Label fraud and safety issues about cardiovascular risk prediction in Switzerland.

A scientific statement by VARIFO

Purpose

Contrary to the terminology of the international atherosclerosis society, coronary heart disease is communicated as a proxy for cardiovascular disease in Switzerland by the Swiss Working Group on Lipids and Atherosclerosis (AGLA) and by the Swiss Heart foundation. This world-wide unique label fraud has the effect of rationing preventive medicine, because true risk is underreported by Swiss medical doctors and Swiss pharmacies and where ever the PROCAM algorithm is used. Due to safety issues, a correction and paradigm change is overdue.

In this statement we furnish the scientific background to size the qualitative and quantitative effect of this label fraud in order to help those in charge with developing risk prediction tools to change their paradigms in the future.

Principle Results and Conclusions

This statement paper compares observational data from a cardiovascular outcome study (ARCO) with results of cardiovascular risk prediction. Methods were assessed using area under the curve, weighted kappa analysis and cox regression survival models. Underestimation of risk occurs with PROCAMchd / AGLAchd when compared to ARCO and SCORE. In order to adapt to this situation, the Swiss calibration factor of 0.7 should be omitted, AGLA risk should be named coronary heart disease risk and users who want to calculate cardiovascular risk, should be asked to calculate SCORE and not AGLA. In low and intermediate risk situations, additional markers of risk are required in order to prescribe statins. E.g. TPA > 22 mm2, CAC SCORE > 100. Action should be taken by AGLA and the Swiss Heart Foundation to apologize for the confusion created by the label fraud and to definitively clarify matters as outlined in this scientific statement. Because of safety concerns, doctors and pharmacists should recalculate cardiovascular risk in all their records and inform their patients about the changes made in the risk assessments.

Introduction

For 20 years I do assess patients regarding cardiovascular risk prediction and I observed that the AGLA calculator too frequently assessed patients to have low risk despite presence of significant amounts of carotid or coronary calcified plaque.

For 20 years I perform atherosclerosis imaging using ultrasound, CMR (only experimental) and computed tomography, what allows me to put results of various tests into a clinical perspective.

Furthermore, together with a busy center within the framework of working medicine, we were able and will publish several primary prevention outcome results from our ARCO study, where 2 842 patients from Olten and Koblenz were assessed for risk and outcome.

What strikes me most from ARCO was the observation, that 85% of all events occurred in the 3rd tertile of carotid plaque area (TPA), whereas 50% of events occurred in the low risk segment of PROCAM.

It appears that the AGLA calculator has not been configured by AGLA to prevent cardiovascular disease, but to avoid eventually unnecessary preventive treatment. This political road may be justified by societal forces that continue to torpedo preventive medicine and put life into danger. However, my perception of goals and dues for AGLA were and remain different. AGLA went far beyond the target. AGLA should prevent as many cardiovascular events as possible without overtreating patients.

It is already quite difficult to appropriately calibrate the AGLA calculator in order to achieve improved cardiovascular risk prediction. Improvements in risk prediction only improve by additional cardiovascular risk markers, more observational studies like ours (ARCO) and TPA is a candidate for this, because is a cost-effective and rapidly performed tool with excellent predictive results, there is no harm from radiation and it is the only method that allows to track prognostically relevant changes in ASCVD risk over time (a feature not provided by CAC, because Statins increase CAC).

Carotid plaque imaging and tracking is therefore an ideal bedside test to assess cardiovascular risk in a reproducible, cheap and – for the patients who see their atherosclerosis reduction with appropriate treatments – able to guide medical treatment decisions regarding the intensity of preventive therapies. Plaque growth can be catched by carotid atherosclerosis tracking and is an additional risk marker [1].

I have published several studies that show the difference of cardiovascular risk prediction using AGLA and SCORE, and the differences are substantial [2]. The Swiss Society of Cardiology entrusted the AGLA with cardiovascular risk prevention and risk prediction. AGLA calculator is now widely used in Switzerland and is the golden standard in primary care. The PROCAM formula was used since over 15 years and it reflects risk for fatal or non-fatal myocardial infarction. It does not include other coronary diseases such as coronary artery disease, unstable angina or need for coronary revascularisation. Furthermore, it does not include the risk for stroke.

PROCAM has a developed calculator, that calculates stroke risk separately. My collaborator calculated online the risk for stroke in 2 842 primary care patients, and their PROCAMchd risk was 4.8% and their stroke risk was 1.5%, so PROCAMchd increased to PROCAMcvd from 4.8% to 6.3%, a relative increase of risk by 31%. If we included the occurrence of all coronary diseases into observed event rates, we found that PROCAMchd risk should be multiplied by up to 3.45 and ALGAchd risk by up to 4.93 in order to reflect observed versus predicted risk.

The Label Fraud

It is unfortunate, that AGLA communicates CHD risk as CVD risk. Several publications [3,4], the AGLA website and the AGLA pocket guide prove such a confusion since 2013. This cannot be accepted in view of what is scientifically known and what we have reproduced with remarkable similarity in our ARCO study. Many patients with low or intermediate risk defined by AGLAchd are in a higher risk category. We found in risk category 7% risk shifts for stroke and 35% for coronary disease and stroke.

Table 1: agreement between PROCAM and PROCAM with added stroke and ASCVD risk

This is an analysis of reclassification of patients

By adding the information of AGLA risk for Stroke, 7% of patients would be reclassified into a higher AMI STROKE risk category

AMI STROKE Reclassification of PROCAM

		CVD			N	%
		L	M	H	195	7
CHD	L	2304	134	1		
	M	0	228	60		
	H	0	0	115		

By adding the information of AGLA risk for ASCVD, 35% of patients would be reclassified into a higher ASCVD risk category

ASCVD Reclassification of PROCAM

		CVD			N	%
		L	M	H	995	35
CHD	L	1732	572	135		
	M	0	0	288		
	H	0	0	115		

In a clinical setting, where 80% of the population seek the attention of a physician for prevention issues per year (https://saez.ch/article/doi/saez.2020.19409), risk prediction plays an important role in daily medical practice. Many physicians promptly calculate the AGLA risk and find a low risk. Then they communicate to their patients that risk is low and that no further action regarding preventive medications is needed. However, about 2.5 Mio people have non-low risk despite being labeled as low risk. If we assume, that these 2.5 Mio people have a cardiovascular risk of 12% in 10 years, then we can expect 301 963 cardiovascular events in 10 years or 30 196 events per year in patients erroneously defined as low risk respite having intermediate risk. If we further assume that with appropriate treatment, we achieve a relative risk reduction of 50%, then 15 098 events could be prevented per year. One may question this number. But we should do such calculations in order to understand the magnitude of the problem.

The Assmann Foundation (https://www.assmann-stiftung.de/procam-tests/) provides an online calculator for the risk of myocardial infarction and an additional risk calculator for stroke risk. AGLA should use this approach and correct the wording regarding the confusion about CHD and CVD. Another possibility would be to inform the medical community, that AGLA just gives numbers about myocardial infarction risk and if a physician is interested In CVD instead of CHD risk, he or she should calculate the SCORE risk. Further SCORE should be online available with results presented nearby the AGLA risk. We have developed a full risk calculator using primary and secondary prevention and the possibility to use arterial instead of chronological age (https://docfind.ch/AspirinStatinCompass.xlsx) and it includes also cost-efficacy calculations. The tutelage of the medical profession by AGLA in risk prediction should in any case be turned off immediately and all physicians should be informed about the error committed by AGLA. The reason for this is, that the Swiss population is unsafe with the AGLA calculator and physicians should be asked to recalculate their patient's risk for CVD in order to detect the many patients who should receive intensified preventive treatments. t is not a political question here either, but rather that the risk is calculated according to the current state of knowledge. AGLA should then discuss the available evidence and future developments. And I would also like to know, why the Swiss Society of Cardiology has accepted the CHD versus CVD confusion created by AGLA.

Regarding the Pulse broadcast: we filed a complaint about a pulse broadcast (https://www.srf.ch/sendungen/puls/schlussbericht-zu-puls-beitrag-ueber-cholesterinsenker). It would be valuable for AGLA to read this and the answers provided by SRF, because this example shows, that AGLA and not SRF was responsible for the confusion about risk created in the broadcast. In the pulse broadcast with Mr. Harry Roos, it was discussed whether there was a statin indication. The risk according to PROCAM in this 65-year-old with smoking habit over mor than 30 years (!) was 14.6% (AGLA: 10.2%). Blood pressure 130 mm Hg, LDL 3.5 mmol / l. Assumption: HDL 1.5 mmol / l, TG 1.5 mmol / l, cholesterol 5.7 mmol / l. This results in a SCORE risk of 7.9%,

which is a high and almost very high risk for CVD (the Swiss Medical Board would multiply SCORE with 5.5 to obtain also events survived, e.g. 43% CVD risk, and Prof. Bertel discussed a factor of four, e.g. 40% risk). According to the AGLA recommendation, an LDL lowering is indicated, the LDL should be below 3.0 mmol / l at that time. Prof. Av Eckardstein however said, a statin treatment is not necessary, there are other recommendations. Prof. Thomas Lüscher recommends a statin with no ifs and buts and Prof. Nicolas Rodondi recommends a statin, but says that as a non-smoker the risk would be 7%, then no statin would be necessary. The fact that the 7% risk can only be reached after a few years is ignored here. Prof. Pascal Meier says, statins are generally not indicated in "primary care". This communicative mess is hardly to bear.

When we look at the CTT results [5], CHD must be multiplied by a factor of 1.4 to obtain AMI + STROKE risk (Figure 1 in the CTT paper) and by a factor of 2.5 to obtain risk for AMI + STROKE + REVASC. Therefore, the risk of Harry Roos would be at least 25% for AGLAcvd. These numbers and our findings, which add the presence of coronary artery disease in ARCO (defined by a narrowing of 50% or more found with invasive coronary angiography) and also the correction factor for AMI + STROKE we found to be identical with CTT (1.4) clearly shows that the scientific evidence has been there and the AGLA risk calculator could have been appropriately adopted since 2013. Why AGLA missed this opportunity and put so many patients at an eventually life-threatening risk, remains obscure.

It is clear to me that the AGLA's error is not simply a trivial matter and accordingly the error must be dealt with and the people responsible should be held accountable. AGLA has produced a major public health problem.

Table 2: Calibration factors for PROCAM and AGLA

Observation (ARCO) and Estimation (PROCAM, AGLA)					
FU Time	5.9	2.6	2.7	2.9	3.3
ARCO		AMI	AMISTR	AMISTRCABG	ALL
Event Rate (%)		1.44	2.01	2.7	5.4
		10 year			
Outcome		**AMI**	**AMISTR**	**AMISTRCABG**	**ALL**
ARCO		5.5	7.4	9.3	16.6
Baseline	Estimates	Calibration			
PROCAMchd	4.8	0.87	0.64	0.52	0.29
PROCAMcvd	6.3	1.14	0.85	0.68	0.38
AGLA chd	3.4	0.61	0.45	0.36	0.20
AGLA cvd	4.4	0.80	0.59	0.47	0.27
Correction		Correction factors			
PROCAMchd		1.15	1.55	1.94	3.45
PROCAMcvd		0.88	1.18	1.48	2.63
AGLA chd		1.65	2.22	2.77	4.93
AGLA cvd		1.26	1.69	2.11	3.76
Example		6% risk multiplied by correction factor			
PROCAMchd		6.92	9.31	11.64	20.71
PROCAMcvd		5.27	7.09	8.87	15.78
AGLA chd		9.89	13.29	16.63	29.58
AGLA cvd		7.54	10.13	12.67	22.54
Discrimination		ROC AUC Analysis			
PROCAMchd			0.84	0.83	0.83
PROCAMcvd			0.85	0.84	0.84
TPA			0.83	0.85	0.89
Survival		Survival Analysis (Cox pro haz model)			
PROCAMchd			N.S.	N.S.	N.S.
PROCAMcvd			N.S.	N.S.	N.S.
TPA			<0.0001	<0.0001	<0.0001

Label Fraud and Gender Medicine

According to a study published by the World Healt Organization WHO, for every myocardial infarction, 5 strokes occur in men and 9 strokes occur in women [6]. Therefore, for women it is even more important to receive correct results regarding AMI + STROKE risk and in women, AMI = AMI + STROKE is even more misleading than in men.

Label Fraud by the Swiss Heart Foundation

The Swiss Heart Foundation sells a risk assessment tool (HerzCheck ®) to patients who visit Swiss pharmacies all over Switzerland.

Figure 1: Example of a risk calculator used by Swiss Pharmacists in collaboration with the Swiss Heart Foundation

Protokoll Apotheke für HerzCheck®-Test

Alter: ___ Geschlecht: ☐ männlich ☒ weiblich Messung: ☐ nüchtern ☐ nicht nüchtern

Alter		Risiko-Score		Metab. Syndrom
35 – 39	40 – 44	0	6	
45 – 49	50 – 54	11	16	
55 – 59	≥ 60	21	26	
Familiäre Belastung: Herzinfarkt oder Hirnschlag bei einem Verwandten ersten Grades, Männer vor dem 55. und Frauen vor dem 65. Lebensjahr				
Nein			0	
Ja			4	
Rauchen: Sind Sie RaucherIn?				
Nein (seit 2 Jahren nicht mehr geraucht)			0	
Ja			8	
Zusätzliche Fragen an Frauen:				

The test is sold as a marker for myocardial infarction and stroke risk.

Figure 2: Example of a risk calculator used by Swiss Pharmacists in collaboration with the Swiss Heart Foundation, where myocardial infarction risk is calculated but communicated as cardiovascular risk

HERZCHECK

Was Herz und Hirn fürs neue Jahr brauchen

Weshalb schenken wir unseren Gönnern und Gönnerinnen einen HerzCheck®? Hier die drei wichtigsten Vorteile.

3. Nur zertifizierte Apotheken

In der Schweiz sind über 500 Apotheken für den Herz-Check nach Vorgaben der Schweizerischen Herzstiftung zertifiziert. Dies ist ein Zeichen für die hohe Qualität und

2. Ein ausgeklügelter Check

Der HerzCheck beurteilt das Herz-Kreislauf-Gesamtrisiko aufgrund wissenschaftlich nachgewiesener Risikofaktoren. Neben einer kurzen Befragung zum Lebensstil werden folgende Werte ermittelt: Bauchumfang, Blutdruck, Blutfettwerte und Blutzucker. Dies erfolgt anonym und dauert etwa 30 bis 40 Minuten. Das individuelle Risikoprofil erhalten Sie mit Empfehlungen im persönlichen Herz-Pass.

Punkte 50–58
bei 10-Jahres-Risiko zwischen 10–20 %

Empfehlung: Ihr Risiko für eine koronare Herzkrankheit (Angina pectoris, Herzinfarkt) oder einen Hirnschlag ist leicht erhöht. Durch einige Verhaltensänderungen liesse sich Ihre Situation optimieren. Wir empfehlen Ihnen, Ihren Arzt bei einer nächsten Konsultation darauf anzusprechen.

Punkte ≤ 49
bei 10-Jahres-Risiko < 10 %

Empfehlung: Herzlichen Glückwunsch! Ihr Risiko für eine koronare Herzkrankheit (Angina pectoris, Herzinfarkt) oder einen Hirnschlag liegt unter dem Durchschnitt. Tragen Sie zu Ihrer Gesundheit Sorge wie bisher.

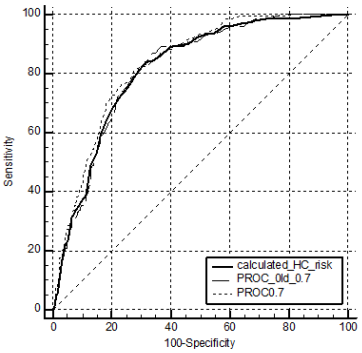
The algorithm behind is the number calculator of the PROCAM calculator, which is outdated and which calculates only the risk for myocardial infarction, but NOT the risk for stroke. We analyzed each patient in the ARCO study (with omitting menopausal status) and found a risk for all patients with AGLAold of 3.8%±5.2% and for HerzCheck® of 4.1%±5.1% (r^2=0.876 when compared to the old PROCAM formula multiplied by 0.7 [1]). AGLAnew compared to AGLA old was 3.5%±4.8% (r^2=0.863).

Regarding discrimination analysis (ROC curves), PROCAM based results were quite similar with values around 0.82 regarding all events we observed in ARCO (N=154).

Table and Fig. 3: AUC analysis for HerzCheck, AGLA old and AGLA

Variable	AUC	SE a	95% CI b
HerzCheck Risk	0.816	0.015	0.802 to 0.830
PROC_0ld_0.7	0.816	0.0146	0.801 to 0.830
PROC0.7	0.832	0.0139	0.818 to 0.846

a DeLong et al., 1988
b Binomial exact



Regarding survival analysis in a multivariate Cox proportional variate model with HerzCheck®, PROCAMnew, Framingham and TPA (total plaque area, a continuous marker of carotid atherosclerosis), only Framingham and TPA remained significant predictors of event free survival, which included 41 AMI, 16 Strokes and 21 CABG.

Table 4: Cox proportional hazard survival analysis for HerzCheck, PROCAM, FRAMINGHAM and total carotid plaque area (TPA)

Survival time	timem
Endpoint	Hard_EV
Method	Enter

Cases summary

Number of events [a]	78	2.74%
Number censored [b]	2764	97.26%
Total number of cases	2842	100.00%

[a] Hard_EV = 1
[b] Hard_EV = 0

Coefficients and Standard Errors

Covariate	b	SE	Wald	P	Exp(b)	95% CI of Exp(b)
HerzCheck	0.04209	0.03364	1.5656	0.2108	1.0430	0.9764 to 1.1141
PROCAMca	-0.01938	0.02505	0.5983	0.4392	0.9808	0.9338 to 1.0302
FRAMca	0.05041	0.01505	11.2238	0.0008	1.0517	1.0211 to 1.0832
TPA	0.009232	0.001018	82.3115	<0.0001	1.0093	1.0073 to 1.0113

Therefore, HerzCheck® reflects risk for myocardial infarction (AMI), but not for AMI + STROKE and not for AMI + STROKE + REVASC. The communication to patients, that their cardiovascular risk has been assessed, is a fraudulent labeling.

[1] =RUNDEN(WENN(T28="M";0.7;WENN(U28="N";0.175;0.7))*(100*(1-POTENZ(0.9369;EXP(((V28*0.103)+(W28*0.01)+((X28*38.66)*0.013)-((Y28*38.66)*0.032)+(0.317*((LN(Z28*88.57))))+(WENN(AA28="N";0;1)*0.658)+(WENN(AB28="N";0;1)*0.399)+(WENN(AC28="N";0;1)*0.385))-8.9769))));1) / for more details refer to https://www.kardiolab.ch/MONICA-PROCAM3_RA1.html

The unacceptable exclusion of old people from Statin-therapy

The summary recommendations of AGLA [7] based on the 2019 ESC guidelines regarding lipid therapy [8] contained an error regarding statin eligibility of patients aged 75 years or more was mainly based on a narrative study by Ponce et al [9]. Unfortunately, this low value study was not even mentioned in the ESC guides 2019. Thereafter, I submitted a metaanalysis to Swiss Medical Weekly based upon available data. This review was criticized by anonymous reviewers and I had not the time to answer all the questions for resubmission.
Reviewers comments are provided here, which I leave to the readers to comment:

Reviewer #1:
I believe the authors have to state in their conclusion that the recent AGLA recommendations (to not prescribe statin for patients over 75 years old) should be revised and changed based on the meta-analysis provided by this ms.

Reviewer #2:
The issue of appropriateness of statin prescription in the elderly (Eur J Intern Med. 2018 Apr;50:33-40. doi: 10.1016/j.ejim.2017.12.011) is debated, as yet, and still remains of high interest.
Few points:
The Authors should comment on secondary prevention, and retrospective studies (Eur J Intern Med. 2018 Apr;50:33-40. doi: 10.1016/j.ejim.2017.12.011). Any difference among statins or statin dosages? Does the present article contain any specific limitation? Please mention.
What about the very elderlies, i.e. >80 year of age?
The recent article "Discontinuing statins or not in the elderly? Study protocol for a randomized controlled trial." should be quoted and discussed (Trials. 2020 Apr 19;21(1):342. doi: 10.1186/s13063-020-04259-5).
The use of statins in the elderly is associated with less severe hypoglycemia in patient with diabetes. (Diabetes Res Clin Pract. 2020 Jan 29;162:108034. doi: 10.1016/j.diabres.2020.108034)
Mortality and Cholesterol Metabolism in Subjects Aged 75 Years and Older: The Helsinki Businessmen Study. (J Am Geriatr Soc. 2020 Feb;68(2):281-287. doi: 10.1111/jgs.16305)

Reviewer #3:
The authors present a meta-analysis on the preventive effect of statins against atherosclerotic cardiovascular disease (ASCVD) and all-cause mortality in persons aged 75 years and older. There was a clear rationale to analyse this, as recently guidelines for/against the use of statins in the very elderly were recommended to be changed in Switzerland, based on the outcomes of a study published in 2018. This study claimed that there was no benefit of statin use with regard to ASCVD in the very elderly. The authors argue that said study had major flaws. Moreover, they provide indications with their own analysis that statins do have major health benefits for older people.
Major concerns:
There has already been a large meta-analysis published in The Lancet last year (PMID: 30712900), which analyses statin safety and efficacy in much more detail, including many more studies. It is not directly clear to me what additional or new information the meta-analysis presented here brings. This should be clearly specified in the manuscript.
The Methods section is minimalistic and needs to include a more detailed description of the analysis from literature search to statistical analysis. See other publications as for instance the The Lancet publication mentioned above.
Other comments:
1) In lines 27- 39 of the results section, the authors explicate why the study by Ramos et al. was flawed.
"More than 40% of non-diabetic patients presented no data about lipids and patients did not report statin side effects. Patient thus did not take statins in a sufficient amount or duration and therefore absolutely no preventive effect was observed. Indeed, the complete lack of preventive effects is counterintuitive and raises many questions about the study design and the lack of proof of statin ingestion during the study period or during a pilot-study, that was unfortunately also not performed."
I would like to ask the authors to rephrase this section to make their point better accessible, as this seems to be a crucial part of the argumentation. As I understand from skimming through the paper by Ramos et al., the main problem with their study was that they could not be sure that patients actually adhered to statin treatment throughout the study, because data that could show adherence (e.g. prescriptions were regularly renewed) was completely missing, and also blood lipid profile data was lacking for a large part of the persons assessed. As I understand the argumentation, the authors think it is possible that a major proportion of the non-diabetic patients did not actually take statins, as they did not report side effects. Maybe site a paper that presents the number of people not adhering to statin medication due to side effects, as this is a well-known problem.
2) In lines 13-18 in the discussion section, the authors mention an important point, which is that recommendation to use statins in the very elderly need to also take contraindications into account.
"By inference, very elderly patients with atherosclerosis in primary prevention should be treated with statins, unless contraindications are present."
I think, the manuscript would benefit from discussing the indications for adverse effects or other contraindications, against which the health benefits they describe have to be weighed. Ultimately, any recommendation for or against the usage must take this into consideration.

Reviewer #4:
Authors must be commended for questioning the quality of the evidence underpinning a recent change of practice recommendations. However, the reporting of the methods and results is not sufficiently transparent which is a major concern. Some of the key issues are explained below.
The manuscript presents the results of a meta-analysis. Therefore, the recommendations of the relevant reporting guideline (PRISMA, see http://www.prisma-statement.org/PRISMAStatement/PRISMAStatement) should be followed. This requires adding a substantial amount of additional details but would improve transparency greatly, i.e. would enable the reader to understand and indeed scrutinize the methods used in the manuscript.
While all (!) items of the checklist should be addressed, more details are needed especially regarding the searches (item #8), the study selection and data extraction (items #6, #9, #10, #11, #17, and #18), the risk of bias assessment (items #12, #15, #19, and #20) and the synthesis methods (items #13, #14, #16, #21, and #23). The manuscript would also greatly benefit from a clearer structure of the discussion (items #24 to #26) as well as from a comparison of the results of this paper to other reviews in the area, especially systematic reviews of high quality.
The review here reported only analyses the efficacy of the statins on ASCVD and mortality. However, the prescribing recommendations for these agents need to be based on the balanced judgement between overall benefits and risks. Authors need to interpret the limitations including potential adverse events that may be attributed to these agents. This needs to be done in the context of clinical practice, i.e. patients on pharmacological regimens involving a number of drugs.

Authors explain that both observational studies and RCTs were included in the review, However, no distinction appears obvious in the pooling of outcomes. This appears inappropriate; therefore, a careful interpretation needs to be made on the results (see items #14, #16, #21, #23, and #25). Reported meta-analyses show considerable heterogeneity. This need to be addressed or at least acknowledged as a major limitation, see sections 10.10 and 10.11 of the Cochrane Handbook (https://training.cochrane.org/handbook/current).
Some minor observations:
* The term "very elderly" should be defined
* Abbreviations should be given in full when first used, e.g. ASCVD
* Statements of personal opinion should be omitted or limited to the discussion section where they should be clearly marked, supported by relevant references and discussed, e.g. "…and it may even be stated, that such a study should be withdrawn"
* Rather than focussing on P values, the results section should report effect estimates with corresponding 95 % CIs, see https://amstat.tandfonline.com/doi/full/10.1080/00031305.2016.1154108
* Tables 1 to 4 could be omitted in better quality Figures, e.g. created in the Cochrane RevMan software, would be included.

Here are our results:

Table 1: Evidence from 5 trials in patients aged 70 years (HOPE-3, Jupiter) or 75 years or more on ASCVD outcome

	ASCVD			
	Verum		Placebo	
	N	Event	N	Event
CTT [10]	10926	295	7429	208
EILAT [7]	1255	347	7328	4105
EWTOPIA [11]	1716	89	1695	133
Jupiter [9]	2848	51	2848	82
HOPE-3 [9]	1543	107	1543	125
SUM	18288	889	20843	4653

Figure 1: Meta-analysis of medical trials in the elderly for ASCVD outcomes.

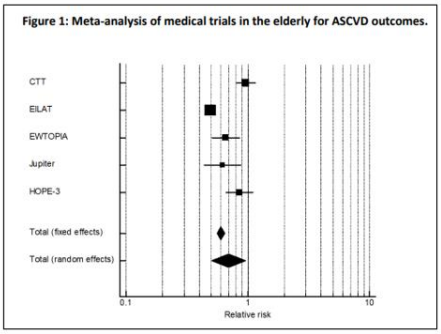


Table 2: Evidence from 2 trials in patients aged 75 years or more on death as the outcome variable

	All Cause Mortality			
	Verum		Placebo	
	N	Event	N	Event
EILAT [7]	436	67	2146	764
EWTOPIA [11]	1716	188	1695	173
SUM	2152	255	3841	937

Table 3: Relative risk for ASCVED meta-analysis using fixed and random effects

Study	Intervention	Controls	Relative risk	95% CI	z	P	Weight (%)	
							Fixed	Random
CTT [10]	295/10926	208/7429	0.964	0.810 to 1.149			17.12	20.98
EILAT [7]	347/1255	4105/7328	0.494	0.450 to 0.541			62.24	21.97
EWTOPIA [11]	89/1716	133/1695	0.661	0.510 to 0.857			7.76	19.52
Jupiter [9]	51/2848	82/2848	0.622	0.440 to 0.879			4.39	17.78
HOPE-3 [9]	107/1543	125/1543	0.856	0.668 to 1.097			8.5	19.74
Total (fixed effects)	889/18288	4653/20843	0.602	0.561 to 0.647	-13.842	<0.001	100	100
Total (random effects)	889/18288	4653/20843	0.699	0.506 to 0.964	-2.187	0.029	100	100

In the meantime, Gencer et al [10] performed a metaanalysis on statins and found statins in random effects metaanalysis to have a relative risk reduction of 18%, which was statistically significant, as our metaanalysis showed.

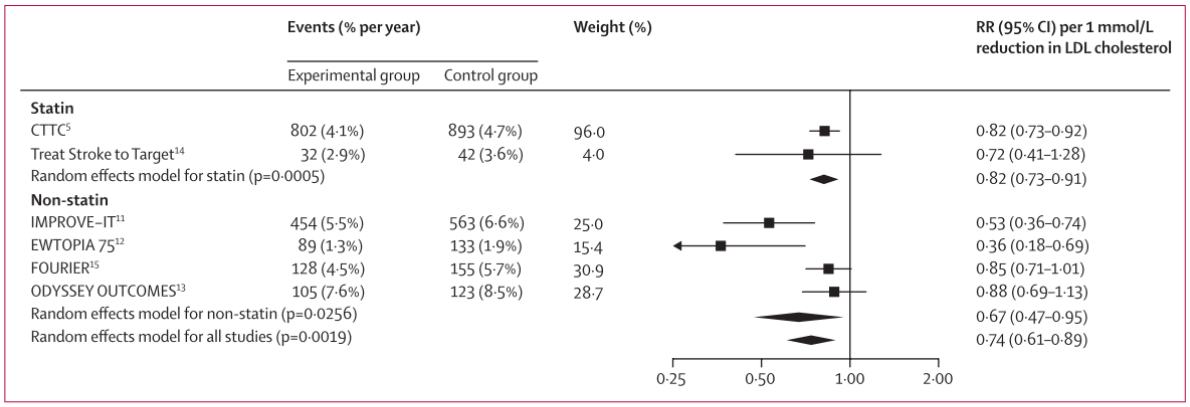


Figure 1: **Effect of LDL cholesterol lowering on the risk of major vascular events with statin and non-statin treatment in older patients**
Older patients were aged 75 years or older. RRs per 1 mmol/L reduction in LDL cholesterol were generated from a random effects model. In the ODYSSEY OUTCOMES trial, the event numbers were provided at 4 years, whereas the RR is for the entire duration of trial. CTTC=Cholesterol Treatment Trialists' Collaboration. EWTOPIA 75=Ezetimibe Lipid-Lowering Trial on Prevention of Atherosclerosclerotic Disease in 75 or Older. FOURIER=Further Cardiovascular Outcomes Research with PCSK9 Inhibition in Patients with Elevated Risk. IMPROVE-IT=Improved Reduction of Outcomes: Vytorin Efficacy International Trial. ODYSSEY OUTCOMES=Evaluation of Cardiovascular Outcomes After an Acute Coronary Syndrome During Treatment with Alirocumab. RR=risk ratio.

It is incomprehensible why AGLA refuses to offer a statin in healthy people over the age of 75 if there is a medical indication to do so.

The poor performance of AGLA in health technology assessments of Statins and Correction (calibration) factors

The Federal Office of Public Health has commissioned a Health Technology Assessment for Statins in primary care and they found a factor for AMI + STROKE to be 1.8. This number is in line with the WHO study and shows the high STROKE risk, especially if women are included in the observations. The problem of AGLA is, that this HTA report discusses deliberately the issue of CHD versus CVD and it labels the SMB report on statins as "narrative". From this, AGLA has two major problems to face. First, CHD is not CVD, why does AGLA need a Dutch HTA team to identify this truth? Second, Statins are cost-efficient and AGLA should have discussed such truths publicly, but it didn't.

Table 5: HTA report about Statins, BAG Nov 2020, regarding cost-efficiency of statins according to level of AGLA risk.

This is an analysis of cost-effectiveness, HTA BAG Nov 2020

The HTA report has been corrected based upon my intervention. The correction factor of the HTA report for AGLAcvd is 1.80, therefore 80% underestimation of risk with AGLAchd.

In slide 3, we found a correction factor of 1.69, which is therefore very similar to the HTA report and suggests, that AGLAcvd is 69% higher than reported by AGLAchd.

This fact shows, that it is inadmissible that AGLA sells CHD for CVD. This is wrong.

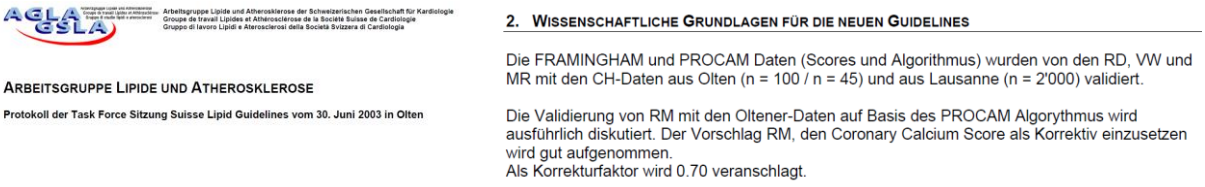
The cost-efficacy of Statins is maintained for all patients up from an AGLA risk of at least 5%, probably 3% (< 100 000 / QALY).

This is similar to our calculations published with Prof. Szucs (we found a threshold of 7%). AGLA never fought publicly against the SMB Statin report. This cannot be tolerated.

Age	AGLA risk					
	1%	5%	10%	15%	20%	25%
Males						
40	39,514	4,518	1,088	-105	-748	-1,154
45	59,300	5,798	925	-466	-1,134	-1,542
50	88,152	8,291	890	-913	-1,652	-2,055
55	114,080	12,185	1,318	-1,297	-2,268	-2,714
60	157,037	18,288	2,694	-1,317	-2,832	-3,472
65	204,759	26,356	5,466	-580	-2,999	-4,115
70	274,366	38,398	10,214	1,565	-2,243	-4,208
75	381,012	59,023	19,420	6,692	677	-2,658
Females						
40	14,133	2,757	471	-722	-1,214	-1,573
45	21,095	3,023	383	-702	-1,320	-1,985
50	35,175	3,114	108	-1,009	-1,653	-2,075
55	61,885	4,348	-370	-1,584	-2,176	-2,563
60	91,027	7,992	-400	-2,322	-2,993	-3,327
65	139,794	15,349	1,200	-2,500	-3,811	-4,345
70	217,042	28,403	5,726	-907	-3,668	-4,963
75	344,412	51,832	16,038	4,660	-634	-3,512

A major issue reflects the AGLA correction factor of 0.7, which was derived from our observation in 100 patients having had a coronary calcium score in the year 2000 (https://cardiovascmed.ch/article/doi/cvm.2005.01103).

Figure 4: From an AGLA meeting 2003, where the correction factor of 0.7 was discussed



AGLA GSLA

Arbeitsgruppe Lipide und Atherosklerose der Schweizerischen Gesellschaft für Kardiologie
Groupe de travail Lipides et Athérosclérose de la Société Suisse de Cardiologie
Gruppo di lavoro Lipidi e Aterosclerosi della Società Svizzera di Cardiologia

ARBEITSGRUPPE LIPIDE UND ATHEROSKLEROSE

Protokoll der Task Force Sitzung Suisse Lipid Guidelines vom 30. Juni 2003 in Olten

2. WISSENSCHAFTLICHE GRUNDLAGEN FÜR DIE NEUEN GUIDELINES

Die FRAMINGHAM und PROCAM Daten (Scores und Algorithmus) wurden von den RD, VW und MR mit den CH-Daten aus Olten (n = 100 / n = 45) und aus Lausanne (n = 2'000) validiert.

Die Validierung von RM mit den Oltener-Daten auf Basis des PROCAM Algorythmus wird ausführlich diskutiert. Der Vorschlag RM, den Coronary Calcium Score als Korrektiv einzusetzen wird gut aufgenommen.
Als Korrekturfaktor wird 0.70 veranschlagt.

However, this correction factor has not been corrected since 2003, despite several issues that contribute to questioning such a number. First, many persons have entered Switzerland from Eastern Europe and Germany, which increase the average cardiovascular risk in Switzerland. Second, the 0.70 factor has not been validated for STROKE + REVASC. Third, from ARCO it becomes apparent, that such a calibration factor is problematic. Fourth, SCORE risk is equal for Germany and Switzerland. Overall, this calibration factor is therefore not well enough validated and appears to be unsafe. It should have been eliminated many years ago.

Conclusions

I am aware that my views and calculations are a disaster for the AGLA and probably also for the Swiss Heart Foundation and the responsible persons in the Swiss Society of Cardiology. I also don't know what the AGLA intends to do now. But I think the political and ethical framework that AGLA / SSC have obviously used up to now must be radically removed. In any case, my claims and calls are on the table and I seek for more safety in risk prediction and prevention of cardiovascular events. AGLA should not torpedo such effort, because people want to remain healthy and do not want to be a victim of unethical rationing of preventive medicine. It cannot be the case that the medical profession continues to jeopardize the lives of patients with prevention rationing. A radical answer from AGLA is the only way out to usher in a new era of AGLA honestly and with a focus on the future. If this does not succeed, AGLA will soon be history.

Millions of people have trusted the AGLA calculator in medical cabinets and Swiss pharmacies. It is overdue to establish communication between patients and medical professionals that differentiates between the risk of myocardial infarction, the cardio-cerebral risk and the risk of ASCVD. Everything else is patronizing patients and leads them to feel like a false sense of security.

Finally, there is still a working group on atherosclerosis imaging within the AGLA, which I led until now and which was never halted. AGLA should discuss, how atherosclerosis imaging may be incorporated in atherosclerosis management in Switzerland.

I am open to contribute with my knowledge and all my data (CH and eventually D [formal consent required]).

Best regards

Michel Romanens, MD, Vascular risk Foundation

Principle statements

AGLA risk should be named coronary heart disease risk

Because of safety concerns, doctors and pharmacists should recalculate cardiovascular risk in all their records and inform their patients about the changes made in the risk assessments.

The Swiss calibration factor of 0.7 should be omitted
Users who want to calculate cardiovascular risk, should be asked to calculate SCORE and not AGLA.

In low and intermediate risk situations, additional markers of risk are required in order to prescribe statins. E.g. TPA > 22 mm2, CAC SCORE > 100.

Action should be taken by AGLA and the Swiss Heart Foundation to apologize for the confusion created by the label fraud and to definitively clarify matters as outlined in this scientific statement.

Additional Material

In this section my co-worker and I performed a detailed analysis of the agreement between PROCAM and SCORE using individual data analysis from ARCO study. The calculators used are as follows:

SCORE CVD (golden standard)	SCOREcvd
PROCAM CHD	PROCAMchd
PROCAM CHD + STROKE	PROCAMas
AGLA CHD	AGLA
PROCAM CHD POINT SCORE Assmann Foundation	PROCAMpoint
PROCAM CHD POINT SCORE Swiss Heart Foundation (HerzCheck ®)	HerzCheck

		PROCAM			N	%	Net %
		L	M	H	87	3.06122449	-27.5510204
SCOREcvd	L	1601	16	0	870	30.6122449	
	M	823	240	71			
	H	15	32	44		**Kappa**	**0.28**

		PROCAMas			N	%	
		L	M	H	130	4.57424349	-21.252639
SCOREcvd	L	1597	17	3	734	25.8268825	
	M	706	318	110			
	H	1	27	63		**Kappa**	**0.37**

		HerzCheck			N	%	
		L	M	H	42	1.47783251	-31.3863476
SCOREcvd	L	1597	20	0	934	32.8641802	
	M	867	245	22			
	H	19	48	24		**Kappa**	**0.25**

		AGLA			N	%	
		L	M	H	20	0.70372977	-36.1717101
SCOREcvd	L	1612	5	0	1048	36.8754398	
	M	975	144	15			
	H	33	40	18		**Kappa**	**0.16**

		PROCAMpoint			N	%	
		L	M	H	34	1.19634061	-33.5679099
SCOREcvd	L	1612	5	0	988	34.7642505	
	M	926	179	29			
	H	18	44	29		**Kappa**	**0.21**

		PROCAMpoint			N	%	
		L	M	H	5	0.17593244	-12.5967628
PROCAMAS	L	2301	3	0	363	12.7726953	
	M	243	117	2			
	H	12	108	56		**Kappa**	**0.50**

		AGLA			N	%	
		L	M	H	0	0	-15.7987333
PROCAMAS	L	2304	0	0	449	15.7987333	
	M	306	56	0			
	H	10	133	33		**Kappa**	**0.35**

		HerzCheck			N	%	
		L	M	H	59	2.07600281	-10.52076
PROCAMAS	L	2249	55	0	358	12.5967628	
	M	224	134	4			
	H	10	124	42		**Kappa**	**0.47**

		PROCAM			N	%	
		L	M	H	0	0	-6.86136524
PROCAMAS	L	2304	0	0	195	6.86136524	
	M	134	228	0			
	H	1	60	115		**Kappa**	**0.76**

		PROCAMpoint			N	%	
		L	M	H	22	0.77410274	-6.01688951
PROCAM	L	2423	16	0	193	6.79099226	
	M	130	152	6			
	H	3	60	52		**Kappa**	**0.65**

SCORE as golden Standard

PROCAM labels 31% of patients as low risk who have intermediate risk by SCORE. Agreement with Kappa statistics is poor.

With the addition of stroke risk, still 26% of patients are labelled as low risk despite having intermediate risk by SCORE

HerzCheck mislabels 33% of patients as low risk despite having intermediate risk by SCORE

AGLA mislabels 37% of patients as low risk despite having intermediate risk by SCORE and showed the lowest kappa value (0.16) among comparators.

PROCAMpoint mislabels 33% of patients as low risk despite having intermediate risk by SCORE

PROCAMas as Golden Standard

As with SCORE, substantial underestimation of intermediate risk is detected when stroke risk is omitted from PROCAM.

PROCAM compared to PROCAMpoint

PROCAM point underestimates PROCAM in the low risk segment (average risk PROCAM 4.8%, average risk PROCAMpoint 3.7%, correction factor 1.30.

References

1. Ahmadi A, Argulian E, Leipsic J, Newby DE, Narula J. From Subclinical Atherosclerosis to Plaque Progression and Acute Coronary Events. *J Am Coll Cardiol* Journal of the American College of Cardiology; 2019;**74**:1608–1617.
2. Romanens M, Szucs T, Sudano I, Adams A. Agreement of PROCAM and SCORE to assess cardiovascular risk in two different low risk European populations. *Prev Med Reports* Elsevier; 2019;**13**:113–117.
3. Walter Riesen hc F. Behandlung modifizierbarer Risikofaktoren FoRtBildung · SchweRpunKt. 2013.
4. AGLApressemitteilung_1096_2013.
5. Cholesterol Treatment Trialists' Ctt Collaborators. The effects of lowering LDL cholesterol with statin therapy in people at low risk of vascular disease: meta-analysis of individual data from 27 randomised trials. *Lancet* 2012;**6736**:1–10.
6. Kaptoge S, Pennells L, Bacquer D De, Cooney MT, Kavousi M, Stevens G, Riley LM, Savin S, Khan T, Altay S, Amouyel P, Assmann G, Bell S, Ben-Shlomo Y, Berkman L, Beulens JW, Björkelund C, Blaha M, Blazer DG, Bolton T, Bonita Beaglehole R, Brenner H, Brunner EJ, Casiglia E, Chamnan P, Choi YH, Chowdry R, Coady S, Crespo CJ, Cushman M, et al. World Health Organization cardiovascular disease risk charts: revised models to estimate risk in 21 global regions. *Lancet Glob Heal* Elsevier Ltd; 2019;**7**:e1332–e1345.
7. Riesen WF, Kaiser W, Gallino A, Eckardstein A von, Theus G-R, Beer JH. Neue ESC/EAS-Dyslipidämie-Guidelines. *Swiss Med Forum – Schweizerisches Medizin-Forum* 2020;**20**:140–148.
8. Mach F, Baigent C, Catapano AL, Koskinas KC, Casula M, Badimon L, Chapman MJ, Backer GG De, Delgado V, Ference BA, Graham IM, Halliday A, Landmesser U, Mihaylova B, Pedersen TR, Riccardi G, Richter DJ, Sabatine MS, Taskinen M-R, Tokgozoglu L, Wiklund O, Mueller C, Drexel H, Aboyans V, Corsini A, Doehner W, Farnier M, Gigante B, Kayikcioglu M, Krstacic G, et al. 2019 ESC/EAS Guidelines for the management of dyslipidaemias: lipid modification to reduce cardiovascular risk. *Eur Heart J* 2020;**41**:111–188.
9. Ponce OJ, Larrea-Mantilla L, Hemmingsen B, Serrano V, Rodriguez-Gutierrez R, Spencer-Bonilla G, Alvarez-Villalobos N, Benkhadra K, Haddad A, Gionfriddo MR, Prokop LJ, Brito JP, Murad MH. Lipid-Lowering Agents in Older Individuals: A Systematic Review and Meta-Analysis of Randomized Clinical Trials. *J Clin Endocrinol Metab* NLM (Medline); 2019;**104**:1585–1594.
10. Gencer B, Marston NA, Im K, Cannon CP, Sever P, Keech A, Braunwald E, Giugliano RP, Sabatine MS. Efficacy and safety of lowering LDL cholesterol in older patients: a systematic review and meta-analysis of randomised controlled trials. *Lancet* 2020;**396**:1637–1643.

Previous Correspondence

Dr. med. Michel Romanens
Innere Medizin FMH, speziell Kardiologie
Spitalstr.9, 4600 Olten
☎ 062 212 44 10
Fax 062 212 44 30
E-Mail: info@kardiolab.ch
Homepage: www.kardiolab.ch

Herrn
Prof. Dr. med. Dr. Dr. h.c. Walter Riesen
Sekretär AGLA
Hintergasse 65
8253 Diessenhofen

Olten, 08.09.2020

Lieber Walter

Ich stelle den Antrag für ein Traktandum «AGLA risk assessment and management» unter Varia in der Sitzung vom 21.10.2020 in Bern.

Ich nehme Bezug auf Deine Mitteilung per email vom Mittwoch, 02.09.2020 betreffend Korrespondenz mit Arnold zum AGLA Pocket Guide sowie die weitere Korrespondenz zwischen mir und der AGLA seit 2004.
Ich schreibe Dir im Auftrag der Vascular Risk Foundation.

Ich bin leider mit der Antwort der AGLA nicht einverstanden. Ein Grund dafür sind eigene Beobachtungen und Analysen, welche zweifelsfrei darauf hindeuten, dass der AGLA Rechner ein relevantes Kalibrierungsproblem aufweist.

Ferner ist die Vermengung von CHD und CVD durch die AGLA wissenschaftlich falsch. Wenn der AGLA Rechner 5 ergibt, ist CVD mindestens 10. Daraus ergeben sich die weiteren Konsequenzen, insbesondere betreffend «the later the worse».

Ich weiss, dass die AGLA im aktuellen gesellschaftlichen Umfeld um Schadensbegrenzung bemüht ist, insbesondere die Attacken der Cholesterin-Lügner sind ja massiv. Ich denke aber nicht, dass die Strategie der defensiven Haltung, wie sie in der PULS SRF Sendung zum Ausdruck kam, zielführend ist. Im Gegenteil. Es ist der Auftrag der AGLA, die Wirkung der Cholesterin-Senkung ohne Rücksichtnahme auf gesellschaftliche Bedenken oder alternative Äusserungen von Ärztinnen und Ärzten darzulegen. Wenn die Wissenschafts-Ergebnisse ungehörig relativiert werden, ist dies eine kommunikative Schwäche, die die Patientinnen und Patienten mit Herzinfarkt, Hirnschlag und kardiovaskulärem Tod bezahlen.

Ich habe in meinem Brief vom 07.09.2020 die Problematik etwas vertieft beleuchtet und möchte die diversen Probleme und Forderungen am nächsten AGLA Meeting im Rahmen der AGLA Mitgliederversammlung unter Varia diskutieren. Dazu benötige ich ca 15 Min. für die Präsentation.

Die dies betreffende Agenda lautet:
1. AGLA Rechner und Kalibrationsprobleme, Insights aus Daten der VARIFO
2. CHD vs CVD, Insights aus Daten der VARIFO
3. Key pitfall der Pulssendung
4. Was kann die AGLA aus Sicht der VARIFO tun?

Ich grüsse Dich wie immer mit Hochachtung

Michel

Dr. med. Michel Romanens
Innere Medizin FMH, speziell Kardiologie
Spitalstrasse 9, 4600 Olten
☎ 062 212 44 10
Fax 062 212 44 30
E-Mail: info@kardiolab.ch
Homepage: www.kardiolab.ch

Herrn
Prof. Dr. med. Dr. Dr. h.c. Walter Riesen
Sekretär AGLA
Hintergasse 65
8253 Diessenhofen

Olten, 07.09.2020

Lieber Walter

Ich nehme Bezug auf Deine Mitteilung per email vom Mittwoch, 02.09.2020 betreffend Korrespondenz mit Arnold zum AGLA Pocket Guide sowie die weitere Korrespondenz zwischen mir und der AGLA seit 2004.
Ich schreibe Dir im Auftrag der Vascular Risk Foundation.

Einleitung

Ich erachte es als Tatsache, dass auf verschiedenen Ebenen der kardiovaskulären Prävention, insbesondere der Risikobeurteilung, der Öffentlichkeitsarbeit und der Entwicklung der AGLA Risikobeurteilung Handlungsbedarf besteht. Hauptproblem ist die Unterversorgung der Bevölkerung mit präventiven Behandlungen, insbesondere mit Statinen, wofür ich auch die AGLA verantwortlich mache. Damit steht die AGLA im Fokus als Institution, welche für vermeidbare kardiovaskulären Ereignisse und Todesfälle mit verantwortlich ist. Dies möchte ich nun im weiteren ausführen.

Kalibration

Im Mai 2005 hat die AGLA beschlossen, den Kalibrationsfaktor von 0.7 zu verwenden. Damit wird das PROCAM Risiko des damaligen Rechners um 30% für die Schweiz adjustiert.
https://ncloud.docfind.ch/index.php/s/PixtCJYg5JXt4kN
Wie dem Dokument entnommen werden kann, basierte dieser Faktor auf einer Schätzung, welche durch die Kenntnis des Ca-Scores bei 100 Patientinnen und Patienten ermöglicht wurde. Dies im Rahmen einer Publikation mit E. Battegay.
https://ncloud.docfind.ch/index.php/s/DBSHaPfZiiXkXEi
Arnold schreibt dazu, dass der Kalibrationsfaktor auf den Monica Daten Strassburg basiere:
https://ncloud.docfind.ch/index.php/s/NmsjTJF9WgEoaqp
Dies stimmt nicht mit unseren Kenntnissen überein
https://www.kardiolab.ch/MONICA-PROCAM3_RA1.html
Aufgrund der Monica Daten beträgt der Kalibrationsfaktor für Strasbourg 0.90 für Männer und 0.88 für Frauen.
Während die Berechnungen mit PROCAM früher zugänglich waren, ist die Berechnung des PROCAM Resultats mit dem neuen Rechner geheim. Tatsache ist, dass der neue Rechner für die Schweiz betreffend Kalibrationsfaktor nicht adjustiert wurde, es gilt weiterhin der alte Wert von 0.7.

Fallbeispiel Nehmen wir einen 60 jährigen Mann, Nichtraucher, kein Diabetes mellitus, keine familiäre KHK-Belastung, Blutdruck 140 mm Hg, Cholesterin 5.7 mmol/l, HDL 1.5 mmol/l, LDL wird im Folgenden variiert, TG 1.5 mmol/l. der Base Case hier beträgt LDL 3.5 mmol/l.

PROCAM old Das Risiko gemäss alter PROCAM Formel beträgt nun für LDL Schritte von 0.5 mmol/l, beginnend mit 2.0 mmol/l 3.2, 4.1, 5.2, 6.7, 8.5, 10.8.

PROCAM new Mit der neuen Formel ergeben sich niedrigere Risikowerte, jeweils mit Faktoren zwischen 0.71-0.78. Der neue Rechner reduziert als das Herzinfarkt-Risiko um 20-30%.

AGLA new Zusammen mit dem alten Kalibrationsfaktor sinkt das alte PROCAM Risiko gegenüber AGLA new um den Faktor 0.50-0.55. Dies bedeutet, dass gegenüber

2005 das Herzinfarkt Risiko gegenüber der PROCAM Kohorte von damals um rund 50% gesenkt wird (dies gilt aber nur für dieses Beispiel).

CHD versus CVD

Der PROCAM Rechner beobachtet ausschliesslich das Risiko für ein Herzinfarktereignis. Im Pocket Guide und auf der Webpage der AGLA wird behauptet, dass CVD berechnet wird. Das Etikett ist somit falsch.

ARCO Die Arco Kohortenstudie der VARIFO umfasst 2 842 Personen (D, CH) welche über 5.9 Jahre im Mittel beobachtet wurden und wo 154 Ereignisse beobachtet wurden, nämlich 41 Myokardinfarkte, 16 Schlaganfälle (=PROCAM x 1.4), 21 Bypass-Operationen (x 1.9), 41 PTCA (x 2.9) und 35 invasiv angiographisch gesicherte koronare Herzkrankheit (x 3.8).

ARCO Herzinfarkt Das Risiko für Myokardinfarkt betrug 1.44%, welche im Mittel nach 2.6 Jahren auftraten, extrapoliert betrug das 10 Jahres Risiko für Myokardinfarkt 5.5%.

ARCO Hirnschlag Das Risiko für Hirnschlag betrug 0.56%, welche im Mittel nach 2.8 Jahren auftraten, extrapoliert betrug das 10 Jahres Risiko für Myokardinfarkt 2.0%.

Das kombinierte Risiko für Herz- und Hirnschlag betrug somit 7.5%.

ARCO PROCAM/AGLA Das Myokardinfarkt Risiko gemäss PROCAM betrug 4.8%, das AGLA Risiko somit 3.3%. Der AGLA Rechner unterschätzt damit das Risiko für Myokardinfarkt in unserer Kohorte um 40%.

Puls Sendung

In der Pulssendung mit Herrn Harry Roos wurde diskutiert, ob eine Statin-Indikation vorlag. Das Risiko nach PROCAM betrug 14.6% (AGLA: 10.2%). Blutdruck 130 mm Hg, LDL 3.5 mmol/l. Annahme: HDL 1.5 mmol/l, TG 1.5 mmol/l, Cholesterin 5.7 mmol/l. Dies ergibt ein SCORE Risiko von 7.9%

AGLA Empfehlung Gemäss AGLA Empfehlung ist eine LDL Senkung indiziert, das LDL sollte unter 3.0 mmol/l betragen.

Av Eckardstein Eine Statinbehandlung sei nicht unbedingt notwendig, es gäbe da auch andere Empfehlungen.

Th. Lüscher Empfiehlt ein Statin ohne wenn und aber

N. Rodondi Empfiehlt ein Statin, sagt aber, als Nichtraucher würde das Risiko 7% betragen, dann wäre kein Statin nötig. Hier wird unterschlagen, dass das Risiko von 7% erst nach einigen Jahren erreicht werden kann.

P. Meier Statine sind im «primary care» in der Regel nicht indiziert.

Cholesterinlüge

Institution Gewichtige Professoren, v.a. aus den Ernährungswissenschaften (Exempel: M. de Lorgeril) agieren mit dem Label einer Institution (Centre de Recherche Nationale de France), wodurch eine gewisse Glaubwürdigkeit entsteht.

Presse Aufgrund des Gewichts der Aussagen ist die Presse mehr oder weniger gezwungen, den Konflikt zu thematisieren.

Beugung der Medizin Im gesellschaftlichen Kontext erscheint der Statinverschreiber als Drogendealer im Interesse der Big Pharma (Meier, Medart 2011). Die Aussagen der Pulssendung sind entsprechend angepasst an diese Realität. Die AGLA hätte kommunizieren müssen, dass a) ein Statin bei Herrn Roos indiziert ist und das Weglassen dieser Medikaton auf eigene Verantwortung geschieht und dass b) das Risiko mit dem AGLA-Rechner in Anbetracht des SCORE Resultats ohnehin unterschätzt wird.

Sanktionierung Wenn Chefärzte (Dr. Imoberdorf, Kantonsspital Winterthur), in Printmedien aussagen, die Cholesterin Theorie «gehört zu den grössten Irrtümern, welche die Medizin produziert hat», werden hier gefährliche, potentiell tödliche Aussagen gemacht. Wenn das KS Winterthur daraufhin keine Sanktionen ergreift, macht sich die Institution mitschuldig. In diesem Fall müsste der Gesundheitsdirektor des Kt. ZH die Entlassung von Dr. Imoberdorf fordern. Doch nichts geschah.

ARCO vs PROCAM

In unserer Studie haben wir die prozentuale Verteilung der Ereignisse in den verschiedenen Risikokategorein angeschaut. Ohne Karotisplaque trat 1% der Ereignisse auf, mit TPA > 62 mm^2 traten 85% der Ereignisse auf. PROCAM < 10% traten 45% der Ereignisse auf, PROCAM < 20% traten 78% der Ereignisse auf.

Eine erste Publikation liegt bereits vor: https://pubmed.ncbi.nlm.nih.gov/32595808/

Weitere drei Studien werden aktuell in verschiedenen Journals eingereicht.

Empfehlungen

Risikorechner Der AGLA Rechner berechnet das Risiko für Herzinfarkt und nicht für kardiovaskuläre Ereignisse. Für die Berechnung kardiovaskulärer Ereignisse ist ein eigener Kalibrationsfaktor notwendig, der mindestens 2.0 betragen sollte.

SMB Die AGLA wird aufgefordert sich dafür einzusetzen, dass der inhaltlich falsche Statinbericht des Swiss Medical Boards zurückgezogen wird.

Puls Sendung	Die AGLA wird aufgefordert, die Probleme in der Pulssendung aufzuarbeiten und ein Comunique zu Handen SRF zu verfassen
Imoberdorf / Pascal Meier	Die AGLA wird aufgefordert, bei den Gesundheitsbehörden der Kantone Zürich und Graubünden zu erwirken, dass sich die beiden Ärzte von Ihren Aussagen distanzieren oder ihren öffentlichen Auftrag verlieren.
HTA	Die AGLA wird aufgefordert, eine eigene Arbeitsgruppe zur Kosteneffektivität der Statine zu bilden. Das BAG führt aktuell eine budget impact analyse zu den Statinen durch und wird diese als nicht kosteneffektiv darstellen, eine Katastrophe für die Prävention. https://ncloud.docfind.ch/index.php/s/8553JtmTnNGE2tN
Imaging	Die Taskforce atherosclerosis imaging der AGLA sollte reaktiviert werden. Die VARIFO stellt zudem die Datenbanken von über 5 000 Patientinnen und Patienten aus der Grundversorgung für Analysen zur Verfügung. Selbstverständlich können diese Daten auch für HTA Berechnungen verwendet werden. Die AGLA soll Empfehlungen zur Indikation und zur Methode für Plaqueimaging mit Ultraschall und Computed Tomography im Setting des Primary Care erarbeiten. Die Varifo stellt hierfür Resourcen zur Verfügung.

Zusammenfassung

Die Situation betreffend Cholesterin-Management droht im Jahr 2020 eskalieren. Verwirrung stiftende Elemente wie Cholesterinlügner, SMB, BAG usw. zwingen die AGLA in eine viel zu defensive Strategie, welche für die Versorgungssicherheit problematisch ist. Die aktuelle faktische Anpassung der AGLA Kommunikationsstrategie an Elemente der Cholesterinlüge und ihrer Versorgungsimplikationen lehne ich kategorisch ab.
Ich erwarte von der AGLA kompromisslose Schritte in der Verteidigung ihres Auftrages betreffend Etablierung einer Statinindikation, Kalibrierungsprobleme, Etikettierungsprobleme und Imaging.
Im folgenden noch zu Eurer Orientierung die Abstracts und Auszüge aus drei Arbeiten, welche im Submission-Prozess sind. Gerne reiche ich die Studien in der aktuellen Form nach und öffne auch nach Absprache mit den Rahmenbedingungen die Datenbanken für die AGLA und bin auch offen für weitere Ko-AutorInnen und die Arbeit in einer Taskforce (Imaging, HTA)

Ich hoffe, dass mein Beitrag für die künftige Arbeit der AGLA fruchtbar gemacht werden kann. Sollte die AGLA sich im bisherigen Rahmen bewegen, würde ich mir schon einen Austritt aus der AGLA überlegen.

Mit freundlichen Grüssen

Michel Romanens

ARCO Studien Abstracts:

Abstract 1:

Comparative prediction of Cardiovascular Outcome with traditional risk equations and medical imaging of carotid atherosclerosis in subjects aged 30-65 years

The Arteris Cardiovascular Outcome (ARCO) cohort study

Authors:
Michel Romanens1, Ansgar Adams2, Isabella Sudano3, Waldemar Bojara4, Sandor Balint5, Walter Warmuth6, Thomas Szucs7

Institutes:
1 Vascular Risk Foundation (Varifo), Olten, Switzerland
2 BAD Gesundheitsvorsorge und Sicherheitstechnik GmbH, Bonn, Germany,
3 University Heart Centre, Cardiology, University Hospital, Zurich, Switzerland
4 Akademisches Lehrkrankenhaus der Universitätsmedizin der Johannes-Gutenberg-Universität Mainz, Klinik für Innere Medizin Schwerpunkt Kardiologie, Koblenz, Germany
5 Privatpraxis, Binningen, Switzerland
6 Gesundheitsforen Leipzig, Leipzig, Germany
7 European Centre of Pharmaceutical Medicine (ECPM), Basel, Switzerland

Corresponding Author:
Michel Romanens, MD
Vascular Risk Foundation
Ziegelfeldstr. 1
CH-4600 Olten, Switzerland
Fax: +41 62 212 44 30
michel.romanens@hin.ch

Word count : 3627

Abstract

Aims

We aim to assess the predictive value of atherosclerosis imaging beyond traditional risk calculators in younger subjects.

Methods

We compared PROCAM, SCORE and FRAM with carotid ultrasound (total plaque area, TPA) and arterial age (AA) was calculated in German and Swiss subjects without known cardiovascular diseases. Follow-up was obtained by phone or mail.

Results

In 2842 subjects (age 50±8, 38% women) 154 (5.4%) cardiovascular events occurred (ASCVD: 41 myocardial infarctions, 16 strokes or TIA, 21 CABG, 41 PTCA, 35 coronary artery disease defined by invasive angiography) during a mean follow-up time of 5.9 (1-12) years. PROCAM risk was 5±6%, SCORE risk 1.3±1.6% and FRAM 10±6%. Both for the primary outcome (AMI, STROKE/TIA, CABG) and the secondary outcome (adding CAD and PTCA) hazards increased significantly for TPA tertiles and AA groups between 1.4 (0.1-16.1) and 21.4 (2.8-163.6) after adjustment for risk factors (age, smoke, sex, systolic BP, lipids, BMI, medication in Model 1) and after adjustment for results from PROCAM, SCORE and FRAM (Model 2). Model performance was statistically improved regarding model fit in all models using TPA and AA, however, calibration improved only for the Framingham models in combination with TPA and AA. Net reclassification improvement (NRI) for PROCAM and SCORE using TPA tertiles or AA age groups increased significantly between 30% to 48%.

Conclusion

TPA and AA added clinically relevant additional prognostic information to conventional risk testing, supporting the assessment of ASCVD risk with carotid ultrasound in younger subjects.

Abstract 2
High very short-term cardiovascular risk: definition and primary-care bedside predictors observed in the ARCO cohort study
The Arteris Cardiovascular Outcome (ARCO) cohort study

Aims
We aim to assess the predictive value of atherosclerosis imaging beyond traditional risk calculators in younger subjects having a high very-short term (3-year) risk.
Method
High very-short term risk is defined by a cardiovascular risk of at least 20% in 3 years. We compared PROCAM and SCORE with carotid ultrasound (total plaque area, TPA) for cardiovascular risk detection during the first 3 years and during complete follow-up.
Results
In 2842 subjects (age 50±8, 38% women) 154 (5.4%) cardiovascular events occurred (ASCVD: 41 myocardial infarctions, 16 strokes or TIA, 21 CABG, 41 PTCA, 35 coronary artery disease defined by invasive angiography) during a mean follow-up time of 5.9 (1-12) years. PROCAM risk was 5±6%, SCORE risk 1.3±1.6%. Net reclassification improvement (NRI) for PROCAM and SCORE using TPA increased significantly between 30% to 48%. At 3 years, 86 events had occurred. Discrimination at 3 years was significantly improved by 5% when TPA was incorporated into PROCAM and SCORE (Bayes posttest risk). Cox proportional-hazards model at 3 years showed that SCORE was not significant, but PROCAM was predicting cardiovascular events ($p=0.0047$) and various amounts of TPA, especially TPA > 140 mm^2, remained a highly significant medical imaging predictor ($p<0.0001$). Patients with high very-short term risk remained undetected by PROCAM and SCORE.
Conclusion
In patients around 50 years of age, TPA detects patients with a high cardiovascular risk occurring during the next 3 years not detected by PROCAM and SCORE. TPA>140 mm^2, a bioimaging marker of arterial age above 75 years, detected 54% of all events that occurred during the first 3 years or 15% of all events that occurred during the whole observation period. High very-short term risk may help patients to understand the need for installing preventive therapies and we show that TPA integrated into PROCAM and SCORE significantly improves discrimination of such patients.

Abstract 3
Cost-Effectiveness-Analysis of Statins in primary care. Results from the Arteris Cohort Study
Background
The Federal Office of Public Health plans a health technology assessment regarding statins in primary care. The chosen models may lead to the situation where a clinically indicated statin therapy is estimated not to be cost-effective.
Methods
We performed a cohort study regarding cardiovascular events, compared SCORE and AGLA risk categories with tertiles of carotid plaque burden and used two models for CEA of high-potency statins at current prices.
Results
Subjects (N=2 842) were followed for 5.9 ± 2.8 years with occurrence of 154 cardiovascular events (extrapolated 10-year risk was 10%). Carotid plaque imaging significantly improved cardiovascular risk prediction when compared to AGLA and SCORE regarding event-free survival prediction, test accuracy (discrimination) and calibration. Discrimation was significantly improved by about 4% percent with TPA. CEA using QALY and sensitivity analyses (based on 16 models) ranged between CHF 144'496 to -128'328 per QALY. CEA using direct and indirect costs showed that even a treat-them-all strategy in the Swiss population would be cost-effective with return-on-investment per patient in 10 years between CHF 4'442 to 19'059 and the use of carotid imaging resulted in cost-effectiveness (ICER 1.23 to 1.84).
Conclusions
Medical imaging using carotid ultrasound significantly improved cardiovascular risk stratification and is cost-effective. The SMB QALY model presents several draw backs, which are shown in our sensitivity analysis, where results vary considerably and are not useful for clinical decision making. A "treat them all" strategy with Statins in the Swiss population aged 30-65 years may be cost-effective, when indirect costs of avoidable cardiovascular events are included, even at an unacceptably low value for life.

Ausschnitt (Diskussionsteil):

Discussion
Our patient-level dual-center cohort study shows that the population is at a 10-year risk of 9.2% for cardiovascular diseases such as myocardial infarction, stroke, coronary arter bypass surgery or stenting or presence of coronary artery disease defined by a coronary stenosis of > 50% defined by an invasive coronary angiogram.
Risk prediction with TPA, AGLA, and SCORE
When we stratified the cohort based on medical imaging with TPA into 4 groups with either no carotid plaque (reference group) or carotid plaque tertiles of TPA, we found that the extrapolated 10-year event rate was 0.3%, 0.7%, 2.9% and 38.2%. Only 7% of patients with events had a risk above AGLA 20% and only 34% had an AGLA risk above 10%; SCORE over 5% was present in only 18% of subjects with events. Throughout TPA tertiles, AGLA remained on average within the low risk category and also SCORE did not exceed an average risk of 2.6%.
We can prove that our first study hypothesis is correct: an important number of cardiovascular events occur in those patients stratified into the low risk group by AGLA or into the low or intermediate risk group by SCORE. A strategy that treats healthy patients with statins having high-risk AGLA or high-risk SCORE only, does not reach the vast majority of target patients, those who will develop atherosclerotic disease and hence increased life-time risk for higher morbidity, mortality and costs.
Cost-effectiveness analysis (CEA) using QALY
We performed a sensitivity analysis based upon the SMB QALY model by varying the numbers for costs of death, of cardiovascular non-fatal events, the relative risk reduction of statin per 1 mmol/l LDL reduction (either 22% or 29%) and by using additive and multiplicative QALY's21. This sensitivity analysis

produced therefore 16 possible results. We applied the calculation to the average data of the entire population observed and found that statins were cost-effective for any input chosen. Therefore, based upon an aggregate of individual patient-level data with real events in a low risk population, statins at current prices (CHF 1.00 per day to lower LDL by 50%12) were cost-effective, even when all patients would be treated using CEA and a cost-effectiveness level < CHF 150'000 per QALY.

HTA cost-effectiveness analysis using aggregated data for risk categories will be unable to detect patients who will benefit from statins and a denial of any statin treatment in this risk category is unable to positively influence the atherosclerotic epidemy. On the other hand, a stratification of patients with SCORE, but not with AGLA (due to calibration problems), eventually extended by additional clinical informations, e.g. from medical imaging of carotid atherosclerosis or calcified coronary plaque (using computed tomography) is likely to filter out patients who benefit the most from statins. We show an extremely large range of possible results using CEA, which points to the problem, that QALY models can be easily used to calculate desired cost-efficacies. We show that the variability of CEA using the QALY concept is high with costs per QALY ranging between 144'496 and -128'328. Our second study hypothesis is correct and QALY should not be used to guide medical decisions.

Cost-effectiveness analysis (CEA) using direct and indirect cost estimates

The "treat them all with statins" is not only cost-effective, but it will also save lives and avoid morbidity in the Swiss population aged 30-65 years or beyond. Annually, 4'186 cardiovascular deaths and 18'836 cardiovascular events could be avoided with cost-savings of CHF 1.4 to 7.0 Mia annualy (direct and indirect costs). The efficacy of statins will increase with a more selected use resulting from personalized clinical stratification using TPA with cost savings of CHF 3.4 to 10.0 Mia annually. Therefore, this CEA shows that statins are cost-effective in primary care and this lends support to our third study hypothesis, that statins should be reimbursed in primary care, but cost optimization with carotid imaging is possible with an ICER of 1.23 to 1.84, if the imaging costs are 75 CHF per patient.

Using more sophisticated QALY models with inclusion of life-time calculations, discounted QALY and adding pill-taking disutility (which in fact is very disputable), a statin treatment regardless of LDL even for patients at borderline risk (7.5% ASCVD risk in 10 years) would be likely to very cost-effective22,23.

Should we "QALY"?

Health economist like to "qaly" medicine. In this context, "I qaly" the health care system, is the expression of an evolving mathematical machinery24, that aims to give answers to the question, whether a medical therapy is indicated or not. Health economist claim, that QALY is a reliable metric like body size or weight. However, QALY are influenced by cultural, social, individual, extrinsic or intrinsic observations and factors, and experience of life quality based upon physical, psychological, interpersonal, socio-economic and spiritual dimensions that are never constant over time. The constancy of the multiplicative utility function over time is not evidence based, the function can never be evidence based at the individual level. Too many variables influence utility and therefore, QALY are expressing a fixed utility over time25, which creates an axiomatic expression21 of what is claimed to be real and is completely unrelated to human life quality despite the claims of health-economists to measure life quality. QALY are not reproducible as a metric, hampered by several biases (especially response shift and recall bias) and there is no golden standard for QALY26,27. Therefore, QALY cannot provide indications for medical interventions and merely serve for mathematical experiments that compare expenditures and their affordability across several societal activities (health care, schools, street infrastructure ecc). The aim of economists is resource allocation of finite resources and rationing based on the QALY concept. This gives economists an immense power over medicine. If health care authorities nevertheless favor models of health care economists over evidence-based medicine to indicate a medical intervention, then we should have evidence-based health economy which tests for the claimed positive effects. So far it appears that short-term QALY calculations serve budget impact analysis to ration medically indicated interventions. But the side-effect of this strategy, namely producing even higher medical and societal costs in the long-term, has not been properly addressed by the health economical faculty. Therefore, QALY based models are still experimental and may cause more harm than good. Fundamental ethical drawbacks were expressed against the use of QALY 28–31, while others favored QALY 32. Indeed, quality of life measurements integrated into QALY have been criticized

for subjectivity and ethical considerations 33, calculations of value-based prices are difficult 34 and the results of such fixed pricing are dependent on the average risk levels and the chosen cutoff of CHF or USD per QALY gained 18,35. As an alternative, estimates of direct and indirect costs per cardiovascular event can be related to costs of a lipid lowering drug and the individually expected achieved LDL reduction using refined risk stratifications strategies, e.g. with TPA, as presented in this paper.

Target patient identification

Preventive medicine should target those patients who will develop a cardiovascular event in the future. Conventionally, risk equations such as SCORE and AGLA stratified patients into risk categories from which the intensity of preventive medications was derived. If such an approach serves as the prior probability for CEA, it should be known that the precision to identify target patients is sufficiently high in order to make recommendations. In the actual situation we are confronted with the fact, that most target patients (82% for SCORE and 93% for AGLA in our study) are stratified to low or to intermediate risk levels, although they should appear in the high-risk level, as is the case with the 3rd TPA tertile, where 85% of all events occurred. Similar findings were apparent in the Lausanne CoLaus outcome study 7, where non-high risk was observed in 48% (AGLA) and 41% (SCORE) of all events. Another observation in adults hospitalized with a first acute coronary syndrome showed that 37% of patients were identified as high-risk patients by SCORE and 35% by AGLA and most of patients were not on statins when the event occurred36. In view of the very high costs of CHF 10 Mia / annum for the treatment of cardiovascular disease in Switzerland16, it should be concluded that the target patient identification needs substantial improvement. In view of our results in patients aged 30-65 years, it appears that most events (85%) occur in the highest TPA tertile and that imaging carotid plaque using the TPA method is cost-effective and cost-efficient.

Limitations

Several limitations have to be addressed. We present a practice-based analysis and not a random-sample population-based analysis. Therefore, absolute numbers of risk may be biased. However, cardiovascular prevention takes place at the practice level and not in a random sample of the population. The QALY model we used is a pure mirror of the SMB Model published in 2013/201413. Several critiques that may certainly be justified when using this model have been expressed4,5 and we agree, that the SMB QALY model should not be used for clinical decision making. Further, CEA analysis of the SMB showed cost per QALY of CHF 210’000 in 5 years and of CHF 160’000 in 10 years (for SCORE 7.5%) which was due to several errors in the input (e.g. LDL was allowed to be lowered only by 1.0 mmol/l, calculations were not based on Swiss LDL levels derived from an observational study, only additive QALY were used) and we have corrected these errors elsewhere37. We have unsuccessfully asked the SMB several times to withdraw their CEA report on statins.

Further, we tried to estimate indirect costs of a cardiovascular event and acknowledge, that several assumptions are completely arbitrary. One special point regards the value of a statistical life (VSL) that is used for CEA. The SMB used costs of CHF 8’500 for case-fatality, thus avoiding indirect costs. We used CHF 150’000 VSL/year and the dramatic effect of such differences on CEA are outlined in Table 7. VSL/year was $182’000 (Australia 201438) and $ 129’000 (USA 200939) and around €150’000 in Europe40. Although Statin side effects may occur, they are usually mild and reversible upon discontinued therapy. The disutility of having to ingest a daily pill was not quantified but is marginal, when motivation of patients is not hampered by scary informations about side-effects. Our calculations are on-treatment effects and disregard short-comings observed in intention-to-treat analysis.

PROCAM Rechner Harry Roos, Puls Sendung

'ROCAM-Schnelltest | **PROCAM-Gesundheitstest** | PROCAM-Schlaganfalltest

PROCAM-Gesundheitstest

Der PROCAM-Gesundheitstest basiert auf der PROCAM-Studie und gilt für Frauen und Männer im Alter von 20 bis 75 Jahren zur Ermittlung des Risikos für einen Herzinfarkt innerhalb der nächsten 10 Jahre.

Bei einem Ergebnis im gelben oder roten Bereich (Herzinfarktrisiko über 10% in 10 Jahren) sollten Sie Ihren Arzt konsultieren.

Einheiten: mmol/l

Alter: 65 Jahre

Geschlecht: Männlich | Weiblich

Diabetes mellitus / BZ >= 6.66 mmol/l: Nein | Ja — ? Hinweis

Zigarettenrauchen (zur Zeit): Nein | Ja — ? Hinweis

Familienanamnese positiv: Nein | Ja — ? Hinweis

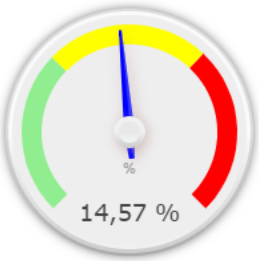
Systolischer Blutdruck: 130 mmHg

LDL-Cholesterin: 3.5 mmol/l

HDL-Cholesterin: 1.5 mmol/l

Triglyzeride: 1.5 mmol/l

Herzinfarktrisiko: 14.57%**



Neue Initiative gestartet:

PROCAM-Schlaganfalltest

Der PROCAM-Schlaganfalltest basiert auf der PROCAM-Studie und gilt für Frauen und Männer im Alter von 35 bis 65 Jahren zur Ermittlung des Risikos für einen Schlaganfall innerhalb der nächsten 10 Jahre.

Bei einem Ergebnis im roten Bereich sollten Sie Ihren Arzt konsultieren.

Alter: 65 Jahre

Geschlecht: Männlich | Weiblich

Diabetes mellitus / BZ >= 120 mg/dL: Nein | Ja — ? Hinweis

Zigarettenrauchen (zur Zeit): Nein | Ja — ? Hinweis

Systolischer Blutdruck: 130 mmHg

Zurücksetzen

Schlaganfallrisiko: >= 11.5% (>=1.98-fach erhöht)**

Neue Initiative gestartet:

AGLA Risikorechner

Mit der Nutzung des AGLA Risikorechners bestätigen Sie, dass Sie die Nutzungsbedingungen gelesen haben und damit einverstanden sind.

Bitte beachten Sie die Erläuterungen zum AGLA Risikorechner.

Allgemeine Angaben

Alter in Jahren (20–75 Jahre)

65 Jahre

Syst. BD in mmHg (100–225 mmHg)

130 mmHg

Geschlecht

(•) Mann ( ) Frau

Blutfettwerte

LDL (1.94–6.47 mmol/l)

3.5 mmol/l

HDL (0.65–1.94 mmol/l)

1.5 mmol/l

TG (0.57–4.52 mmol/l)

1.5 mmol/l

Weitere Angaben

Raucher

(•) Ja ( ) Nein

Diabetes

( ) Ja (•) Nein

Herzinfarkt bei Eltern, Grosseltern oder Geschwister vor dem 60. Lebenjahr

( ) Ja (•) Nein

Rechnen | Eingaben löschen

Bewertung

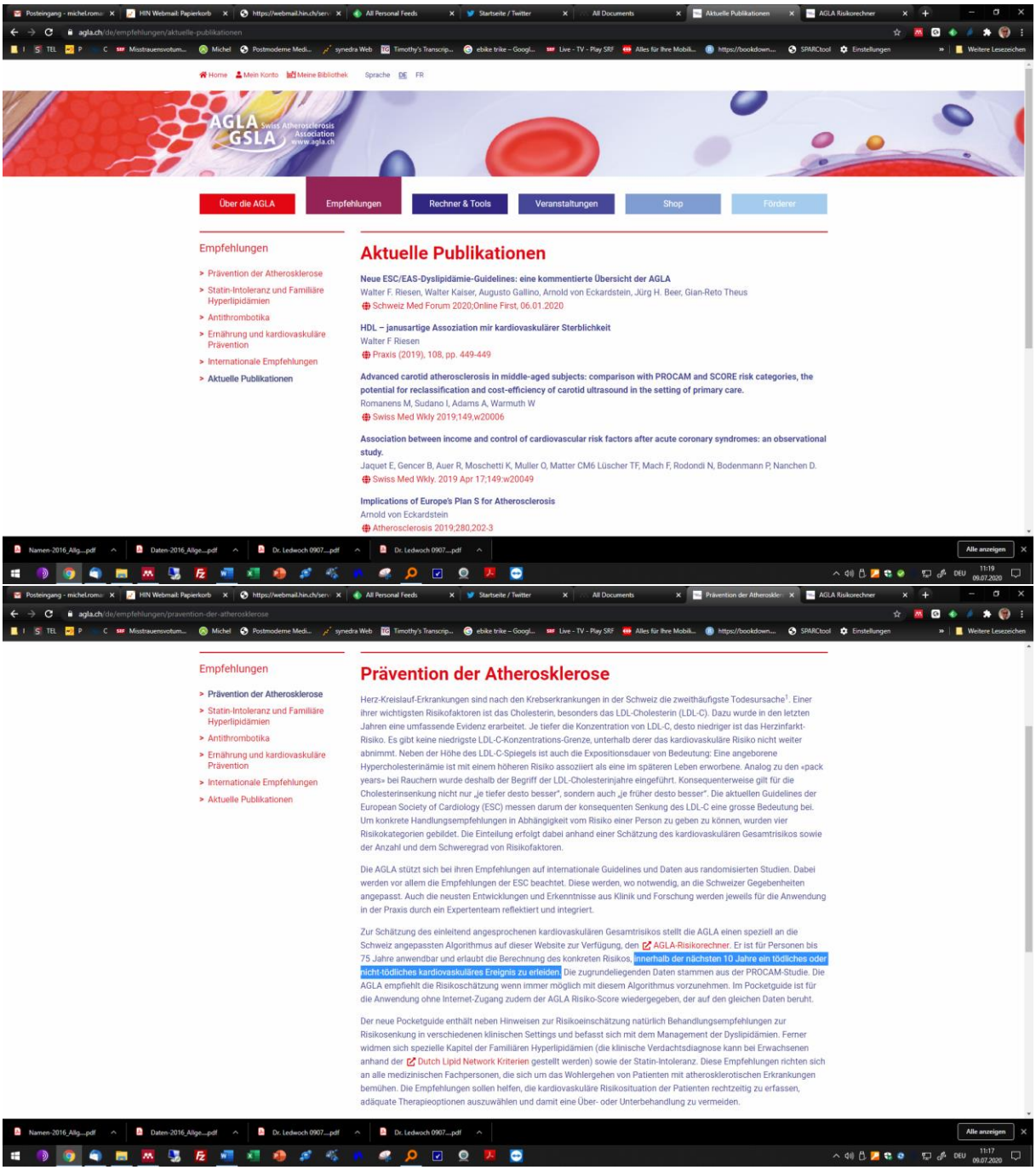
10.2%

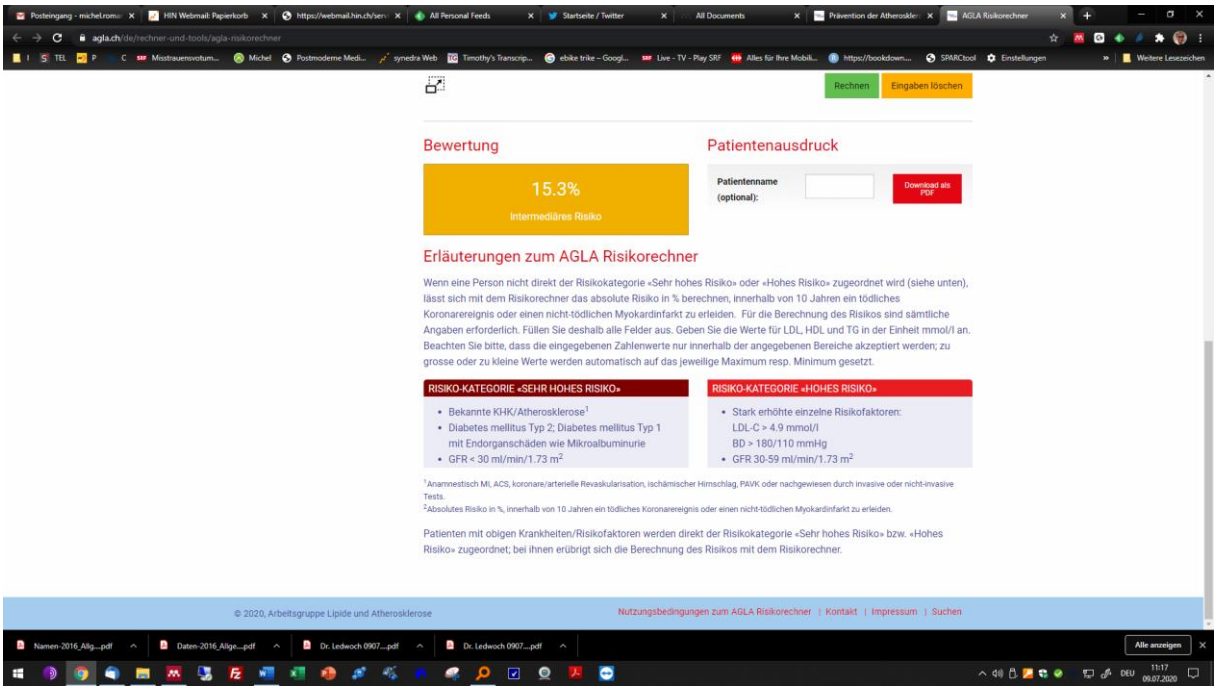
Intermediäres Risiko

Patientenausdruck

Patientenname (optional):

Download als PDF


Home
Mein Konto
Meine Bibliothek
Sprache DE FR
AGLA Swiss Atherosclerosis Association www.agla.ch
GSLA
Über die AGLA
Empfehlungen
Rechner & Tools
Veranstaltungen
Shop
Förderer
Empfehlungen
Prävention der Atherosklerose
Statin-Intoleranz und Familiäre Hyperlipidämien
Antithrombotika
Ernährung und kardiovaskuläre Prävention
Internationale Empfehlungen
Aktuelle Publikationen
Aktuelle Publikationen
Neue ESC/EAS-Dyslipidämie-Guidelines: eine kommentierte Übersicht der AGLA
Walter F. Riesen, Walter Kaiser, Augusto Gallino, Arnold von Eckardstein, Jürg H. Beer, Gian-Reto Theus
Schweiz Med Forum 2020;Online First, 06.01.2020
HDL – janusartige Assoziation mir kardiovaskulärer Sterblichkeit
Walter F Riesen
Praxis (2019), 108, pp. 449-449
Advanced carotid atherosclerosis in middle-aged subjects: comparison with PROCAM and SCORE risk categories, the potential for reclassification and cost-efficiency of carotid ultrasound in the setting of primary care.
Romanens M, Sudano I, Adams A, Warmuth W
Swiss Med Wkly 2019;149,w20006
Association between income and control of cardiovascular risk factors after acute coronary syndromes: an observational study.
Jaquet E, Gencer B, Auer R, Moschetti K, Muller O, Matter CM6 Lüscher TF, Mach F, Rodondi N, Bodenmann P, Nanchen D.
Swiss Med Wkly. 2019 Apr 17;149:w20049
Implications of Europe's Plan S for Atherosclerosis
Arnold von Eckardstein
Atherosclerosis 2019;280,202-3
Empfehlungen
Prävention der Atherosklerose
Statin-Intoleranz und Familiäre Hyperlipidämien
Antithrombotika
Ernährung und kardiovaskuläre Prävention
Internationale Empfehlungen
Aktuelle Publikationen
Prävention der Atherosklerose
Herz-Kreislauf-Erkrankungen sind nach den Krebserkrankungen in der Schweiz die zweithäufigste Todesursache[1]. Einer ihrer wichtigsten Risikofaktoren ist das Cholesterin, besonders das LDL-Cholesterin (LDL-C). Dazu wurde in den letzten Jahren eine umfassende Evidenz erarbeitet. Je tiefer die Konzentration von LDL-C, desto niedriger ist das Herzinfarkt-Risiko. Es gibt keine niedrigste LDL-C-Konzentrations-Grenze, unterhalb derer das kardiovaskuläre Risiko nicht weiter abnimmt. Neben der Höhe des LDL-C-Spiegels ist auch die Expositionsdauer von Bedeutung: Eine angeborene Hypercholesterinämie ist mit einem höheren Risiko assoziiert als eine im späteren Leben erworbene. Analog zu den «pack years» bei Rauchern wurde deshalb der Begriff der LDL-Cholesterinjahre eingeführt. Konsequenterweise gilt für die Cholesterinsenkung nicht nur „je tiefer desto besser", sondern auch „je früher desto besser". Die aktuellen Guidelines der European Society of Cardiology (ESC) messen darum der konsequenten Senkung des LDL-C eine grosse Bedeutung bei. Um konkrete Handlungsempfehlungen in Abhängigkeit vom Risiko einer Person zu geben zu können, wurden vier Risikokategorien gebildet. Die Einteilung erfolgt dabei anhand einer Schätzung des kardiovaskulären Gesamtrisikos sowie der Anzahl und dem Schweregrad von Risikofaktoren.
Die AGLA stützt sich bei ihren Empfehlungen auf internationale Guidelines und Daten aus randomisierten Studien. Dabei werden vor allem die Empfehlungen der ESC beachtet. Diese werden, wo notwendig, an die Schweizer Gegebenheiten angepasst. Auch die neusten Entwicklungen und Erkenntnisse aus Klinik und Forschung werden jeweils für die Anwendung in der Praxis durch ein Expertenteam reflektiert und integriert.
Zur Schätzung des einleitend angesprochenen kardiovaskulären Gesamtrisikos stellt die AGLA einen speziell an die Schweiz angepassten Algorithmus auf dieser Website zur Verfügung, den AGLA-Risikorechner. Er ist für Personen bis 75 Jahre anwendbar und erlaubt die Berechnung des konkreten Risikos, innerhalb der nächsten 10 Jahre ein tödliches oder nicht-tödliches kardiovaskuläres Ereignis zu erleiden. Die zugrundeliegenden Daten stammen aus der PROCAM-Studie. Die AGLA empfiehlt die Risikoschätzung wenn immer möglich mit diesem Algorithmus vorzunehmen. Im Pocketguide ist für die Anwendung ohne Internet-Zugang zudem der AGLA Risiko-Score wiedergegeben, der auf den gleichen Daten beruht.
Der neue Pocketguide enthält neben Hinweisen zur Risikoeinschätzung natürlich Behandlungsempfehlungen zur Risikosenkung in verschiedenen klinischen Settings und befasst sich mit dem Management der Dyslipidämien. Ferner widmen sich spezielle Kapitel der Familiären Hyperlipidämien (die klinische Verdachtsdiagnose kann bei Erwachsenen anhand der Dutch Lipid Network Kriterien gestellt werden) sowie der Statin-Intoleranz. Diese Empfehlungen richten sich an alle medizinischen Fachpersonen, die sich um das Wohlergehen von Patienten mit atherosklerotischen Erkrankungen bemühen. Die Empfehlungen sollen helfen, die kardiovaskuläre Risikosituation der Patienten rechtzeitig zu erfassen, adäquate Therapieoptionen auszuwählen und damit eine Über- oder Unterbehandlung zu vermeiden.


agla.ch/de/rechner-und-tools/agla-risikorechner
Rechnen
Eingaben löschen
Bewertung
15.3%
Intermediäres Risiko
Patientenausdruck
Patientenname (optional):
Download als PDF
Erläuterungen zum AGLA Risikorechner
Wenn eine Person nicht direkt der Risikokategorie «Sehr hohes Risiko» oder «Hohes Risiko» zugeordnet wird (siehe unten), lässt sich mit dem Risikorechner das absolute Risiko in % berechnen, innerhalb von 10 Jahren ein tödliches Koronarereignis oder einen nicht-tödlichen Myokardinfarkt zu erleiden. Für die Berechnung des Risikos sind sämtliche Angaben erforderlich. Füllen Sie deshalb alle Felder aus. Geben Sie die Werte für LDL, HDL und TG in der Einheit mmol/l an. Beachten Sie bitte, dass die eingegebenen Zahlenwerte nur innerhalb der angegebenen Bereiche akzeptiert werden; zu grosse oder zu kleine Werte werden automatisch auf das jeweilige Maximum resp. Minimum gesetzt.
RISIKO-KATEGORIE «SEHR HOHES RISIKO»
Bekannte KHK/Atherosklerose[1]
Diabetes mellitus Typ 2; Diabetes mellitus Typ 1 mit Endorganschäden wie Mikroalbuminurie
GFR < 30 ml/min/1.73 m²
RISIKO-KATEGORIE «HOHES RISIKO»
Stark erhöhte einzelne Risikofaktoren:
LDL-C > 4.9 mmol/l
BD > 180/110 mmHg
GFR 30-59 ml/min/1.73 m²
[1] Anamnestisch MI, ACS, koronare/arterielle Revaskularisation, ischämischer Hirnschlag, PAVK oder nachgewiesen durch invasive oder nicht-invasive Tests.
[2] Absolutes Risiko in %, innerhalb von 10 Jahren ein tödliches Koronarereignis oder einen nicht-tödlichen Myokardinfarkt zu erleiden.
Patienten mit obigen Krankheiten/Risikofaktoren werden direkt der Risikokategorie «Sehr hohes Risiko» bzw. «Hohes Risiko» zugeordnet; bei ihnen erübrigt sich die Berechnung des Risikos mit dem Risikorechner.
© 2020, Arbeitsgruppe Lipide und Atherosklerose
Nutzungsbedingungen zum AGLA Risikorechner | Kontakt | Impressum | Suchen