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Self-perception of cardiovascular disease risk among smokers

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References: 19

Abstract

Objectives: Previous studies suggest that smokers have a misperception of their 10-year cardiovascular risk. We aimed to compare 10-year cardiovascular risk self-perception and calculated risk among smokers willing to quit and assess the determinants of a possible misperception.

Design: Cross-sectional analysis of the baseline data of a randomized controlled trial

Participants: 514 participants, mean age 51.1 years, 46% women, 98% Caucasian. Eligible participants were regular smokers, aged between 40 and 70 years, with a consumption of at least 10 cigarettes per day for at least a year. None of them had experienced CVD before. Exclusion criteria comprised history of myocardial infarction, coronary heart disease (CHD), stroke, heart failure, peripheral vascular disease, carotid atherosclerosis or cardiac arrhythmia. Participants with renal or liver failure, psychiatric disorders, substance and alcohol abuse and with smoking cessation therapies were excluded.

Interventions: Participants were asked to estimate their 10-year cardiovascular risk using a 3-item scale corresponding to high, moderate and low risk categories. We compared their risk perception with the Framingham and Procam score. We used multi-variable adjusted logistic regression models to determine characteristics of participants who underestimate their risk vs. those who correctly or overestimate it.

Results: Between 38-42% of smokers correctly perceived their 10-year cardiovascular risk, 39-50% overestimated their 10-year cardiovascular risk while 12-19% underestimated it compared to their calculated 10-year cardiovascular risk depending on the score used. Underestimation of 10-year cardiovascular risk was associated with male gender (OR 8.16; CI 3.83-17.36), age (OR 1.06; CI 1.02-1.09), hyperlipidemia (OR 2.71; CI 1.47-5.01) and diabetes mellitus (OR 13.93; CI 3.83-50.66).

Conclusions: Among smokers, misperception of their 10-year cardiovascular risk is common, with one fifth underestimating it. These findings may help physicians target patients with such characteristics to help them change their health behavior and adherence to risk-reduction therapy.

Strengths and limitations of this study

- This study carefully assessed self-perceived CVD risk among smokers and compared self-perception with two validated cardiovascular scores.
- The study highlights determinants of underestimation of CVD risk among smokers: male gender, age, hyperlipidemia and diabetes mellitus.
- The analyses are restricted to smokers and no comparison is possible between CVD perception of smokers, non smokers or former smokers.

INTRODUCTION

Cardiovascular disease (CVD) is the leading cause of death worldwide. Ischemic heart disease and stroke are responsible for 13.2 % and 11.9 % of deaths, respectively[1]. Smoking is the most important modifiable risk factor for CVD and smoking cessation prevents cardiovascular mortality and morbidity in a rapid and effective manner[2]. Thus, the main strategy for CVD prevention is based on controlling modifiable risk factors such as smoking through population-wide interventions. These include smoking bans in public places, tax raises on cigarette packs as well as individual health-care interventions like counseling and medication for smokers willing to quit in primary prevention.

An adequate perception of cardiovascular disease risk might be required to better understand the goal of preventive interventions and adhere to CVD prevention. Studies assessing CVD risk using questionnaires, registration form, visual analogue scale and self-rated measurements, conducted in general practices by Frijling[3] and van der Weijden[4], have suggested that smoking predicted higher levels of risk perception. Smokers' perception of health risks is complex and underestimation or overestimation of CVD risk depends on how risk perception is assessed[5]. For instance, Weinstein et al.[5] have reported that smokers consistently acknowledged that smoking increased their risk of developing heart disease, lung cancer, bronchitis and stroke but within a smaller range compared with non-smokers. Furthermore, smokers tended to minimize their health risks. Individual misperception of smokers has also been described in another study that showed that only a minority of smokers (29 to 39%) perceived themselves at higher risk than the average for myocardial infarction[6]. One could argue that smoking, as part of a complex addiction mechanism, might be the cause of misperception but CVD risk is also difficult to assess for experimented physicians and young doctors[7]. To our knowledge, few studies focused on CDV risk perception among

smokers[3,4], and little or no information about CVD risk (calculated by scores) was provided.

Prediction scores such as Framingham[8], Procam[9], or the European Scores[10] have been developed to estimate the 10-year CVD risk. These prediction models are increasingly used to identify high-risk patients who would benefit from interventions on one or several risk factors and to motivate others to adhere to risk-reduction therapy. Based on previous publications, the Procam score seems to be the most appropriate score in Switzerland [9,11]. However the Framingham score is still often used for clinical or research purposes (it is the one used in International Lipid guidelines[12]) despite its tendency to overestimate the cardiovascular risk in European populations.

Awareness of cardiovascular disease risk associated with cigarette smoking might have changed during the last two decades with more prevention and information campaigns. Moreover, whether smokers have a correct perception of their own CVD risk compared with calculated CVD risk prediction scores has never been assessed and little is known about determinants that could explain the potential misperception of smokers.

The primary objective of this study was to assess the accuracy of perception of CVD risk among smokers and identify determinants associated with potential misperception in a single-center study conducted with smokers in Switzerland.

METHODS

Study population

We did a cross-sectional analysis of the baseline data of the CAROSS study, a randomized controlled trial assessing the effect of carotid plaque screening on smoking cessation[13]. Participants were recruited in the general population using advertisements in newspaper.

Eligible participants were regular smokers, aged between 40 and 70 years, with a consumption of at least 10 cigarettes per day for at least a year. None of them had experienced CVD before, as exclusion criteria comprised history of myocardial infarction, coronary heart disease (CHD), stroke, heart failure, peripheral vascular disease, carotid atherosclerosis or cardiac arrhythmia. Participants with renal or liver failure, psychiatric disorders, substance and alcohol abuse, and those taking smoking cessation therapies were also excluded.

All participants provided written informed consent. The study was approved by the local ethic commission of the University of Lausanne, Switzerland.

Variables of interest

Data on medical and smoking history, home and work environment, education and medication use were collected using questionnaires. Professional activity was initially classified as « Employed », « Unemployed or on social security » and « Retired ». For the need of the multi-variable adjusted analysis and assuming that « Retired » participants where once « Employed », we secondarily merged « Employed » and « Retired » participants and obtained two categories « Employed or retired» and « Unemployed or on social security ». Education was dichotomized by < 12 years and >12 years of education.

Weight and height were measured at baseline as well as blood pressure in a sitting position with an appropriately sized cuff according to guidelines. Fasting glucose and lipids levels were measured at baseline. We defined cardiovascular risk factors as follows: Hypertension as ≥ 140 systolic mmHg and/or 90 diastolic mmHg[14] , except for participants with diabetes mellitus ≥ 130 and/or 80 mmHg; Hyperlipidemia according to ATP-III guidelines[15] as LDL-cholesterol ≥ 2.6 mmol/L, ≥ 3.4 mmol/L, ≥ 4.1 mmol/L for high (>20%), moderate (10-20%) and low (<10%) risk participants, respectively; Diabetes mellitus as fasting blood glucose ≥ 7.0 mmol/L[16].

At baseline, a nurse trained in smoking cessation asked each participant about his or her perception of CVD risk. The question was standardized to avoid influencing the participants and worded as: « How do you perceive your risk of heart attack in 10 years? ». The possible responses were « none or low risk », « intermediate risk », « high risk », « don't know » and « refuse to answer ». Participants who « didn't know » or « refused to answer » were invited once to reconsider their choice. In this study we restricted analysis for participants who answered the self-perceived CVD risk question and had complete baseline data.

To determine the reliability and reproducibility of the CVD risk perception assessment, we asked a consecutive convenience subsample of participants (n=48) to reassess their CVD risk one month after the last evaluation.

We calculated the Framingham scores based on ATP III guidelines[17]. We used the following variables at baseline to calculate the score: sex, age, cholesterol, smoking status, blood pressure, HDL-cholesterol, triglyceridemia and being treated with antihypertensive drugs. Framingham score was then encoded and CVD risk was computed for each participant.

According to Framingham scores, men with scores ≤11 were classified as low risk (10-year risk of cardiovascular events 8%), those with scores between12 and 14 as intermediate risk

(10-year risk of cardiovascular events 10-16%), and those with scores ≥ 15 as high risk (10-year risk of cardiovascular events ≥ 20%). For women, low, intermediate and high risk corresponded to Framingham risk scores of 19 (10-year risk of cardiovascular events 8%), 20-22 (10 year risk of cardiovascular events11-17%) and ≥23 (10 year risk of cardiovascular events ≥ 22%) points respectively.

The following variables at baseline were used to calculate Procam score: sex, age, LDL-cholesterol, HDL-cholesterol, triglyceridemia, blood pressure, diabetes, cardiovascular disease before 60 years old among relatives. Procam score was encoded based on PROCAM study [18]and CVD risk was computed for each participants. Low, intermediate and high risk was defined as 10-year risk of cardiovascular events of < 10%, between 10-20% and ≥ 20% respectively. By convention, women had their risk divided by four.

Statistical Analysis

The primary outcome was misperception of CVD risk. For statistical convenience we merged participants who correctly or overestimated their risk together, believing that correct or overestimation is less detrimental than underestimation in terms of preventive medicine. We compared participants who underestimated their 10-year CVD risk to those who correctly or overestimated it. The comparison between the baseline characteristics of both groups was performed using Chi square tests and Anova or Fisher tests.

We first used uni-variable logistic regression to obtain the odds ratio (OR) and 95% confidence intervals (CI) and identify potential predictors of underestimation, compared to correct or overestimation of 10-year CVD risk. Variables that were significant with a p-value < 0.05 (sex, age, education, working status, hypertension, hyperlipidemia, diabetes,

cardiovascular medication) were then integrated in a multi-variable adjusted analysis. Multi-variable adjusted logistic regression was used to identify variables associated with underestimation of the CVD risk compared with correct or overestimation.

We considered p-values < 0.05 as significant. All data were proceeded with STATA 10 software (StataCorp, College Station; Texas).

RESULTS

The study included 536 participants, amongst whom 22 (4%) had incomplete baseline data (18 without self-perceived CVD risk, and 4 whose high triglycerides prevented calculation of LDL-cholesterol level). Among the 514 remaining participants, 98% were Caucasians and 234 (46%) were female (**Table 1**). Mean age at baseline was 51.1±7.3 years. Most participants were employed or retired (92%) the rest being unemployed or on social security. About two third had lower education (< 12 years; apprenticeship or no formation). Participants were smoking with an average of 24.5 (9.8 SD) cigarettes per day for a mean duration of tobacco smoking of 32.1 (7.9 SD) years, corresponding to 39 (20 SD) pack-years. Two hundred and fifty-eight (50%) participants had hyperlipidemia, whereas 27% had hypertension and 3.5% had diabetes.

Using the Framingham score, half of participants (51%) were classified as low risk at 10 years, 38% as intermediate risk and 11% as high risk (**Table 2A**). Using the Procam risk score the proportion of low risk participant was 76%, medium risk 13% and high risk 11% (**Table 2B**). Participants perceived themselves at low risk for 38% of them, intermediate risk for 34% and high risk for 28% of them, using the self-perceived CVD risk questionnaire. In a

subsample of 48 participants, re-assessment of CVD risk perception (by telephone, one month after the initial evaluation) showed 83% of consistent answers (40/48) (data not shown).

According to Framingham score, less than half of the participants (42%) correctly estimated their CVD risk, 39% overestimated it and 19% underestimated it (**Table 2A**). According to Procam score, 38% correctly estimated their CVD risk, 50% overestimated it and 12% underestimated it (**Table 2B**).

Among high-risk participants, 62-69% underestimated their CVD risk (depending on the score used) whereas 33-34% underestimate it among intermediate risk participants (**Table 2A and 2B**).

Using the Framingham score, male gender (OR 9.45; CI 4.9-18.2), age (OR 1.05; CI 1.02-1.08), body mass index (OR 1.09; CI 1.03-1.14), hyperlipidemia (OR 5.71; CI 3.34-9.76), diabetes (OR 9.27; CI 3.39-25.38) and being on CVD medication (OR 1.75; CI 1.08-2.82) were associated with underestimation of CVD risk in univariate analysis (data not shown). In the multivariable-adjusted analysis, underestimation of CVD risk was associated with male gender (OR 8.16; CI 3.83-17.36), age (OR 1.06; CI 1.02-1.09), hyperlipidemia (OR 2.71; CI 1.47-5.01) and diabetes mellitus (OR 13.93; CI 3.83-50.66) (**Figure 1**). We found no association between underestimation and body mass index, socio-economical status, high blood pressure or being under CVD medication in the multivariable-adjusted analysis. Using the Procam risk score, we found similar results (data not shown).

DISCUSSION

In the present study, between 58% (for the Framingham score) and 62% (for the Procam score) of participants had a misperception of their CVD risk at 10 years. Results were almost similar when low, intermediate and high CVD risk categories were taken separately. A minority of participants (12-19%) underestimated their CVD risk whereas 39%-50% overestimated it, depending of the score used the evaluation of the cardiovascular risk. Only 3% of participants couldn't provide an estimation of their CVD risk.

A majority of participants had inadequate perception of CVD risk, which is consistent with previous studies. In our study, the CVD risk was perceived inappropriately in 62-69% of high CVD risk participants and 57-61% of low risk participant, whereas Van der Weijden et al. found that 80% of high risk and 20% of low risk participants had a misperception of their CVD risk in general practices[4].

The use of the Procam risk score generated a higher proportion of low risk participants compared to the Framingham risk score, but a lower proportion of medium risk participants. The proportion of high risk participants was similar using both scores. As a consequence, compared with Framingham, a smaller proportion of participants underestimated their CVD risk when using the Procam risk score probably reflecting a better accuracy of this score in a European population.

We found that male gender, hyperlipidemia and diabetes were determinants of underestimation of CVD risk. Our results contrast at least with two other studies. Three quarter of participants with hypertension or diabetes overestimated their CVD risk in the study of Frijling et al.[3]. Similarly, Van der Weijden et al.[4] highlighted that men and diabetic participants were more likely to perceive their CVD risk inappropriately. Participants in our study responded to an advertisement inviting them to a study to help them quit smoking

whereas Frijling et al. gave questionnaires to patients visiting general office who fulfilled inclusion criteria. The fact that the participants to our study needed to actively respond to an advertisement in order to be recruited, might explain why motivation, as well as health awareness, might have been higher in the participants of the present study. This could also explain the low percentage of participants who failed to provide an estimation (correct or wrong) of their CVD risk.

Interestingly, more participants overestimated their CVD risk (too pessimistic) than underestimated it in our study. Nonetheless, we decided to focus on those who underestimated their CVD risk (too optimistic), assuming it to be more detrimental than overestimation. In our opinion, underestimation of CVD risk might decrease compliance to treatment or lifestyle modifications as well as reduce the efficacy of primary prevention and thus increase the absolute risk of CVD event. Overestimation may cause increased stress, medical seeking or overmedication, which can affect the quality of life rather than the absolute CVD risk.

To our surprise, diabetes was a determinant of underestimation of CVD risk, even though participants with diabetes presumably have had regular medical interaction and lifestyle education. However, caution is advised considering the small proportion of diabetic participants (4%) in our study. Hyperlipidemia was also a determinant of underestimation whereas other CVD risk factors such as high blood pressure or BMI were not associated with underestimation. Finally male gender was also associated with higher odds of underestimation. Studies suggest that men are less health conscious compared with women and might be less susceptible to seek medical help [19].

Our study carefully assessed self-perceived CVD risk among smokers and compared it with two validated calculated risk score. However, because our study was limited to current smokers, we could not compare smokers' misperception to that of non-smokers or former

smokers. It would be interesting to assess risk perception among non-smokers in our general population to better contrast CVD risk perception between smokers and non-smokers.

Clinicians widely use clinical scores to estimate CVD risk in order to discuss primary prevention. This approach is only efficient when patients understand and adhere to risk reduction therapy. Smokers represent a challenge for general practitioners due to strong nicotine dependence and denial of personal risk from smoking (optimistic bias)[6].

We found that 12- 19% of smokers have a misperception of their 10-year CVD risk in the form of an underestimation, which may hinder the efficiency of interventions aimed at reducing or preventing CVD risk factors. This could lead to an increase in morbidity and mortality. Therefore clinicians must be aware that about a fifth of smokers underestimate their 10-year CVD risk and that men as well as people suffering from hyperlipidemia or diabetes, are at increasing risk of underestimating their 10-year CVD risk.

CONTRIBUTORSHIP STATEMENT

Study concept and design: Rodondi, Collet, Cornuz and Desgraz. *Acquisition of data:* Rodondi and the CARROSS study team *Analysis and interpretation of data:* Desgraz, Collet, Clair. *Drafting of manuscript:* Desgraz. *Critical revision of the manuscript for important intellectual content:* Clair, Collet, Rodondi, Cornuz. *Statistical analysis:* Collet, Desgraz *Administrative, technical and material support:* Rodondi, Cornuz *Study supervision:* Clair, Collet

COMPETING INTERESTS

The authors declare that they do not have any conflict of interest.

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DATA SHARING STATEMENT

All illustrations and figures in the manuscript are entirely original and do not require reprint permission. There is no additional unpublished data.

PREVIOUS PRESENTATION

Intermediate results were presented at SGIM meeting in Orlando, in May 2012.

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Legends for Tables:

* Full time, part time, independent or at home

† Low Blood Pressure defined as < 140/90 mmHg; High Blood Pressure defined as ≥140 and/or 90, ≥130 and/or 80mmHg if diabetic

‡ Definition: treated patient (statin of fibrate); High Risk: LDL-Chol ≥ 2.6 mmol/L; Intermediate Risk: LDL-Chol ≥ 3.4 mmol/L; Low Risk: LDL-Chol ≥ 4.1 mmol/L

§ Fasting Glycemia ≥ 7 mmol/L or Glycemia ≥ 11.1 mmol/L

1

Table 1 : Characteristics of study participants

	Overall (n=514)	
Demographics		
Age (years), mean ± SD	51.1	**7.3**
Women nbr, %	234	**45.5**
Education nbr, %		
< 12 years	381	**74.1**
> 12 years	133	**25.9**
Professional activity nbr, %		
Employed*	433	**84.2**
Unemployed or on social security	40	**7.8**
Retired	41	**8.0**
Cardiovascular medication nbr, %		
No treatment	390	**75.9**
Aspirine, statine, anti-HTA, anti-Diabetic	124	**24.1**
Cardiovascular variables		
Systolic Blood Pressure mmHg ± SD	123.0	**15.4**
Systolic Blood Pressure (per 10 mmHg)		
Categories nbr, %		
Low Blood Pressure†	376	**73.2**
High Blood Pressure†	138	**26.8**
BMI mean ± SD	24.9	**4.1**
Dyslipidemia‡ nbr, %	258	**50.2**
treated nbr, %	60	**11.7**
Diabetes type 2§ nbr, %	18	**3.5**
Tobacco smoking		
Number of cigarettes per day mean ± SD	24.5	**9.8**
Number of pack-years py ± SD	39	**20**
Fagerström Score for nicotine dependence mean ± SD (0 low dependence - 10 very high dependence)	5.0	**2.1**

Table 2 A:

Meshing table between perceived CVD risk and calculated CVD risk according to Framingham score. Numbers in absolute; () is percentage of total, in column.

Perceived CV risk T0	Framingham risk score			
	Low	Intermediate	High	Total
Low risk	111	64	22	197 (38.3)
Intermediate risk	79	81	14	174 (33.8)
High risk	70	51	22	143 (27.8)
Total	260 (50.5)	196 (38.1)	58 (11.2)	514 (100)

Underestimated CVD risk	19%
Correctly estimated CVD risk	42%
Overestimated CVD risk	39%

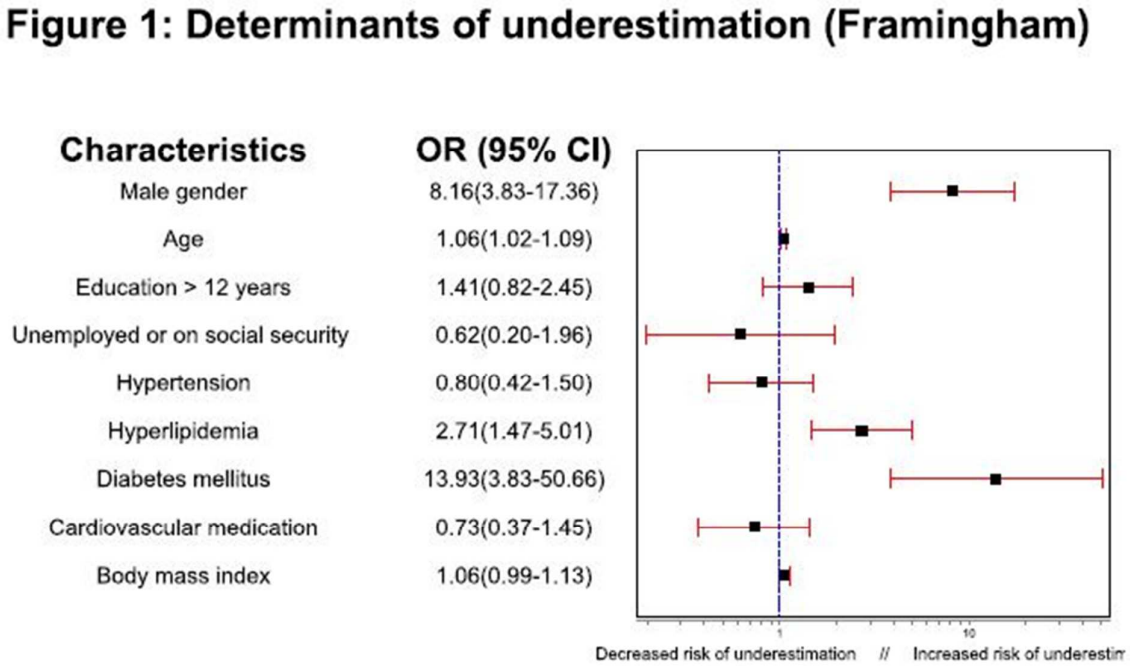
Table 2 B:

Meshing table between perceived CVD risk and calculated CVD risk according to Procam score. Numbers in absolute; () is percentage of total, in column.

Perceived CV risk T0	Procam risk score			Total
	Low	Intermediate	High	
Low risk	153	23	21	197 (38.3)
Intermediate risk	130	27	17	174 (33.8)
High risk	109	17	17	143 (27.8)
Total	392 (76.3)	67 (13.0)	55 (10.7)	514 (100)

Underestimated CVD risk	12%
Correctly estimated CVD risk	38%
Overestimated CVD risk	50%

Figure 1: Determinants of underestimation according to Framingham



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

	Item No	Recommendation	STATUS
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	Done (in abstract page 3)
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	Done
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Done (page 6-7)
Objectives	3	State specific objectives, including any prespecified hypotheses	Done (page 7 last paragraph)
Methods			
Study design	4	Present key elements of study design early in the paper	Done (page 8)
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Done (page 8, study pop.)
Participants	6	*Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	Done
		(*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	NA
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Done (page 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	Done (page 8-10)
Bias	9	Describe any efforts to address potential sources of bias	Done Multivariable model page 11)
Study size	10	Explain how the study size was arrived at	NA (secondary analyses of a RCT)
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Done (see methods)
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	Done (page 10-11)
		(*b*) Describe any methods used to examine subgroups and interactions	NA
		(*c*) Explain how missing data were addressed	Done (results page 11)

Cross-sectional study—If applicable, describe analytical methods taking account of sampling strategy	NA
(*e*) Describe any sensitivity analyses	NA

Continued on next page

Results			STATUS
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	Done (results page 11)
		(b) Give reasons for non-participation at each stage	Done
		(c) Consider use of a flow diagram	Not provided
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Done (results page 11)
		(b) Indicate number of participants with missing data for each variable of interest	Done page 11
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	NA
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	NA
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	NA
		Cross-sectional study—Report numbers of outcome events or summary measures	Done (page 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	Done (page 12)
		(*b*) Report category boundaries when continuous variables were categorized	NA
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	NA
Discussion			
Key results	18	Summarise key results with reference to study objectives	Done (page 13)
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	Done (page 14-15)
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Done
Generalisability	21	Discuss the generalisability (external validity) of the study results	Done
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	Done (page 16)

*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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Self-perception of cardiovascular disease risk among smokers

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Self-perception of cardiovascular disease risk among smokers

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Abstract

Objectives: Previous studies suggest that smokers have a misperception of their 10-year cardiovascular risk. We aimed to compare 10-year cardiovascular risk self-perception and calculated risk among smokers willing to quit and assess the determinants of a possible misperception.

Design: Cross-sectional secondary analysis of baseline data from a randomized controlled trial of smoking cessation.

Participants: 514 participants, mean age 51.1 years, 46% women, 98% Caucasian. Eligible participants were regular smokers, aged between 40 and 70 years, with a consumption of at least 10 cigarettes per day for at least a year. None of them had experienced CVD before. Exclusion criteria comprised history of myocardial infarction, coronary heart disease (CHD), stroke, heart failure, peripheral vascular disease, carotid atherosclerosis or cardiac arrhythmia. Participants with renal or liver failure, psychiatric disorders, substance and alcohol abuse and with smoking cessation therapies were excluded.

Interventions: Participants were asked to estimate their 10-year cardiovascular risk using a 3-item scale corresponding to high, moderate and low risk categories. We compared their risk perception with the Framingham and Procam score. We used multi-variable adjusted logistic regression models to determine characteristics of participants who underestimate their risk vs. those who correctly or overestimate it.

Results: Between 38-42% of smokers correctly perceived their 10-year cardiovascular risk, 39-50% overestimated their 10-year cardiovascular risk while 12-19% underestimated it compared to their calculated 10-year cardiovascular risk depending on the score used. Underestimation of 10-year cardiovascular risk was associated with male gender (OR 8.16; CI

3.83-17.36), older age (OR 1.06; CI 1.02-1.09), and the presence of hyperlipidemia (OR 2.71; CI 1.47-5.01) and diabetes mellitus (OR 13.93; CI 3.83-50.66).

Conclusions: Among smokers, misperception of their 10-year cardiovascular risk is common, with one fifth underestimating it. These findings may help physicians target patients with such characteristics to help them change their health behavior and adherence to risk-reduction therapy.

Strengths and limitations of this study

- This study carefully assessed self-perceived CVD risk among smokers and compared self-perception with two validated cardiovascular scores in a cross-sectional secondary data analysis of baseline data collected in a randomized controlled trial assessing the effect of carotid plaque screening on smoking cessation.
- The study highlights predictors of underestimation of CVD risk among smokers: male gender, older age, and the presence of hyperlipidemia and diabetes mellitus.
- The analyses are restricted to smokers and no comparison is possible between CVD perception of smokers, non smokers or former smokers.

INTRODUCTION

Cardiovascular disease (CVD) is the leading cause of death worldwide. Ischemic heart disease and stroke are responsible for 13.2 % and 11.9 % of deaths, respectively[1]. Smoking is the most important modifiable risk factor for CVD and smoking cessation prevents cardiovascular mortality and morbidity in a rapid and effective manner[2]. Thus, the main strategy for CVD prevention is based on controlling modifiable risk factors such as smoking through population-wide interventions. These include smoking bans in public places, tax raises on cigarette packs as well as individual health-care interventions like counseling and medication for smokers willing to quit in primary prevention.

An adequate perception of cardiovascular disease risk might be required to better understand the goal of preventive interventions and adhere to CVD prevention. Studies assessing CVD risk using questionnaires, registration form, visual analogue scale and self-rated measurements, conducted in general practices by Frijling[3] and van der Weijden[4], have suggested that smoking predicted higher levels of risk perception. Smokers' perception of health risks is complex and underestimation or overestimation of CVD risk depends on how risk perception is assessed[5]. For instance, Weinstein et al.[5] have reported that smokers consistently acknowledged that smoking increased their risk of developing heart disease, lung cancer, bronchitis and stroke but within a smaller range compared with non-smokers. Furthermore, smokers tended to minimize their health risks. Individual misperception of smokers has also been described in another study that showed that only 29 to 39% of smokers perceived themselves at higher risk than the average for myocardial infarction[6]. One could argue that smoking, as part of a complex addiction mechanism, might be the cause of misperception but CVD risk is also difficult to assess for physicians [7]. To our knowledge,

few studies focused on CDV risk perception among smokers[3,4], and little or no information about CVD risk (calculated by scores) was provided.

Prediction scores such as Framingham[8], Procam[9], or the European Scores[10] have been developed to estimate the 10-year CVD risk. These prediction models are increasingly used to identify high-risk patients who would benefit from interventions on one or several risk factors and to motivate others to adhere to risk-reduction therapy. Based on previous publications, the Procam score seems to be the most appropriate score in Switzerland [9,11]. However the Framingham score is still often used for clinical or research purposes (it is the one used in International Lipid guidelines[12]) despite its tendency to overestimate the cardiovascular risk in European populations.

Awareness of cardiovascular disease risk associated with cigarette smoking might have changed during the last two decades with more prevention and information campaigns. Moreover, whether smokers have a correct perception of their own CVD risk compared with calculated CVD risk prediction scores has never been assessed and little is known about determinants that could explain the potential misperception of smokers.

The primary objective of this study was to assess the accuracy of perception of CVD risk among smokers and identify determinants associated with potential misperception in a single-center study conducted with smokers in Switzerland.

METHODS

Study population

We did a cross-sectional secondary analysis of the baseline data of the CAROSS trial, a randomized controlled trial assessing the effect of carotid plaque screening on smoking cessation [13]. Participants were recruited in the general population using advertisements in newspaper in multiple recruitment waves.

Eligible participants were regular smokers, aged between 40 and 70 years, with a consumption of at least 10 cigarettes per day for at least a year and no periods of smoking abstinence of at least 3 months in the previous year. None of them had experienced CVD before, as exclusion criteria comprised history of myocardial infarction, coronary heart disease (CHD), stroke, heart failure, peripheral vascular disease, carotid atherosclerosis or cardiac arrhythmia. Participants with renal or liver failure, psychiatric disorders, substance and alcohol abuse, and those taking smoking cessation therapies were also excluded.

All participants provided written informed consent. The study was approved by the local ethic commission of the University of Lausanne, Switzerland.

Variables of interest

Data on medical and smoking history, home and work environment, education and medication use were collected using questionnaires. Professional activity was initially classified as « Employed », « Unemployed or on social security » and « Retired ». For the need of the multi-variable adjusted analysis and assuming that « Retired » participants where once « Employed », we secondarily merged « Employed » and « Retired » participants and

obtained two categories « Employed or retired» and « Unemployed or on social security ». Education was dichotomized by < 12 years and ≥ 12 years of education. Both of these variables were used as a proxy for socio-economic status.

Weight and height were measured at baseline as well as blood pressure in a sitting position with an appropriately sized cuff according to guidelines. Fasting glucose and lipids levels were measured at baseline. We defined cardiovascular risk factors as follows: Hypertension as ≥ 140 systolic mmHg and/or 90 diastolic mmHg[14] , except for participants with diabetes mellitus ≥ 130 and/or 80 mmHg; Hyperlipidemia according to ATP-III guidelines[15] as LDL-cholesterol ≥ 2.6 mmol/L, ≥ 3.4 mmol/L, ≥ 4.1 mmol/L for high (>20%), moderate (10-20%) and low (<10%) risk participants, respectively; Diabetes mellitus as fasting blood glucose ≥ 7.0 mmol/L[16].

At baseline, a nurse trained in smoking cessation asked each participant about his or her perception of CVD risk. The question was standardized to avoid influencing the participants and worded as: « How do you perceive your risk of heart attack in 10 years? ». The possible responses were « none or low risk », « intermediate risk », « high risk », « don't know » and « refuse to answer ». Participants who « didn't know » or « refused to answer » were invited once to reconsider their choice. In this study we restricted analysis for participants who answered the self-perceived CVD risk question and had complete baseline data.

To determine the reliability and reproducibility of the CVD risk perception assessment, we asked a consecutive convenience subsample of participants (n=48) to reassess their CVD risk one month after the last evaluation.

We calculated the Framingham scores based on ATP III guidelines[17]. We used the following variables at baseline to calculate the score: sex, age, cholesterol, smoking status,

blood pressure, HDL-cholesterol, triglyceridemia and being treated with antihypertensive drugs. Framingham score was then encoded and CVD risk was computed for each participant.

According to Framingham scores, men with scores ≤11 were classified as low risk (10-year risk of cardiovascular events 8%), those with scores between12 and 14 as intermediate risk (10-year risk of cardiovascular events 10-16%), and those with scores ≥ 15 as high risk (10-year risk of cardiovascular events ≥ 20%). For women, low, intermediate and high risk corresponded to Framingham risk scores of 19 (10-year risk of cardiovascular events 8%), 20-22 (10 year risk of cardiovascular events11-17%) and ≥23 (10 year risk of cardiovascular events ≥ 22%) points respectively.

The following variables at baseline were used to calculate Procam score: sex, age, LDL-cholesterol, HDL-cholesterol, triglyceridemia, blood pressure, diabetes, cardiovascular disease before 60 years old among relatives. Procam score was encoded based on PROCAM study [18]and CVD risk was computed for each participants. Low, intermediate and high risk was defined as 10-year risk of cardiovascular events of < 10%, between 10-20% and ≥ 20% respectively. By convention, women had their risk divided by four.

Statistical Analysis

The primary outcome was misperception of CVD risk. For statistical convenience we merged participants who correctly or overestimated their risk together, believing that correct or overestimation is less detrimental than underestimation in terms of preventive medicine. We compared participants who underestimated their 10-year CVD risk to those who correctly or overestimated it. The comparison between the baseline characteristics of both groups was performed using Chi square tests and Anova or Fisher tests.

We first used uni-variable logistic regression to obtain the odds ratio (OR) and 95% confidence intervals (CI) and identify potential predictors of underestimation, compared to correct or overestimation of 10-year CVD risk. Variables that were significant with a p-value < 0.05 (sex, age, education, working status, hypertension, hyperlipidemia, diabetes, cardiovascular medication) were then integrated in a multi-variable adjusted analysis. Multi-variable adjusted logistic regression was used to identify variables associated with underestimation of the CVD risk compared with correct or overestimation.

We considered p-values < 0.05 as significant. All data were proceeded with STATA 10 software (StataCorp, College Station; Texas).

RESULTS

The study included 536 participants, amongst whom 22 (4%) had incomplete baseline data (18 without self-perceived CVD risk, and 4 whose high triglycerides prevented calculation of LDL-cholesterol level). Among the 514 remaining participants, 98% were Caucasians and 234 (46%) were female (**Table 1**). Mean age at baseline was 51.1±7.3 years. Most participants were employed or retired (92%) the rest being unemployed or on social security. About two third had lower education (< 12 years; apprenticeship or no formation). Participants were smoking with an average of 24.5 (9.8 SD) cigarettes per day for a mean duration of tobacco smoking of 32.1 (7.9 SD) years, corresponding to 39 (20 SD) pack-years. Two hundred and fifty-eight (50%) participants had hyperlipidemia, whereas 27% had hypertension and 3.5% had diabetes.

Using the Framingham score, half of participants (51%) were classified as low risk at 10 years, 38% as intermediate risk and 11% as high risk (**Table 2A**). Using the Procam risk score the proportion of low risk participant was 76%, medium risk 13% and high risk 11% (**Table 2B**). Participants perceived themselves at low risk for 38% of them, intermediate risk for 34% and high risk for 28% of them, using the self-perceived CVD risk questionnaire. In a subsample of 48 participants, re-assessment of CVD risk perception (by telephone, one month after the initial evaluation) showed 83% of consistent answers (40/48) (data not shown).

According to Framingham score, less than half of the participants (42%) correctly estimated their CVD risk, 39% overestimated it and 19% underestimated it (**Table 2A**). According to Procam score, 38% correctly estimated their CVD risk, 50% overestimated it and 12% underestimated it (**Table 2B**).

Among high-risk participants, 62-69% underestimated their CVD risk (depending on the score used) whereas 33-34% underestimate it among intermediate risk participants (**Table 2A and 2B**).

Using the Framingham score, male gender (OR 9.45; CI 4.9-18.2), older age (OR 1.05; CI 1.02-1.08), body mass index (OR 1.09; CI 1.03-1.14), hyperlipidemia (OR 5.71; CI 3.34-9.76), diabetes (OR 9.27; CI 3.39-25.38) and being on CVD medication (OR 1.75; CI 1.08-2.82) were associated with underestimation of CVD risk in univariate analysis (data not shown). In the multivariable-adjusted analysis, underestimation of CVD risk was associated with male gender (OR 8.16; CI 3.83-17.36), older age (OR 1.06; CI 1.02-1.09), hyperlipidemia (OR 2.71; CI 1.47-5.01) and diabetes mellitus (OR 13.93; CI 3.83-50.66) (**Figure 1**). We found no association between underestimation and body mass index, socio-

economical status, hypertension or being under CVD medication in the multivariable-adjusted analysis. Using the Procam risk score, we found similar results (Table 3).

DISCUSSION

In the present study, between 58% (for the Framingham score) and 62% (for the Procam score) of participants had a misperception of their CVD risk at 10 years. Results were almost similar when low, intermediate and high CVD risk categories were taken separately. A minority of participants (12-19%) underestimated their CVD risk whereas 39%-50% overestimated it, depending of the score used the evaluation of the cardiovascular risk. Only 3% of participants couldn't provide an estimation of their CVD risk.

A majority of participants had inadequate perception of CVD risk, which is consistent with previous studies. In our study, the CVD risk was perceived inappropriately in 62-69% of high CVD risk participants and 57-61% of low risk participant, whereas Van der Weijden et al. found that 80% of high risk and 20% of low risk participants had a misperception of their CVD risk in general practices[4].

The use of the Procam risk score generated a higher proportion of low risk participants compared to the Framingham risk score, but a lower proportion of medium risk participants. The proportion of high risk participants was similar using both scores. As a consequence, compared with Framingham, a smaller proportion of participants underestimated their CVD risk when using the Procam risk score (61 vs 100 participants respectively) probably reflecting a better accuracy of this score in a European population. Table 3 compares the determinants of underestimation of the cardiovascular risk as calculated with the Framingham or the Procam scores. Of note, important differences between confidence intervals width

occurs in male gender and diabetes variables in Procam compared to Framingham. Interestingly, these 2 variables remain statistically significant even though the strengths of association were less robust mainly due to the smaller proportion of participants in Procam and the few diabetic patients of our study (n=18). In fact, both of these scores consider type 2 diabetes as a high CVD risk regardless of other factors. Thus, diabetic patients were automatically considered in the highest risk category which could explain why diabetes has such a high odds ratio. Further studies in a population with diabetes specifically remain needed.

We found that older age, male gender, hyperlipidemia and diabetes were determinants of underestimation of CVD risk. Our results contrast at least with two other studies. Three quarter of participants with hypertension or diabetes overestimated their CVD risk in the study of Frijling et al.[3]. Similarly, Van der Weijden et al.[4] highlighted that men and diabetic participants were more likely to perceive their CVD risk inappropriately. Participants in our study responded to an advertisement inviting them to a study to help them quit smoking whereas Frijling et al. gave questionnaires to patients visiting general office who fulfilled inclusion criteria. The fact that the participants to our study needed to actively respond to an advertisement in order to be recruited, might explain why motivation, as well as health awareness, might have been higher in the participants of the present study than in the general population of long term smokers who do not want to quit. This could also explain the low percentage of participants who failed to provide an estimation (correct or wrong) of their CVD risk.

Interestingly, more participants overestimated their CVD risk (too pessimistic) than underestimated it in our study. Nonetheless, we decided to focus on those who underestimated

their CVD risk (too optimistic), assuming it to be more detrimental than overestimation. In our opinion, underestimation of CVD risk might decrease compliance to treatment or lifestyle modifications as well as reduce the efficacy of primary prevention and thus increase the absolute risk of CVD event. Overestimation may cause increased stress, medical seeking or overmedication, which can affect the quality of life rather than the absolute CVD risk.

To our surprise, diabetes was a determinant of underestimation of CVD risk, even though participants with diabetes presumably have had regular medical interaction and lifestyle education. However, caution is advised considering the small proportion of diabetic participants (4%) in our study. Hyperlipidemia was also a determinant of underestimation whereas other CVD risk factors such as hypertension or BMI were not associated with underestimation. Finally male gender was also associated with higher odds of underestimation. Studies suggest that men are less health conscious compared with women and might be less susceptible to seek medical help [19].

Our study carefully assessed self-perceived CVD risk among smokers and compared it with two validated calculated risk score. However, because our study was limited to current smokers, we could not compare smokers' misperception to that of non-smokers or former smokers. It would be interesting to assess risk perception among non-smokers in our general population to better contrast CVD risk perception between smokers and non-smokers.

We assessed CVD risk perception asking about the risk of developing a heart attack within 10 years. It would also have been interesting to assess whether the self-perceived risk of heart attack vs stroke would have been different in smokers. However, we used the perceived risk of heart attack as a proxy for the overall cardiovascular risk and did not collect any data about stroke.

Clinicians widely use clinical scores to estimate CVD risk in order to discuss primary prevention. This approach is only efficient when patients understand and adhere to risk reduction therapy. Smokers represent a challenge for general practitioners due to strong nicotine dependence and denial of personal risk from smoking (optimistic bias)[6].

We found that 12- 19% of smokers have a misperception of their 10-year CVD risk in the form of an underestimation, which may hinder the efficiency of interventions aimed at reducing or preventing CVD risk factors. This could lead to an increase in morbidity and mortality. Therefore clinicians must be aware that about a fifth of smokers underestimate their 10-year CVD risk and that men as well as people suffering from hyperlipidemia or diabetes, are at increasing risk of underestimating their 10-year CVD risk.

CONTRIBUTORSHIP STATEMENT

Study concept and design: Rodondi, Collet, Cornuz and Desgraz. *Acquisition of data:* Rodondi and the CARROSS study team *Analysis and interpretation of data:* Desgraz, Collet, Clair. *Drafting of manuscript:* Desgraz. *Critical revision of the manuscript for important intellectual content:* Clair, Collet, Rodondi, Cornuz. *Statistical analysis:* Collet, Desgraz *Administrative, technical and material support:* Rodondi, Cornuz *Study supervision:* Clair, Collet

COMPETING INTERESTS

None Declared

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DATA SHARING STATEMENT

All illustrations and figures in the manuscript are entirely original and do not require reprint permission. There is no additional unpublished data.

PREVIOUS PRESENTATION

1 Intermediate results were presented at SGIM meeting in Orlando, in May 2012.

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Legends for Tables:

* Full time, part time, independent or at home

† Low Blood Pressure defined as < 140/90 mmHg; High Blood Pressure defined as ≥140 and/or 90, ≥130 and/or 80mmHg if diabetic

‡ Definition: treated patient (statin of fibrate); High Risk: LDL-Chol ≥ 2.6 mmol/L; Intermediate Risk: LDL-Chol ≥ 3.4 mmol/L; Low Risk: LDL-Chol ≥ 4.1 mmol/L

§ Fasting Glycemia ≥ 7 mmol/L or Glycemia ≥ 11.1 mmol/L

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2 **Table 1 : Characteristics of study participants**

	Overall (n=514)	
Demographics		
Age (years), mean ± SD	51.1	**7.3**
Women nbr, %	234	**45.5**
Education nbr, %		
< 12 years	381	**74.1**
≥ 12 years	133	**25.9**
Professional activity nbr, %		
Employed*	433	**84.2**
Unemployed or on social security	40	**7.8**
Retired	41	**8.0**
Cardiovascular medication nbr, %		
No treatment	390	**75.9**
Aspirine, statine, anti-HTA, anti-Diabetic	124	**24.1**
Cardiovascular variables		
Systolic Blood Pressure mmHg ± SD	123.0	**15.4**
Systolic Blood Pressure (per 10 mmHg)		
Categories nbr, %		
Low Blood Pressure†	376	**73.2**
High Blood Pressure†	138	**26.8**
BMI mean ± SD	24.9	**4.1**
Dyslipidemia‡ nbr, %	258	**50.2**
treated nbr, %	60	**11.7**
Diabetes type 2§ nbr, %	18	**3.5**
Tobacco smoking		
Number of cigarettes per day mean ± SD	24.5	**9.8**
Number of pack-years py ± SD	39	**20**
Fagerström Score for nicotine dependence mean ± SD (0 low dependence - 10 very high dependence)	5.0	**2.1**

Table 2 A:

Meshing table between perceived CVD risk and calculated CVD risk according to Framingham score. Numbers in absolute; () is percentage of total, in column.

Perceived CV risk T0	Framingham risk score			Total
	Low	Intermediate	High	
Low risk	111	64	22	197 (38.3)
Intermediate risk	79	81	14	174 (33.8)
High risk	70	51	22	143 (27.8)
Total	260 (50.5)	196 (38.1)	58 (11.2)	514 (100)

Underestimated CVD risk	19%
Correctly estimated CVD risk	42%
Overestimated CVD risk	39%

Table 2 B:

Meshing table between perceived CVD risk and calculated CVD risk according to Procam score. Numbers in absolute; () is percentage of total, in column.

Perceived CV risk T0	Procam risk score			Total
	Low	Intermediate	High	
Low risk	153	23	21	197 (38.3)
Intermediate risk	130	27	17	174 (33.8)
High risk	109	17	17	143 (27.8)
Total	392 (76.3)	67 (13.0)	55 (10.7)	514 (100)

Underestimated CVD risk	12%
Correctly estimated CVD risk	38%
Overestimated CVD risk	50%

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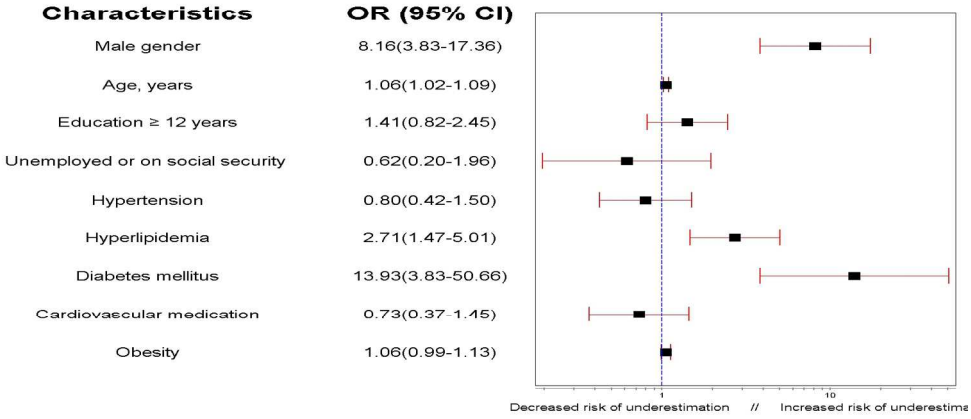
Table 3: Determinants of underestimation according to Framingham or Procam score

	FRAMINGHAM			PROCAM		
Variables	**Odds Ratio**	**[95% Conf. Interval]**		**Odds Ratio**	**[95% Conf. Interval]**	
Male gender	**8.16**	3.83	17.36	**38.82**	7.28	206.91
Age, years	**1.06**	1.02	1.09	**1.22**	1.15	1.30
Education ≥ 12 years	**1.41**	0.82	2.45	**0.70**	0.31	1.60
Unemployed or on social security	**0.62**	0.20	1.96	**0.52**	0.09	3.10
Hypertension	**0.80**	0.42	1.50	**0.35**	0.14	0.89
Hyperlipidemia	**2.71**	1.47	5.01	**4.49**	1.59	12.70
Diabetes mellitus	**13.93**	3.83	50.66	**192.49**	24.82	1493.12
Cardiovascular medication	**0.73**	0.37	1.45	**0.29**	0.11	0.80
Obesity	**1.06**	0.99	1.13	**1.10**	1.00	1.21

Figure 1: Determinants of underestimation (Framingham)



"The odds ratios and respective 95% confidence intervals are presented on a log scale. Values above 1.0 (right of the dashed vertical line) present an increased risk of underestimating cardiovascular risk according to Framingham risk score (ref 8, D'Agostino and al, Circulation, 2008), while values below 1.0 (left of the dashed line) present a decreased risk of underestimating cardiovascular risk.
All characteristics were analyzed as categorical variables, except for age in years as a continuous variable. The presence of hypertension was defined as a blood pressure ≥140/90mmHg in patients without diabetes and ≥130/80mmHg in patients with diabetes. The presence of hyperlipidemia was defined according to the level of cardiovascular risk: The threshold for patients with high, intermediate and low cardiovascular risk was ≥2.6mmol/l, ≥3.4 mmol/l and ≥4.1mmol/l, respectively. The presence of diabetes was defined by levels of fasting glucose ≥7mmol/l or glucose at any time ≥11.1mmol/l. Obesity was defined as a body mass index ≥30kg/m2 (weight in kilograms divided by height in meters squared)."

675x342mm (72 x 72 DPI)

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

	Item No	Recommendation	STATUS
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	Done (in abstract page 3)
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	Done
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Done (page 6-7)
Objectives	3	State specific objectives, including any prespecified hypotheses	Done (page 7 last paragraph)
Methods			
Study design	4	Present key elements of study design early in the paper	Done (page 8)
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Done (page 8, study pop.)
Participants	6	*Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	Done
		(*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	NA
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Done (page 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	Done (page 8-10)
Bias	9	Describe any efforts to address potential sources of bias	Done Multivariable model page 11)
Study size	10	Explain how the study size was arrived at	NA (secondary analyses of a RCT)
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Done (see methods)
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	Done (page 10-11)
		(*b*) Describe any methods used to examine subgroups and interactions	NA
		(*c*) Explain how missing data were addressed	Done (results page 11)

Cross-sectional study—If applicable, describe analytical methods taking account of sampling strategy	NA
(*e*) Describe any sensitivity analyses	NA

Continued on next page

Results			**STATUS**
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	Done (results page 11)
		(b) Give reasons for non-participation at each stage	Done
		(c) Consider use of a flow diagram	Not provided
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Done (results page 11)
		(b) Indicate number of participants with missing data for each variable of interest	Done page 11
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	NA
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	NA
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	NA
		Cross-sectional study—Report numbers of outcome events or summary measures	Done (page 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	Done (page 12)
		(*b*) Report category boundaries when continuous variables were categorized	NA
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	NA
Discussion			
Key results	18	Summarise key results with reference to study objectives	Done (page 13)
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	Done (page 14-15)
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Done
Generalisability	21	Discuss the generalisability (external validity) of the study results	Done
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	Done (page 17)

*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.

BMJ Open

Comparison of self-perceived cardiovascular disease risk among smokers with Framingham and Procam scores: a cross-sectional analysis of baseline data from a randomized controlled trial

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Comparison of self-perceived cardiovascular disease risk among smokers with Framingham and Procam scores: a cross-sectional analysis of baseline data from a randomized controlled trial

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References: 20

Abstract

Objectives: Previous studies suggest that smokers have a misperception of their 10-year cardiovascular risk. We aimed to compare 10-year cardiovascular risk self-perception and calculated risk among smokers willing to quit and assess the determinants of a possible misperception.

Design: Cross-sectional secondary analysis of baseline data from a randomized controlled trial of smoking cessation.

Participants: 514 participants, mean age 51.1 years, 46% women, 98% Caucasian. Eligible participants were regular smokers, aged between 40 and 70 years, with a consumption of at least 10 cigarettes per day for at least a year. None of them had experienced CVD before. Exclusion criteria comprised history of myocardial infarction, coronary heart disease (CHD), stroke, heart failure, peripheral vascular disease, carotid atherosclerosis or cardiac arrhythmia. Participants with renal or liver failure, psychiatric disorders, substance and alcohol abuse and with smoking cessation therapies were excluded.

Interventions: Participants were asked to estimate their 10-year cardiovascular risk using a 3-item scale corresponding to high, moderate and low risk categories. We compared their risk perception with the Framingham and Procam score. We used multi-variable adjusted logistic regression models to determine characteristics of participants who underestimate their risk vs. those who correctly or overestimate it.

Results: Between 38-42% of smokers correctly perceived their 10-year cardiovascular risk, 39-50% overestimated their 10-year cardiovascular risk while 12-19% underestimated it compared to their calculated 10-year cardiovascular risk depending on the score used. Underestimation of 10-year cardiovascular risk was associated with male gender (OR 8.16; CI

3.83-17.36), older age (OR 1.06; CI 1.02-1.09), and the presence of hyperlipidemia (OR 2.71; CI 1.47-5.01) and diabetes mellitus (OR 13.93; CI 3.83-50.66).

Conclusions: Among smokers, misperception of their 10-year cardiovascular risk is common, with one fifth underestimating it. These findings may help physicians target patients with such characteristics to help them change their health behavior and adherence to risk-reduction therapy.

Strengths and limitations of this study

- This study carefully assessed self-perceived CVD risk among smokers and compared self-perception with two validated cardiovascular scores in a cross-sectional secondary data analysis of baseline data collected in a randomized controlled trial assessing the effect of carotid plaque screening on smoking cessation.
- The study highlights predictors of underestimation of CVD risk among smokers: male gender, older age, and the presence of hyperlipidemia and diabetes mellitus.
- The analyses are restricted to smokers and no comparison is possible between CVD perception of smokers, non-smokers or former smokers.
- The analyses are restricted to smokers who underestimated their cardiovascular risk and predictors of overestimation were not assessed.

INTRODUCTION

Cardiovascular disease (CVD) is the leading cause of death worldwide. Ischemic heart disease and stroke are responsible for 13.2 % and 11.9 % of deaths, respectively[1]. Smoking is the most important modifiable risk factor for CVD and smoking cessation prevents cardiovascular mortality and morbidity in a rapid and effective manner[2]. Thus, the main strategy for CVD prevention is based on controlling modifiable risk factors such as smoking through population-wide interventions. These include smoking bans in public places, tax raises on cigarette packs as well as individual health-care interventions like counselling and medication for smokers willing to quit.

An adequate perception of cardiovascular disease risk might be required to better understand the goal of preventive interventions and adhere to CVD prevention. Studies assessing CVD risk using questionnaires, registration form, visual analogue scale and self-rated measurements, conducted in general practices by Frijling[3] and van der Weijden[4], have suggested that smoking predicted higher levels of risk perception. Smokers' perception of health risks is complex and underestimation or overestimation of CVD risk depends on how risk perception is assessed[5]. For instance, Weinstein et al.[5] have reported that smokers consistently acknowledged that smoking increased their risk of developing heart disease, lung cancer, bronchitis and stroke but within a smaller range compared with non-smokers. Furthermore, smokers tended to minimize their health risks. Individual misperception of smokers has also been described in another study that showed that only 29 to 39% of smokers perceived themselves at higher risk than the average for myocardial infarction[6]. One could argue that smoking, as part of a complex addiction mechanism, might be the cause of misperception but CVD risk is also difficult to assess for physicians [7]. To our knowledge,

few studies focused on CDV risk perception among smokers[3,4], and little or no information about CVD risk (calculated by scores) was provided.

Prediction scores such as Framingham[8], Procam[9], or the European Scores[10] have been developed to estimate the 10-year CVD risk. These prediction models are increasingly used to identify high-risk patients who would benefit from interventions on one or several risk factors and to motivate others to adhere to risk-reduction therapy. Based on previous publications, the Procam score seems to be the most appropriate score in Switzerland [9,11]. However the Framingham score is still often used for clinical or research purposes (it is the one used in International Lipid guidelines[12]) despite its tendency to overestimate the cardiovascular risk in European populations.

Awareness of cardiovascular disease risk associated with cigarette smoking might have changed during the last two decades with more prevention and information campaigns. Moreover, whether smokers have a correct perception of their own CVD risk compared with calculated CVD risk prediction scores has never been assessed and little is known about determinants that could explain the potential misperception of smokers.

The primary objective of this study was to assess the accuracy of perception of CVD risk among smokers and identify determinants associated with potential misperception in a single-center study conducted with smokers in Switzerland.

METHODS

Study population

We did a cross-sectional secondary analysis of the baseline data of the CAROSS trial, a randomized controlled trial assessing the effect of carotid plaque screening on smoking cessation [13]. Participants were recruited in the general population using advertisements in newspaper in multiple recruitment waves.

Eligible participants were regular smokers, aged between 40 and 70 years, with a consumption of at least 10 cigarettes per day for at least a year and no periods of smoking abstinence of at least 3 months in the previous year. None of them had experienced CVD before, as exclusion criteria comprised history of myocardial infarction, coronary heart disease (CHD), stroke, heart failure, peripheral vascular disease, carotid atherosclerosis or cardiac arrhythmia. Participants with renal or liver failure, psychiatric disorders, substance and alcohol abuse, and those taking smoking cessation therapies were also excluded.

All participants provided written informed consent. The study was approved by the local ethic commission of the University of Lausanne, Switzerland.

Variables of interest

Data on medical and smoking history, home and work environment, education and medication use were collected using questionnaires. At baseline, a nurse trained in smoking cessation asked each participant about his or her perception of CVD risk. The question was standardized to avoid influencing the participants and worded as: « How do you perceive your risk of heart attack in 10 years? ». The possible responses were « none or low risk »,

« intermediate risk », « high risk », « don't know » and « refuse to answer ». Participants who « didn't know » or « refused to answer » were invited once to reconsider their choice. In this study we restricted analysis for participants who answered the self-perceived CVD risk question and had complete baseline data.

To determine the reliability and reproducibility of the CVD risk perception assessment, we asked a consecutive convenience subsample of participants (n=48) to reassess their CVD risk one month after the last evaluation.

We calculated the Framingham scores based on ATP III guidelines[14]. We used the following variables at baseline to calculate the score: sex, age, cholesterol, smoking status, blood pressure, HDL-cholesterol, triglyceridemia and being treated with antihypertensive drugs. Framingham score was then encoded and CVD risk was computed for each participant.

According to Framingham scores, men with scores ≤11 were classified as low risk (10-year risk of cardiovascular events 8%), those with scores between12 and 14 as intermediate risk (10-year risk of cardiovascular events 10-16%), and those with scores ≥ 15 as high risk (10-year risk of cardiovascular events ≥ 20%). For women, low, intermediate and high risk corresponded to Framingham risk scores of 19 (10-year risk of cardiovascular events 8%), 20-22 (10-year risk of cardiovascular events11-17%) and ≥23 (10-year risk of cardiovascular events ≥ 22%) points respectively.

The following variables at baseline were used to calculate Procam score: sex, age, LDL-cholesterol, HDL-cholesterol, triglyceridemia, blood pressure, diabetes, cardiovascular disease before 60 years old among relatives. Procam score was encoded based on PROCAM study [15] and CVD risk was computed for each participants. Low, intermediate and high risk was defined as 10-year risk of cardiovascular events of < 10%, between 10-20% and ≥ 20% respectively. By convention, women had their risk divided by four.

Professional activity was initially classified as « Employed », « Unemployed or on social security » and « Retired ». For the need of the multi-variable adjusted analysis and assuming that « Retired » participants where once « Employed », we secondarily merged « Employed » and « Retired » participants and obtained two categories « Employed or retired» and « Unemployed or on social security ». Education was dichotomized by < 12 years and ≥ 12 years of education. Both of these variables were used as a proxy for socio-economic status.

Weight and height were measured at baseline as well as blood pressure in a sitting position with an appropriately sized cuff according to guidelines. Fasting glucose and lipids levels were measured at baseline. We defined cardiovascular risk factors as follows: Hypertension as ≥ 140 systolic mmHg and/or 90 diastolic mmHg[16] , except for participants with diabetes mellitus ≥ 130 and/or 80 mmHg; Hyperlipidemia according to ATP-III guidelines[17] as LDL-cholesterol ≥ 2.6 mmol/L, ≥ 3.4 mmol/L, ≥ 4.1 mmol/L for high (>20%), moderate (10-20%) and low (<10%) risk participants, respectively; Diabetes mellitus as fasting blood glucose ≥ 7.0 mmol/L[18].

Statistical Analysis

The primary outcome was misperception of CVD risk. For statistical convenience we merged participants who correctly or overestimated their risk together, believing that correct or overestimation is less detrimental than underestimation in terms of preventive medicine. We compared participants who underestimated their 10-year CVD risk to those who correctly or overestimated it. The comparison between the baseline characteristics of both groups was performed using Chi square tests and Anova or Fisher tests.

We first used uni-variable logistic regression to obtain the odds ratio (OR) and 95% confidence intervals (CI) and identify potential predictors of underestimation, compared to correct or overestimation of 10-year CVD risk. Variables that were significant with a p-value < 0.05 (sex, age, education, working status, hypertension, hyperlipidemia, diabetes, cardiovascular medication) were then integrated in a multi-variable adjusted analysis. Multi-variable adjusted logistic regression was used to identify variables associated with underestimation of the CVD risk compared with correct or overestimation.

We considered p-values < 0.05 as significant. All data were proceeded with STATA 10 software (StataCorp, College Station; Texas).

RESULTS

The study included 536 participants, amongst whom 22 (4%) had incomplete baseline data (18 without self-perceived CVD risk, and 4 whose high triglycerides prevented calculation of LDL-cholesterol level). Among the 514 remaining participants, 98% were Caucasians and 234 (46%) were female (**Table 1**). Mean age at baseline was 51.1±7.3 years. Most participants were employed or retired (92%) the rest being unemployed or on social security. About two third had lower education (< 12 years; apprenticeship or no education). Participants were smoking with an average of 24.5 (9.8 SD) cigarettes per day for a mean duration of tobacco smoking of 32.1 (7.9 SD) years, corresponding to 39 (20 SD) pack-years. Two hundred and fifty-eight (50%) participants had hyperlipidemia, whereas 27% had hypertension and 3.5% had diabetes.

Using the Framingham score, half of participants (51%) were classified as low risk at 10 years, 38% as intermediate risk and 11% as high risk (**Table 2A**). Using the Procam risk score the proportion of low risk participant was 76%, medium risk 13% and high risk 11% (**Table 2B**). Participants perceived themselves at low risk for 38% of them, intermediate risk for 34% and high risk for 28% of them, using the self-perceived CVD risk questionnaire. In a subsample of 48 participants, re-assessment of CVD risk perception (by telephone, one month after the initial evaluation) showed 83% of consistent answers (40/48) (data not shown).

According to Framingham score, less than half of the participants (42%) correctly estimated their CVD risk, 39% overestimated it and 19% underestimated it (**Table 2A**). According to Procam score, 38% correctly estimated their CVD risk, 50% overestimated it and 12% underestimated it (**Table 2B**).

Among high-risk participants, 62-69% underestimated their CVD risk (depending on the score used) whereas 33-34% underestimate it among intermediate risk participants (**Table 2A and 2B**).

Using the Framingham score, male gender (OR 9.45; CI 4.9-18.2), older age (OR 1.05; CI 1.02-1.08), body mass index (OR 1.09; CI 1.03-1.14), hyperlipidemia (OR 5.71; CI 3.34-9.76), diabetes (OR 9.27; CI 3.39-25.38) and being on CVD medication (OR 1.75; CI 1.08-2.82) were associated with underestimation of CVD risk in univariate analysis (data not shown). In the multivariable-adjusted analysis, underestimation of CVD risk was associated with male gender (OR 8.16; CI 3.83-17.36), older age (OR 1.06; CI 1.02-1.09), hyperlipidemia (OR 2.71; CI 1.47-5.01) and diabetes mellitus (OR 13.93; CI 3.83-50.66) (**Figure 1**). We found no association between underestimation and body mass index, socio-

economical status, hypertension or being under CVD medication in the multivariable-adjusted analysis. Using the Procam risk score, we found similar results (Table 3).

DISCUSSION

In the present study, between 58% (for the Framingham score) and 62% (for the Procam score) of participants had a misperception of their CVD risk at 10 years. Results were almost similar when low, intermediate and high CVD risk categories were taken separately. A minority of participants (12-19%) underestimated their CVD risk whereas 39%-50% overestimated it, depending of the score used for the evaluation of the cardiovascular risk. Only 3% of participants couldn't provide an estimation of their CVD risk.

A majority of participants had inadequate perception of CVD risk, which is consistent with previous studies. In our study, the CVD risk was perceived inappropriately in 62-69% of high CVD risk participants and 57-61% of low risk participant, whereas Van der Weijden et al. found that 80% of high risk and 20% of low risk participants had a misperception of their CVD risk in general practices[4].

The use of the Procam risk score generated a higher proportion of low risk participants compared to the Framingham risk score, but a lower proportion of medium risk participants. The proportion of high risk participants was similar using both scores. As a consequence, compared with Framingham, a smaller proportion of participants underestimated their CVD risk when using the Procam risk score (61 vs 100 participants respectively) probably reflecting a better accuracy of this score in a European population. Table 3 compares the determinants of underestimation of the cardiovascular risk as calculated with the Framingham or the Procam scores. Of note, important differences between confidence intervals width

occurs in male gender and diabetes variables in Procam compared to Framingham. Interestingly, these 2 variables remain statistically significant even though the strengths of association were less robust mainly due to the smaller proportion of participants in Procam and the few diabetic patients of our study (n=18). In fact, both of these scores consider type 2 diabetes as a high CVD risk regardless of other factors. Thus, diabetic patients were automatically considered in the highest risk category which could explain why diabetes has such a high odds ratio. Further studies in a population with diabetes specifically remain needed.

We found that older age, male gender, hyperlipidemia and diabetes were determinants of underestimation of CVD risk. Our results contrast at least with two other studies. Three quarter of participants with hypertension or diabetes overestimated their CVD risk in the study of Frijling et al.[3]. Similarly, Van der Weijden et al.[4] highlighted that men and diabetic participants were more likely to perceive their CVD risk inappropriately. However, caution is advised when comparing these studies because the design and the baseline population differ substantially. First, only 29% and 20% of participants were smokers in Van der Weijden et al., and Frijling et al., respectively. Secondly, participants in our study responded to an advertisement inviting them to a study to help them quit smoking whereas Frijling et al. gave questionnaires to patients visiting general office who fulfilled inclusion criteria. The fact that the participants to our study needed to actively respond to an advertisement in order to be recruited, might explain why motivation, as well as health awareness, might have been higher in the participants of the present study than in the general population of long term smokers who do not want to quit. This could also explain the low percentage of participants who failed to provide an estimation (correct or wrong) of their CVD risk.

Interestingly, more participants overestimated their CVD risk (too pessimistic) than underestimated it in our study. Nonetheless, we decided to focus on those who underestimated their CVD risk (too optimistic), assuming it to be more detrimental than overestimation. In our opinion, underestimation of CVD risk might decrease compliance to treatment or lifestyle modifications as well as reduce the efficacy of primary prevention and thus increase the absolute risk of CVD event. Overestimation may cause increased stress, medical seeking or overmedication, which can affect the quality of life rather than the absolute CVD risk.

To our surprise, diabetes was a determinant of underestimation of CVD risk, even though participants with diabetes presumably have had regular medical interaction and lifestyle education. However, caution is advised considering the small proportion of diabetic participants (4%) in our study. Hyperlipidemia was also a determinant of underestimation whereas other CVD risk factors such as hypertension or BMI were not associated with underestimation. Finally male gender was also associated with higher odds of underestimation. Studies suggest that men are less health conscious compared with women and might be less susceptible to seek medical help [19].

Our study carefully assessed self-perceived CVD risk among smokers and compared it with two validated calculated risk score. However, because our study was limited to current smokers, we could not compare smokers' misperception to that of non-smokers or former smokers. It would be interesting to assess risk perception among non-smokers in our general population to better contrast CVD risk perception between smokers and non-smokers.

We assessed CVD risk perception asking about the risk of developing a heart attack within 10 years. It would also have been interesting to assess whether the self-perceived risk of heart attack vs stroke would have been different in smokers. However, we used the perceived risk

of heart attack as a proxy for the overall cardiovascular risk and did not collect any data about stroke.

Patients with psychiatric disorders are known to be at risk for substance abuse and have a high prevalence of smoking, and consequently are exposed to high morbidity [20]. These patients were excluded from the CAROSS trial to ensure that consent was fully informed and that participants would carefully follow the smoking cessation advices. This understudied population would benefit from future trials specifically aimed at new approaches for smoking cessation.

Clinicians widely use clinical scores to estimate CVD risk in order to discuss primary prevention. This approach is only efficient when patients understand and adhere to risk reduction therapy. Smokers represent a challenge for general practitioners due to strong nicotine dependence and denial of personal risk from smoking (optimistic bias)[6].

We found that 12- 19% of smokers have a misperception of their 10-year CVD risk in the form of an underestimation, which may hinder the efficiency of interventions aimed at reducing or preventing CVD risk factors. This could lead to an increase in morbidity and mortality. Therefore clinicians must be aware that about a fifth of smokers underestimate their 10-year CVD risk and that men as well as people suffering from hyperlipidemia or diabetes, are at increasing risk of underestimating their 10-year CVD risk.

CONTRIBUTORSHIP STATEMENT

Study concept and design: Rodondi, Collet, Cornuz and Desgraz. *Acquisition of data:* Rodondi, Collet and the CAROSS trial team. *Analysis and interpretation of data:* Desgraz, Clair, Collet, Rodondi, Cornuz. *Drafting of manuscript:* Desgraz. *Critical revision of the manuscript for important intellectual content:* Desgraz, Clair, Collet, Rodondi, Cornuz. *Statistical analyses:* Collet, Desgraz. *Administrative, technical and material support:* Rodondi, Cornuz. *Study supervision:* Clair, Collet, Rodondi, Cornuz.

COMPETING INTERESTS

None Declared

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DATA SHARING STATEMENT

All illustrations and figures in the manuscript are entirely original and do not require reprint permission. There is no additional unpublished data.

PREVIOUS PRESENTATION

Intermediate results were presented at SGIM meeting in Orlando, in May 2012.

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Legends for Tables:

* Full time, part time, independent or at home

† Low Blood Pressure defined as < 140/90 mmHg; High Blood Pressure defined as ≥140 and/or 90, ≥130 and/or 80mmHg if diabetic

‡ Definition of hyperlipidemia:

- Any treated patient (statin or fibrate);
- For high risk patients when LDL-cholesterol ≥ 2.6 mmol/L;
- For intermediate risk patients when LDL-cholesterol ≥ 3.4 mmol/L;
- For low risk patients when LDL-cholesterol ≥ 4.1 mmol/L

§ Fasting Glycemia ≥ 7 mmol/L or Glycemia ≥ 11.1 mmol/L

1 1

2 **Table 1 : Characteristics of study participants**

	Overall (n=514)	
Demographics		
Age (years), mean ± SD	51.1	**7.3**
Women nbr, %	234	**45.5**
Education nbr, %		
< 12 years	381	**74.1**
≥ 12 years	133	**25.9**
Professional activity nbr, %		
Employed*	433	**84.2**
Unemployed or on social security	40	**7.8**
Retired	41	**8.0**
Cardiovascular medication nbr, %		
No treatment	390	**75.9**
Aspirine, statine, anti-HTA, anti-Diabetic	124	**24.1**
Cardiovascular variables		
Systolic Blood Pressure mmHg ± SD	123.0	**15.4**
Systolic Blood Pressure (per 10 mmHg)		
Categories nbr, %		
Low Blood Pressure†	376	**73.2**
High Blood Pressure†	138	**26.8**
BMI mean ± SD	24.9	**4.1**
Hyperlipidemia‡ nbr, %	258	**50.2**
treated nbr, %	60	**11.7**
Diabetes type 2§ nbr, %	18	**3.5**
Tobacco smoking		
Number of cigarettes per day mean ± SD	24.5	**9.8**
Number of pack-years py ± SD	39	**20**

Fagerström Score for nicotine dependence mean ± SD (0 low dependence - 10 very high dependence)	5.0	**2.1**

Table 2 A:

Meshing table between perceived CVD risk and calculated CVD risk according to Framingham score. Numbers in absolute; () is percentage of total, in column.

Perceived CV risk T0	Framingham risk score			
	Low	Intermediate	High	Total
Low risk	111	64	22	197 (38.3)
Intermediate risk	79	81	14	174 (33.8)
High risk	70	51	22	143 (27.8)
Total	260 (50.5)	196 (38.1)	58 (11.2)	514 (100)

Underestimated CVD risk	19%
Correctly estimated CVD risk	42%
Overestimated CVD risk	39%

Table 2 B:

Meshing table between perceived CVD risk and calculated CVD risk according to Procam score. Numbers in absolute; () is percentage of total, in column.

Perceived CV risk T0	Procam risk score			Total
	Low	Intermediate	High	
Low risk	153	23	21	197 (38.3)
Intermediate risk	130	27	17	174 (33.8)
High risk	109	17	17	143 (27.8)
Total	392 (76.3)	67 (13.0)	55 (10.7)	514 (100)

Underestimated CVD risk	12%
Correctly estimated CVD risk	38%
Overestimated CVD risk	50%

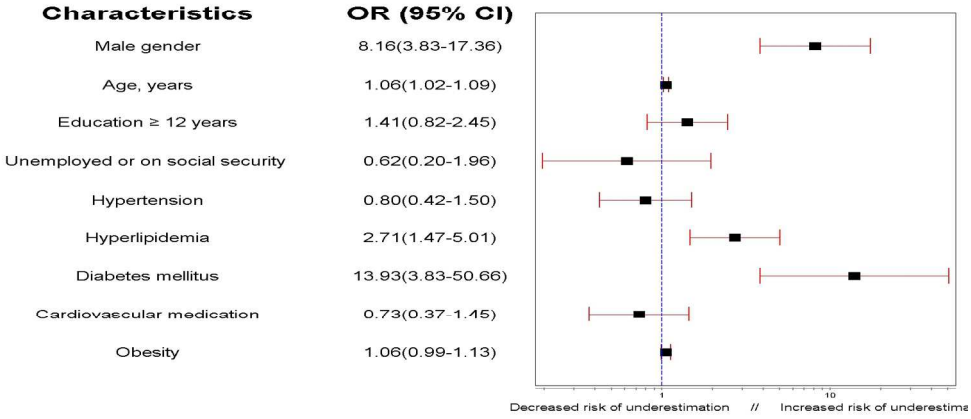
1

2

Table 3: Determinants of underestimation according to Framingham or Procam score

	FRAMINGHAM			PROCAM		
Variables	Odds Ratio	[95% Conf. Interval]		Odds Ratio	[95% Conf. Interval]	
Male gender	**8.16**	3.83	17.36	**38.82**	7.28	206.91
Age, years	**1.06**	1.02	1.09	**1.22**	1.15	1.30
Education ≥ 12 years	**1.41**	0.82	2.45	**0.70**	0.31	1.60
Unemployed or on social security	**0.62**	0.20	1.96	**0.52**	0.09	3.10
Hypertension	**0.80**	0.42	1.50	**0.35**	0.14	0.89
Hyperlipidemia	**2.71**	1.47	5.01	**4.49**	1.59	12.70
Diabetes mellitus	**13.93**	3.83	50.66	**192.49**	24.82	1493.12
Cardiovascular medication	**0.73**	0.37	1.45	**0.29**	0.11	0.80
Obesity	**1.06**	0.99	1.13	**1.10**	1.00	1.21

Figure 1: Determinants of underestimation (Framingham)



"The odds ratios and respective 95% confidence intervals are presented on a log scale. Values above 1.0 (right of the dashed vertical line) present an increased risk of underestimating cardiovascular risk according to Framingham risk score (ref 8, D'Agostino and al, Circulation, 2008), while values below 1.0 (left of the dashed line) present a decreased risk of underestimating cardiovascular risk.
All characteristics were analyzed as categorical variables, except for age in years as a continuous variable. The presence of hypertension was defined as a blood pressure ≥140/90mmHg in patients without diabetes and ≥130/80mmHg in patients with diabetes. The presence of hyperlipidemia was defined according to the level of cardiovascular risk: The threshold for patients with high, intermediate and low cardiovascular risk was ≥2.6mmol/l, ≥3.4 mmol/l and ≥4.1mmol/l, respectively. The presence of diabetes was defined by levels of fasting glucose ≥7mmol/l or glucose at any time ≥11.1mmol/l. Obesity was defined as a body mass index ≥30kg/m2 (weight in kilograms divided by height in meters squared)."

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

	Item No	Recommendation	STATUS
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	Done (in abstract page 3)
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	Done
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Done (page 6-7)
Objectives	3	State specific objectives, including any prespecified hypotheses	Done (page 7 last paragraph)
Methods			
Study design	4	Present key elements of study design early in the paper	Done (page 8)
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Done (page 8, study pop.)
Participants	6	*Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	Done
		(*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	NA
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Done (page 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	Done (page 8-10)
Bias	9	Describe any efforts to address potential sources of bias	Done Multivariable model page 11)
Study size	10	Explain how the study size was arrived at	NA (secondary analyses of a RCT)
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Done (see methods)
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	Done (page 10-11)
		(*b*) Describe any methods used to examine subgroups and interactions	NA
		(*c*) Explain how missing data were addressed	Done (results page 11)

Cross-sectional study—If applicable, describe analytical methods taking account of sampling strategy	NA
(*e*) Describe any sensitivity analyses	NA

Continued on next page

Results			STATUS
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	Done (results page 11)
		(b) Give reasons for non-participation at each stage	Done
		(c) Consider use of a flow diagram	Not provided
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Done (results page 11)
		(b) Indicate number of participants with missing data for each variable of interest	Done page 11
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	NA
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	NA
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	NA
		Cross-sectional study—Report numbers of outcome events or summary measures	Done (page 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	Done (page 12)
		(*b*) Report category boundaries when continuous variables were categorized	NA
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	NA
Discussion			
Key results	18	Summarise key results with reference to study objectives	Done (page 13)
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	Done (page 14-15)
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Done
Generalisability	21	Discuss the generalisability (external validity) of the study results	Done
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	Done (page 17)

*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.