 3	17 (19%)
Hypertension (systolic blood pressure > 160 mmHg)	42 (46%)
Abnormal kidney / liver function	8 (9%)
Stroke	14 (15%)

Bleeding	1 (1%)
Labile INR values	1 (1%)
Elderly (age > 65 years)	72 (79%)
Drugs or alcohol (1 point) Drugs and alcohol (2 points)	16 (18%) 2 (2%)

Table 1. CHA_2DS_2-VASc and HAS-BLED Scores and individual risk factors. TIA: transient ischaemic attack; INR: international normalized ratio.

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Figure legends

Figure 1: CHA_2DS_2-VASc and HAS-BLED scores of individual patients, including our classification into low, intermediate, high and very high stroke risk groups (stratified by CHA_2DS_2-VASc score).

Figure 2: Correlation of CHA_2DS_2-VASc score and subjective assessed stroke risk.

Figure 3: Correlation of HAS-BLED score and subjective assessed bleeding risk.

Figure 4: Amount of correct answered assessment of stroke risk in patients with different self-assessed levels of information.

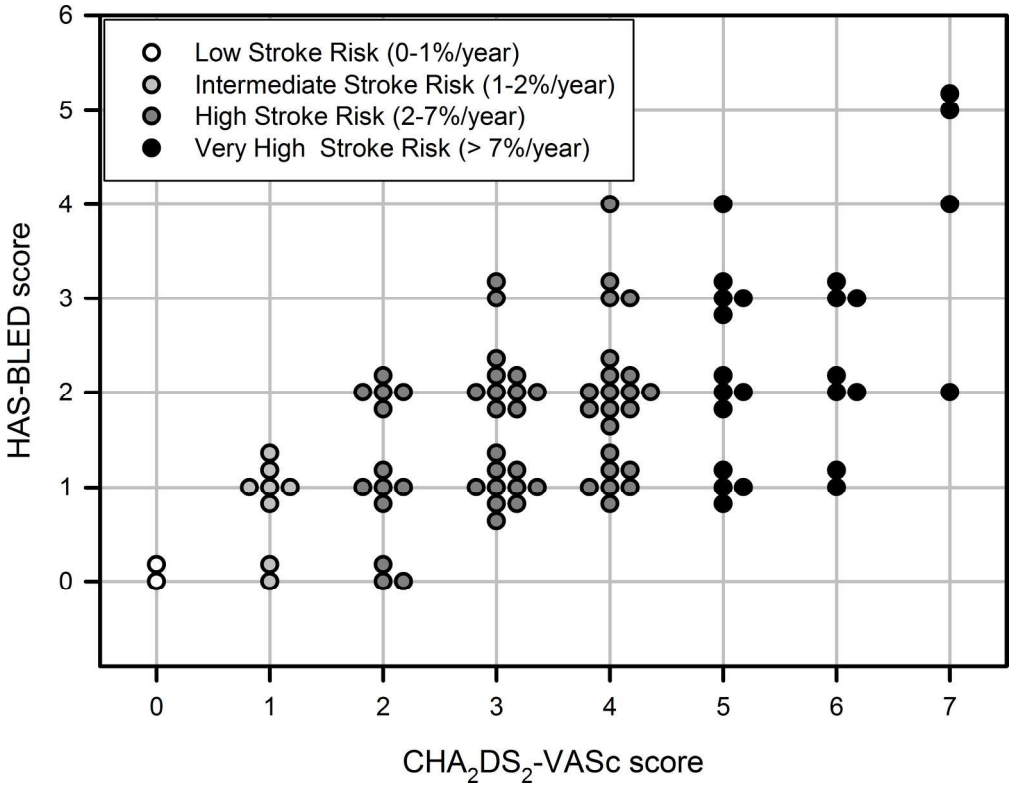

Figure 1: CHA_2DS_2-VASc and HAS-BLED scores of individual patients, including our classification into low, intermediate, high and very high stroke risk groups (stratified by CHA_2DS_2-VASc score).

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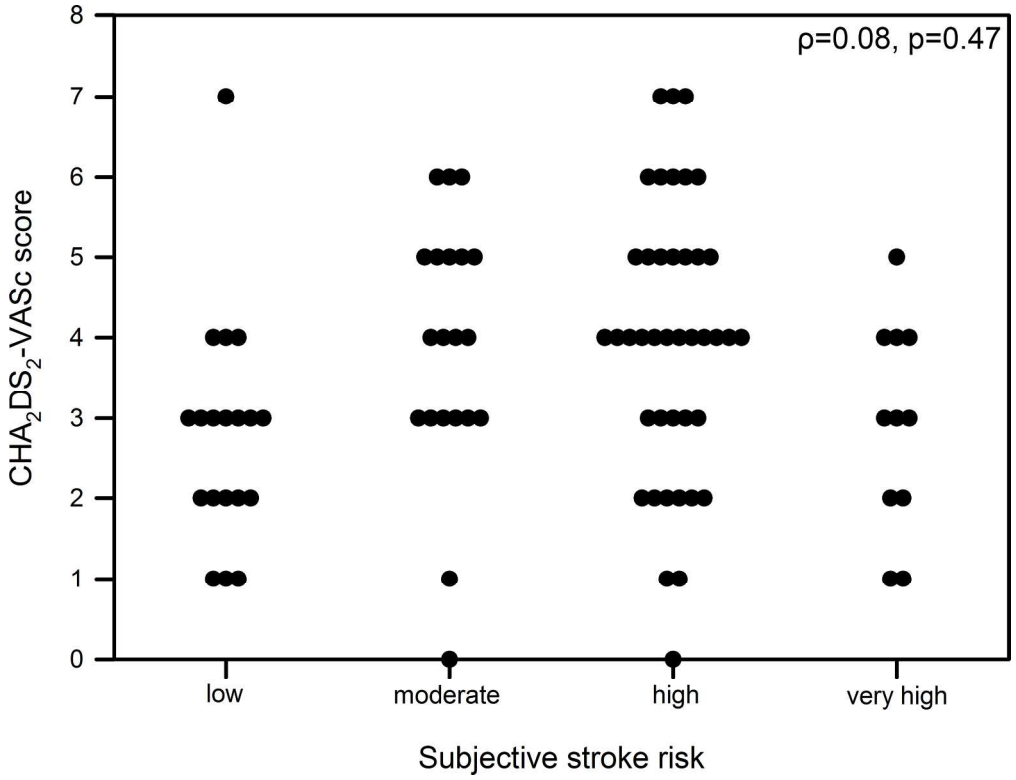

Figure 2: Correlation of CHA_2DS_2-VASc score and subjective assessed stroke risk.

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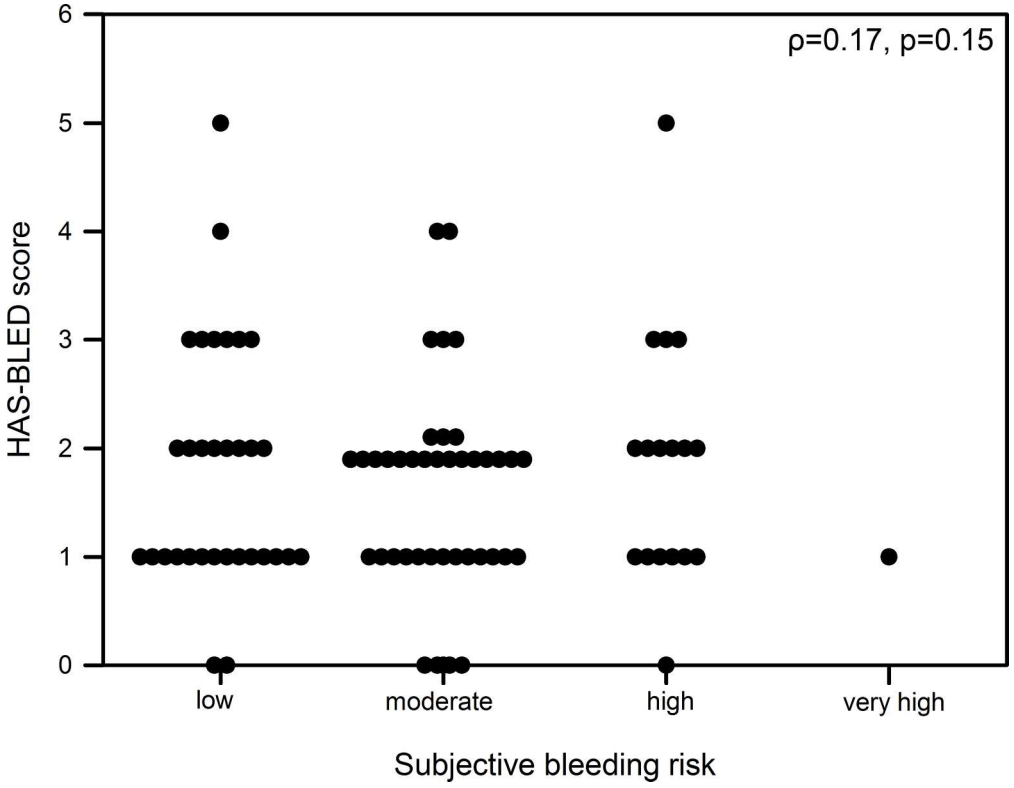

Figure 3: Correlation of HAS-BLED score and subjective assessed bleeding risk.

107x83mm (600 x 600 DPI)

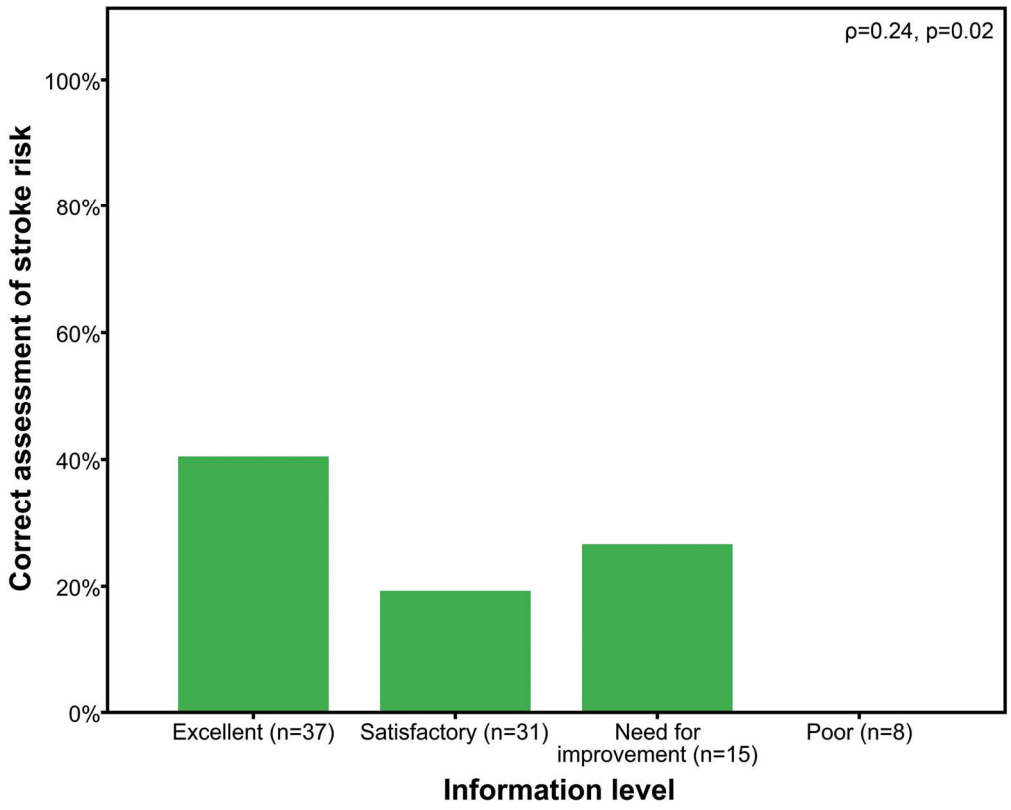

Figure 4: Amount of correct answered assessment of stroke risk in patients with different self-assessed levels of information.

162x129mm (300 x 300 DPI)

Association between subjective risk perception and objective risk estimation in atrial fibrillation patients: a cross-sectional study.

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Supplemental material

Supplemental tables

Part I: To be completed by the patient
1) How do you judge the risk of stroke without anticoagulation? a) Low b) Intermediate c) High d) Very high
2) How do you judge the efficacy of the proposed therapy? How strong is the effect of anticoagulation to avoid a stroke? a) Low b) Intermediate c) High d) Very high
3) The bleeding risk depends on comorbidities. How to you judge the risk of severe haemorrhagic complications within one year? a) Low b) Intermediate c) High d) Very high
4) How do you judge the disadvantages of treatment? How do you think increases the risk of severe haemorrhage if you take your medication appropriately? a) Low b) Intermediate c) High d) Very high

5) Would you discontinue anticoagulation therapy if minor bleedings would occur (e.g. haematoma, epistaxis, gum bleeding)
   a) Yes
   b) No
   c) I don't know

6) What do you fear more: stroke or bleeding complications?
   a) Stroke
   b) Bleeding
   c) I don't know

7) How do judge your general level of information regarding the disease "Atrial fibrillation" and the proposed therapy?
   a) Good
   b) Okay
   c) Improvable
   d) Bad

Part II: To be completed by the physician

1) Demographics
   a) Age (years):
   b) Gender: female/male
   c) Education: compulsory school/apprenticeship/vocational school/grammar school/vocational school with higher entrance qualification/university of applied sciences/university of general sciences

2) Planned type of anticoagulation
   a) Vitamin K antagonist (VKA)
   b) NOAC

c) Low molecular weight heparin

d) Combination with antiplatelet

3) CHA_2DS_2-VASc score

a) C = Congestive heart failure / LV dysfunction

b) H = Hypertension

c) A_2 = Age ≥ 75 years

d) D = Diabetes mellitus

e) S_2 = Stroke/TIA/thrombo-embolism

f) V = Vascular disease

g) A = Age 65-74 years

h) S = Sex category (i.e. female sex)

4) HAS-BLED Score

a) H = Uncontrolled hypertension (systolic blood pressure > 160 mmHg)

b) A = Abnormal renal function (presence of chronic dialysis or renal transplantation or serum creatinine ≥200 mmol/L) or abnormal liver function (chronic hepatic disease [e.g. cirrhosis] or biochemical evidence of significant hepatic derangement [e.g. bilirubin 2 x upper limit of normal, in association with aspartate aminotransferase/alanine aminotransferase/alkaline phosphatase .3 x upper limit normal]) (1 point each)

c) S = Stroke

d) B = Bleeding (previous bleeding history and/or predisposition to bleeding, e.g. bleeding diathesis, anaemia)

e) L = Labile INRs (unstable/high INRs or poor time in therapeutic range [e.g. < 60%])

f) D = Drugs or alcohol (concomitant use of drugs, such as antiplatelet agents, non-steroidal anti-inflammatory drugs, or alcohol abuse) (1 point each)

Supplemental table S1. Questionnaire (English translation). LV: left ventricle; TIA: transitory ischaemic attack; INR: international normalized range

Patients per centre	
LKH Feldbach, Department of Internal Medicine	36 (40%)
Medical University of Graz, Division of Cardiology	18 (20%)
BHB Graz-Marschallgasse, Department of Internal Medicine	9 (10%)
KH Elisabethinen Graz, Department of Internal Medicine	8 (9%)
LKH Feldbach, Department of Neurology	6 (7%)
LKH Fürstenfeld, Department of Internal Medicine	5 (6%)
LKH Hartberg, Department of Internal Medicine	5 (6%)
BHB Graz-Eggenberg, Department of Internal Medicine	2 (2%)
Zweiker, MD, General Practitioner	2 (2%)
Highest completed education (ISCED level)	
Lower secondary education (2)	32 (35%)
Upper secondary vocational education (3B)	25 (28%)
Upper secondary general education (3A)	8 (9%)

Upper secondary vocational education (3C)	4 (4%)
Tertiary general education (5A)	3 (3%)
Post-secondary non-tertiary vocational education (4A)	2 (2%)
Tertiary vocational education (5A)	1 (1%)

Supplemental table S2. Demographics of included patients. ISCED: International Standard Classification of Education.

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	Information can be found in page
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	Abstract
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	Abstract
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	6-7
Objectives	3	State specific objectives, including any prespecified hypotheses	7
Methods			
Study design	4	Present key elements of study design early in the paper	8
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	8-10
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	8
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	Not applicable
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	8-10
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	8-10
Bias	9	Describe any efforts to address potential sources of bias	17
Study size	10	Explain how the study size was arrived at	10
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	8
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	9
		(*b*) Describe any methods used to examine subgroups and interactions	10
		(*c*) Explain how missing data were addressed	10
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up	10

		was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy	
		(*e*) Describe any sensitivity analyses	10
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	11
		(b) Give reasons for non-participation at each stage	11
		(c) Consider use of a flow diagram	Not applicable
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	10
		(b) Indicate number of participants with missing data for each variable of interest	11-13
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	Not applicable
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	Not applicable
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	Not applicable
		Cross-sectional study—Report numbers of outcome events or summary measures	11-13
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	11-13
		(*b*) Report category boundaries when continuous variables were categorized	11-13
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	Not relevant
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Not applicable
Discussion			
Key results	18	Summarise key results with reference to study objectives	14-17
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	17
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	14-17
Generalisability	21	Discuss the generalisability (external validity) of the study results	14-17
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Transparency declaration

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.