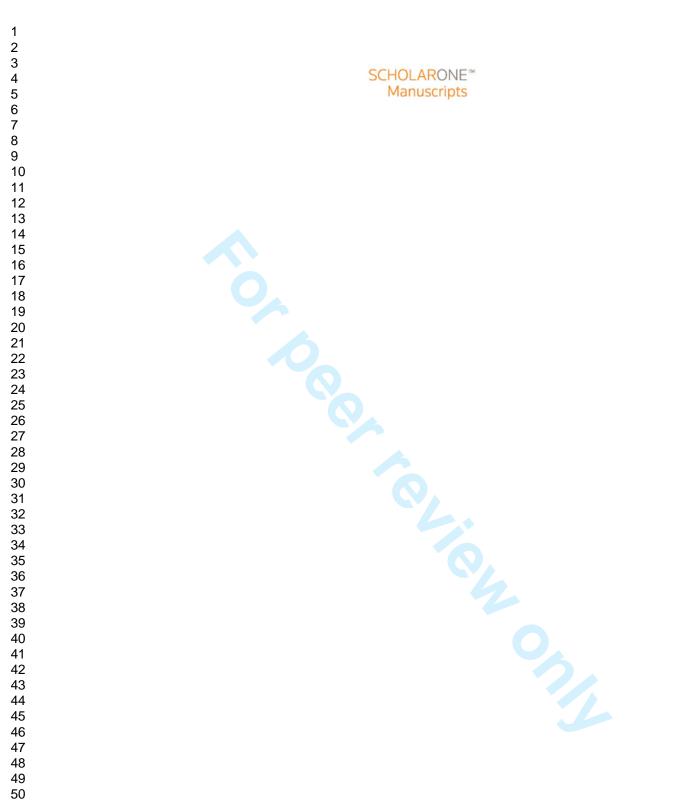


General Practitioners' use of absolute risk versus individual risk factors in cardiovascular disease prevention: An experimental study

Journal:	BMJ Open
Manuscript ID:	bmjopen-2014-004812
Article Type:	Research
Date Submitted by the Author:	08-Jan-2014
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Primary Subject Heading :	Cardiovascular medicine
Secondary Subject Heading:	General practice / Family practice, Evidence based practice
Keywords:	CARDIOLOGY, GENERAL MEDICINE (see Internal Medicine), PUBLIC HEALTH



General Practitioners' use of absolute risk versus individual risk factors in cardiovascular disease prevention: An experimental study

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Word count: 2965

Key words: cardiovascular disease, primary care, general practice, prevention, risk assessment

ABSTRACT

Objective: To understand general practitioners' (GPs) use of individual risk factors (blood pressure and cholesterol levels) versus absolute risk in cardiovascular disease (CVD) risk management decision-making.

Design: Randomised experiment. Absolute risk, systolic blood pressure (SBP), cholesterol ratio (TC/HDL), and age were systematically varied in hypothetical patient cases. High absolute risk was defined as 5 year risk of a cardiovascular event > 15%, high blood pressure levels varied between SBP 147 and 179 mmHg and high cholesterol (TC/HDL ratio) between 6.5 and 7.2 mmol/L.

Setting: 4 GP conferences in Australia.

Participants: 144 Australian GPs.

Outcomes: GPs indicated whether they would prescribe cholesterol and/or blood pressure lowering medication. Analyses involved logistic regression.

Results: For patients with high blood pressure: 93% (95%Cl=86-96%) of high absolute risk patients and 83% (95%Cl=76-88%) of lower absolute risk patients were prescribed blood pressure medication. Conversely, 30% (95%Cl=25-36%) of lower blood pressure patients were prescribed blood pressure medication if absolute risk was high and 4% (95%Cl=3-5%) if lower. 69% of high cholesterol/high absolute risk patients were prescribed cholesterol medication (95%Cl=61-77%) versus 34% of high cholesterol/lower absolute risk patients (95%Cl=28-41%). 36% of patients with lower cholesterol (95%Cl=30- 43%) were prescribed cholesterol medication if absolute risk was high versus 10% if lower (95%Cl=8-13%).

Conclusions: GPs' decision making was more consistent with management of individual risk factors than an absolute risk approach, especially when prescribing blood pressure medication. The results suggest medical treatment of lower risk patients (5 year risk of CVD event < 15%) with mildly elevated blood pressure or cholesterol levels is likely to occur even when an absolute risk assessment is specifically provided. The results indicate a need for improving uptake of absolute risk guidelines and GP understanding of the rationale for using absolute risk.

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STRENGTHS AND LIMITATIONS

- This study uses a rigorous experimental design to systematically investigate how GPs use individual risk factors (blood pressure and cholesterol) versus the absolute risk of a CVD event in their decision making about CVD preventive medication. International guidelines are based on absolute risk, but are used inconsistently.
- The sample size was sufficient to show that GPs' decision making was more consistent with management of individual risk factors than an absolute risk approach, especially when prescribing blood pressure lowering medication.
- Our findings have important clinical implications, suggesting that medical treatment of lower risk patients (5 year risk of CVD event < 15%) with mildly elevated blood pressure or cholesterol is likely to occur even when an absolute risk assessment is specifically provided to GPs.
- The results may over-estimate the use of absolute risk in clinical practice due to: 1) a low response rate that is typical of such GP studies but may have favoured those more interested and positive about absolute risk, 2) reliance on self-reported intentions, which was necessary to enable an experimental design, and 3) explicitly providing GPs with an absolute risk score for each case, since absolute risk is often not assessed in practice.

INTRODUCTION

International guidelines for cardiovascular disease (CVD) prevention encourage the use of absolute risk to guide treatment with blood pressure and cholesterol lowering medication. Several risk prediction models exist that differ in the duration over which they calculate CVD risk (typically 5 or 10 years) and the variables they base the risk on.[1,2] One of the most commonly used absolute risk models is the Framingham Risk Equation (FRE)[3], which estimates the risk of a cardiovascular event based on sex, age, smoking status, diabetes, systolic blood pressure, and cholesterol ratio. The Australian guidelines classify patients with a 5 year risk of > 15% as high risk and recommend that they should be simultaneously treated with cholesterol and blood pressure lowering medication in addition to lifestyle intervention unless contraindicated or clinically inappropriate.[4,5] For lower risk patients ≤ 15% without additional risk factors such as family history, lifestyle intervention is recommended as the primary management approach. Adults with very high individual risk factors (systolic blood pressure ≥180 mmHg or diastolic blood pressure ≥110 mmHg or total cholesterol >7.5 mmol/L) do not require absolute CVD risk assessment because they are already considered to be at high risk of CVD.[4,5]

Using absolute risk is a major shift from the traditional approach of treating high blood pressure and high cholesterol individually. An absolute risk approach is likely to achieve the best balance between preventing CVD events and avoiding unnecessary treatment with medication. It has the potential to reduce overtreatment of people who have an elevated individual risk factor (e.g. blood pressure) but low or moderate overall risk of a CVD event and reducing undertreatment of people with slightly elevated individual risk factors but a combined high overall risk.[6,7] The absolute risk approach has been shown to reduce short-term CVD risk without causing clinical harms.[8]

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However, research suggests that General Practitioners (GPs) often do not use absolute risk to guide their decision making about CVD prevention.[9-13] Past research includes studies exploring barriers to GP's use of absolute risk[13-16] and studies quantifying treatment gaps using clinical databases[6,10,11,17], but individual decision making about absolute risk has not been comprehensively examined quantitatively. In this study we applied a method based on judgments of hypothetical patient cases to analyse GPs' decisions about CVD risk management and their use of absolute risk. Hypothetical patient cases (also called vignettes) have been widely used to measure decision processes in a range of clinical settings[18], including GP decision making about cardiovascular disease.[19-21] Indeed, three recent studies using patient cases suggest that clinicians might not base treatment decisions on absolute risk thresholds (e.g. only treat patients > 15% for 5 year FRE based absolute risk or > 20% for 10 year risk); instead they focus on the levels of the individual risk factors blood pressure and cholesterol.[19-21] However, these studies did not systematically assess different combinations of absolute risk and individual risk factor levels. Therefore, they provide limited interpretation of how GPs use absolute risk versus individual risk factors in decision making.

In the current study we used patient cases in which absolute risk and three individual risk factors (systolic blood pressure, cholesterol (TC/HDL ratio), and age) were systematically varied in order to evaluate their respective influence on GPs' decision making about CVD risk management. Absolute risk levels were derived from the FRE.[3]

METHOD

We presented GPs with 11 paper based cases describing hypothetical patients. Cases were designed to be clinically plausible and relevant. The cases characterised a patient by absolute risk and three

key individual risk factors: systolic blood pressure (SBP), cholesterol ratio (TC/HDL) and total/HDL cholesterol and age, as well as gender and smoking status.

Levels of absolute risk and individual risk factor levels

The levels used to describe elevated absolute risk and the individual risk factors (see Table 1) were based on the 2012 Australian absolute risk guidelines[5] (using the FRE) and informed by practicing GPs (JD, PG). We defined patients with a risk of a cardiovascular event over 5 years greater than 15% as high absolute risk, for whom preventive medication is recommended. The Australian absolute risk guidelines recommend that adults with systolic blood pressure ≥180 mmHg or total cholesterol >7.5 mmol/L do not require absolute CVD risk assessment because they are already known to be at clinically determined high risk of CVD.[5] We ensured that the individual risk factor levels remained below these thresholds and, where possible, we avoided values that were close to the cut off. High blood pressure levels varied between SBP 147 and 179 mmHg and high cholesterol (TC/HDL ratio) between 6.5 and 7.2 mmol/L. Lower blood pressure levels varied between SBP of 110 and 145 mmHg and lower TC/HDL ratio between 3.0 and 6.0 mmol/L. We defined three age categories within the target population for CVD risk assessment: 47, 61, and 72 years.

Different sets of patient cases

We developed four sets of cases (also see Table 1):

A) High IR/lower AR with high individual risk factors (blood pressure only) and lower absolute risk
Aii) High IR/lower AR with high individual risk factors (cholesterol only) and lower absolute risk
B) High IR/high AR with high individual risk factors and high absolute risk,
C) Lower IR/high AR with lower individual risk factors and high absolute risk, and
D) Lower IR/lower AR with lower individual risk factors and lower absolute risk.

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In all cases except high IR/lower AR (Ai and Aii) the levels of individual risk factors were the same across blood pressure and cholesterol (i.e. both lower or both high). For high IR/lower AR (Ai and Aii) blood pressure was high and cholesterol was lower, or vice versa, to enable exploration of their independent effects on GP decision making. This resulted in a core set of 25 cases with different combinations of absolute and individual risk factor levels (see Appendix A for the complete set of cases).

Table 1. The variable levels for absolute risk and individual risk factors blood pressure (SBP) and cholesterol (TC/HDL ratio) plus the relevant case numbers and number of cases (n=144 GPs)⁺

Category Figure 2/ Appendix A	Absolute risk	factors [‡]			
Арреник А		SBP (mmHg)	TC/HDL ratio (mmol/L)	N	Case #
Ai	Lower	High	Lower	431	25-35
Aii	Lower	Lower	High	415	13-24
В	High	High	High	221	7-12
С	High	Lower	Lower	298	36-43
D	Lower	Lower	Lower	219	1-6

[†]See appendix A for the actual values used in these cases.

Gender and smoking status

We constructed a female and male equivalent of each core case (where possible, given the restraints of the FRE and the individual and absolute risk levels defined above). We made all high absolute risk cases smokers and all lower absolute risk cases non-smokers, and we constructed an additional set of cases to test for the potential confounding effect of smoking.

Randomisation

There were 25 core cases (varying in absolute risk, cholesterol, blood pressure, and age) with between one to three versions of each (male, female, smoking/non-smoking comparison). The

combinations generated a total of 43 possible cases. GPs were presented with 11 core cases. All cases were randomly selected and only one of the one to three available versions of each case was presented per GP. All selected cases were presented in random order.

Data collection and measurement

Respondents viewed a generic patient scenario (see Box 1) followed by a table with the relevant values for absolute risk, systolic blood pressure, TC/HDL ratio, HDL, total cholesterol, and age, as well as patient gender and smoking status. GPs were asked how they would manage the patient in the scenario: prescribe cholesterol medication, prescribe blood pressure medication, and/or prescribe aspirin (yes/no for each). In addition, they were asked when they would reassess the patient (open ended). The aspirin and reassessment results are reported separately. We collected information regarding GP characteristics: gender, age, years in practice, practice size. We asked GPs two questions about their use of absolute risk as follows: *"For the cases you just read, how often did you use the absolute risk score to inform your management decision*? and *"In your general practice, how often do you use absolute risk scores, calculators or charts when assessing a patient's level of cardiovascular risk?"* (5 point Likert scale; 1 never – 5 always). The survey was piloted with nine GPs.

Box 1: General patient scenario

'A regular patient of yours presents for a "check-up" and has no current symptoms. He/she has been trying to improve their diet and increase their physical activity levels. You have several previous blood pressure readings at approximately the same level as observed today. A recent test of electrolytes, liver function and renal function was normal.'

BMI: 27

Past medical history: nil of note

Family history: mother died of bowel cancer, nil family history of ischaemic heart disease Social history: married, lives in own home Ethnicity: Caucasian

Recruitment

Practising GPs were recruited between May and November 2012 at four general practice conferences in Australia. GPs read an information sheet and completed the survey at a stall or returned a completed survey that was inserted in their conference pack. A \$500 gift voucher was used as an incentive. Ethical approval was obtained from the University of Sydney Human Research Ethics Committee.

Analysis

GPs' decisions on risk management for the different patient cases were summarized as the percentage of cases in which the GPs would prescribe cholesterol or blood pressure medication. We analysed how the chances of prescribing medication changed according to the risk patterns of the cases (i.e. levels of absolute and individual risk factors). This was done using Generalised Estimation Equations (GEEs) with a logit link (logistic regression) and an exchangeable working correlation matrix to take into account the clustering of cases per GP.

The outcome was whether the GP would prescribe medication for the case, and the covariates were the levels of absolute risk and individual risk factors (i.e. blood pressure and cholesterol levels) presented in the cases. More specifically, four sets of cases were compared: A) high individual risk factors and lower absolute risk, B) high individual risk factors and high absolute risk, C) lower individual risk factors and high absolute risk, and D) lower individual risk factors and lower absolute risk. The 95% confidence intervals for the percentages presented in the results section and Figure 2 were obtained from the GEEs.

We performed exploratory analyses to examine 1) how risk management changed according to GP characteristics (i.e. age, gender, years in practice, practice size, and self-reported use of absolute risk in practice and in the cases); and 2) how risk management changed according to specific characteristics of the cases presented (i.e. age, gender, and smoking status). This was achieved by adding each covariate to the GEEs and testing the main effects and the interaction between levels of absolute and individual risk factors. The statistical analysis was performed with the software SPSS version 21.

RESULTS

Response rate

Over the four General Practice conferences, we had a 30% response rate for surveys that were handed out at a stall (90 surveys completed from 304 distributed at two conferences) and a 3% response rate for surveys that were inserted into GPs' conference packs (55 surveys completed from 1803 surveys inserted into GPs' conference packs at three conferences). One returned survey was excluded due to participant ineligibility (not currently practising). A total of 144 GPs participated in this study.

GP characteristics

The median age of the GPs who participated in the study was 53 (IQR= 47 to 59) and 58% were female. They had been practicing medicine for a median of 28 years (IQR=21 to 35) with a median practice size of five GPs (IQR= 3 to 8). Figure 1 shows GPs' self-reported use of absolute risk in their usual practice and the patient cases. From here on, the hypothetical patient cases will be referred to as patients.

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<Please insert Figure 1>

Prescription of blood pressure lowering medication

For patients in the high blood pressure group (SBP ≥147 mmHg) GPs stated that they would prescribe blood pressure medication for 93% (95%CI=86-96%) of the patients with high absolute risk (5 year risk of a CVD event > 15%) and 83% (95%CI=76-88%) of the patients with lower absolute risk. See Figure 2(I) and Appendix 1, Ai and B. Conversely, 30% (95%CI=25-36%) of patients in the lower blood pressure group were prescribed blood pressure medication if absolute risk was high and 4% (95%CI=3- 5%) of the patients if absolute risk was lower. See Figure 2(I) and Appendix 1, C and D.

<Please insert Figure 2>

Prescription of cholesterol lowering medication

GPs stated they would prescribe cholesterol medication for 69% of patients with high cholesterol (TC/HDL ratio \geq 6.5) and high absolute risk (95%Cl=61-77%; Figure 2b, B). In contrast, a smaller percentage of patients with high cholesterol but lower absolute risk were prescribed cholesterol medication (34%, 95%Cl=28-41%; Figure 2(II) and Appendix 1, Aii). The prescribing pattern for cholesterol medication in patients with lower cholesterol was similar to blood pressure medication. GPs indicated that they would prescribe cholesterol medication in just over a third of patients (36%, 95%Cl=30-43%; Figure 2(II) and Appendix 1, C) if absolute risk was high and 10% of patients if absolute risk was lower (95%Cl=8-13%; Figure 2(II) and Appendix 1, D).

Prescription and patients' characteristics

There were no differences in the pattern of prescribing cholesterol medication for patients of different age groups at similar risk (p=0.331). However, 61 year old patients were twice as likely (OR=2.00, p<0.001, 95%CI=1.52-2.65) to be prescribed blood pressure medication than 72 year old patients with the same risk profile. GPs were also more likely to indicate that they would prescribe cholesterol medication (OR=1.27, p=0.025, 95%CI=1.03-1.56) but not blood pressure medication to men (OR=1.24, p=0.212, 95%CI=0.89-1.72). Smoking status was not associated with the prescription of cholesterol or blood pressure medication (OR=0.66, p=0.077, 95%CI=0.42-1.05).

Prescription and GP characteristics

Older GPs were less likely to prescribe cholesterol medication (OR=0.77, p=0.039, 95%CI=0.60-0.99, per 10 years of age). A similar trend was found for years of practice (OR=0.80, p=0.052, 95%CI=0.65-1.00, per 10 years of practice). GP age and years of practice were not associated with stated prescribing of blood pressure medication (OR=0.81, p=0.160, 95%CI=0.61-1.09, per 10 years of age; OR=0.84, p=0.191, 95%CI=0.65-1.09, per 10 years of practice).

Stated prescribing was not significantly associated with self-reported use of the absolute risk approach in practice or GP gender. However, GPs who reported using absolute risk in the patient cases were more likely to prescribe blood pressure and cholesterol medication for patients with high absolute risk (blood pressure medication: OR=1.29, p=0.042, 95%CI=1.01-1.64; cholesterol medication: OR=1.61, p=0.001, 95%CI=1.22-2.12). For the patients with lower absolute risk these GPs also prescribed more, but this was not statistically significant (blood pressure medication: OR=1.07, p=0.654, 95%CI=0.81-1.41; cholesterol medication: OR=1.22, p=0.077, 95%CI=0.98-1.52).

DISCUSSION

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Our analysis of the prescribing decisions for 144 general practitioners (GPs) over a range of systematically varied patient cases suggests that GPs focus more on the levels of individual CVD risk factors blood pressure and cholesterol than on absolute risk, especially when prescribing blood pressure lowering medication. The results suggest that, inconsistent with the Australian guidelines,[4,5] GPs are likely to prescribe blood pressure and cholesterol lowering medication to lower risk patients (5 year risk of CVD event < 15%) if these risk factors are elevated even when an absolute risk assessment is specifically provided to GPs. These results are in line with previous studies showing that GPs consider medication for people at low levels of absolute CVD risk.[19-21] Age appeared to be largely ignored as a risk factor, and GPs prescribed less blood pressure lowering medication for 72 year old patients in comparison with 61 year olds despite similar descriptions in the scenarios (a relatively healthy fit x year old). This finding is worthy of further exploration, given that age is one of the strongest risk factors for CVD, as it runs counter to the concept of absolute CVD risk and proposals such as the use of the "polypill" based solely on an age cut off.[22]

We acknowledge that in clinical practice GPs may have various and valid reasons for deviating from the guidelines, and strict adherence to guidelines and/or treatment thresholds may undermine the shared decision making (SDM) approach that is now considered gold standard.[23,24] SDM in the current context would entail that a GP assesses absolute CVD risk, explains this and the recommended management approach to the patient, discusses the benefits and harms of the different management options with the patient, and makes a shared decision with the patient. Our study and previous work[9-13] suggests that many GPs do not based their recommendations on absolute risk, so it is unlikely that they can adequately inform their patients about the benefits and harms of CVD risk management and engage them in shared decision making.

Prescribing patterns were different for cholesterol and blood pressure medication. Although explanatory factors were not investigated in this study, historically, anti-hypertensive prescribing dates back to the late 1950s; hypertension was the first major CVD risk factor successfully

treated.[25] In contrast, there was controversy over the treatment of cholesterol until the largescale trials of statins reported in the mid-1990s,[26] which coincided with the emergence of ideas and methods using absolute CVD risk. This history may have influenced the language used for these risk factors; "hypertension" is more commonly used than its lipid analogues such as "hypercholesterolaemia".

The strengths of this study include its sample size, the heterogeneity of the GPs who participated, and the systematic variation of patient cases, but there are also some limitations: First, the response rate was disappointing though typical for such GP studies.[20] However, any bias in our sample is likely to favour GPs more interested and positive about absolute risk, although almost 15% of GPs in our study stated that they never use absolute risk in practice. Second, to keep cases simple and clear we were restrictive in the range of clinical variables and management options presented, excluding lifestyle modification although space was provided for comments. Third, we relied solely on selfreported intentions to prescribe in the different scenarios rather than actual prescribing behaviour. This allowed an experimental design, but the results may not reflect what is actually happening in clinical practice. However, our results are likely to be an over-estimate of the use of absolute risk in actual practice as the patient cases explicitly provided GPs with an absolute risk score. We know from our qualitative work that absolute risk is often not assessed in practice.[13]

In conclusion, GPs' decision making was more consistent with an individual risk factor approach than absolute risk, especially when prescribing blood pressure lowering medication. While more research to explore the cognitions behind these reported behaviours would be worthwhile, our study identifies a clear need to improve guideline recommendations about how GPs should integrate individual risk factor assessment with a management that is guided by absolute CVD risk.

ACKNOWLEDGEMENTS

The authors would like to thank the General Practitioners who participated in the study, and Adam McSorley for assistance with data management.

COMPETING INTERESTS

All authors have completed the Unified Competing Interest form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare: no financial relationships with any organisations that might have an interest in the submitted work in the previous three years, and no other relationships or activities that could appear to have influenced the submitted work.

FUNDING

The study was funded by the National Health and Medical Research Council (NHMRC) project grant 511217. Jesse Jansen and Kirsten McCaffery are supported by NHMRC fellowships. Carissa Bonner was supported by an Australian Postgraduate Award. Robin Turner and Armando Teixeira-Pinto were supported by NHMRC program grant 633003 to the Screening & Test Evaluation Program. Jenny Doust was supported by the NHMRC project grant 511217.

ETHICAL APPROVAL

The University of Sydney human research ethics committee approved this study (No 11-2011/14379).

DATA SHARING

No additional data available.

AUTHOR CONTRIBUTIONS

All authors included on the paper fulfil the criteria of authorship, and there was no one else who fulfils the criteria. JJ contributed to study design, analysis, interpretation, drafting and revising the manuscript. CB contributed to study design, recruitment, data collection, analysis, interpretation, and revising the manuscript. SM contributed to recruitment, data collection, analysis, interpretation, and revising the manuscript. LI contributed to study design, interpretation, and revising the manuscript. JD contributed to study design, interpretation, and revising the manuscript. JD contributed to study design, interpretation, and revising the manuscript. PG contributed to study design, interpretation, and revising the manuscript. ATP contributed to analysis, and revising the manuscript. RT contributed to study design, and revising the manuscript. AH contributed to study design, and revising the manuscript. KM contributed to study design, analysis and interpretation, and revising the manuscript. All authors approved the final version of the manuscript and all authors are guarantors.

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FIGURE LEGENDS

Figure 1. Self-reported use of absolute risk in practice and in the hypothetical patient cases (n=144 GPs).

Figure 2. Percentages of cases in which the General practitioners would prescribe a blood pressure or cholesterol lowering drugs according to different combination of absolute (horizontal axis) and individual risk factors (vertical axis).

The error bars represent the 95% confidence intervals for the percentage of cases (controlled for clustering)

Ai) High IR/lower AR with high individual risk factors (blood pressure only) and lower absolute risk

Aii) High IR/lower AR with high individual risk factors (cholesterol only) and lower absolute risk

B) High IR/high AR with high individual risk factors and high absolute risk,

C) Lower IR/high AR with lower individual risk factors and high absolute risk, and

D) Lower IR/lower AR with lower individual risk factors and lower absolute risk.

See Appendix A for exact AR and IR values

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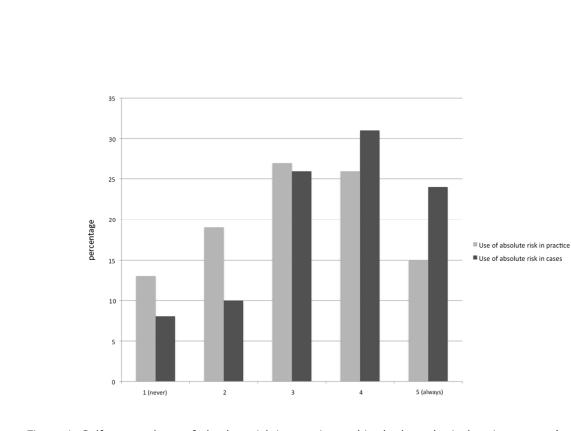


Figure 1. Self-reported use of absolute risk in practice and in the hypothetical patient cases (n=144 GPs). 367x242mm (72 x 72 DPI)

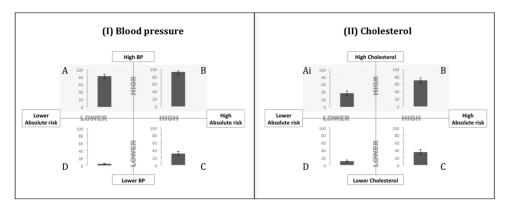


Figure 2. Percentages of cases in which the General practitioners would prescribe a blood pressure or cholesterol lowering drugs according to different combination of absolute (horizontal axis) and individual risk factors (vertical axis).

The error bars represent the 95% confidence intervals for the percentage of cases (controlled for clustering) Ai) High IR/lower AR with high individual risk factors (blood pressure only) and lower absolute risk Aii) High IR/lower AR with high individual risk factors (cholesterol only) and lower absolute risk B) High IR/high AR with high individual risk factors and high absolute risk,

C) Lower IR/high AR with lower individual risk factors and high absolute risk, and

D) Lower IR/lower AR with lower individual risk factors and lower absolute risk.

See Appendix A for exact AR and IR values

352x264mm (72 x 72 DPI)

	Case type	ype AR BP [§] Cholesterol			Age	Gender	Smoker	Case #		
				TC/HDL [#]	Total [#]	HDL [#]	_ 0			
Α	(i)	3.7%	167	3.8	5.1	1.3	47	Female	n	25
	AR: lower	5.5%	167	3.8	5.1	1.3	47	Male	n	26
	IR: high	7.1%	166	3.5	5.1	1.5	61	Female	n	27
	(BP only)	8.9%	156	3.0	4.9	1.6	61	Male	n	28
		8.4%	156	3.1	4.9	1.6	72	Female	n	29
		10.2%	179	6.0	6.0	1.0	47	Male	n	30
		11.9%	169	5.8	6.0	1.0	47	Female	у	31
		12.6%	157	5.2	5.8	1.1	47	Male	У	32
		11.8%	169	5.8	6.0	1.0	61	Female	n	33
		13.5%	147	5.7	5.9	1.0	61	Male	n	34
		13.2%	158	5.0	5.6	1.1	72	Female	n	35
	(i)	2.2%	114	6.7	6.2	0.9	47	Female	n	13
	AR: lower	4.9%	125	7.2	6.3	0.9	47	Male	n	14
	IR: high	6.4%	123	6.8	6.2`	0.9	61	Female	n	15
	(chol only)	8.9%	116	6.5	6.2	1.0	61	Male	n	16
		8.6%	118	6.6	6.3	1.0	72	Female	n	17
		10.9%	130	7.2	6.3	0.9	47	Male	у	18
		13.0%	132	7.2	6.3	0.9	61	Male	n	19
		12.4%	123	6.8	6.2	0.9	61	Female	у	20
		14.8%	110	6.6	6.3	1.0	61	Male	ý	21
		11.2%	128	7.1	6.6	0.9	72	Female	n	22
		13.9%	112	6.8	6.2	0.9	72	Male	n	23
		13.6%	110	6.5	6.2	1.0	72	Female	у	24
В	AR: high	15.6%	177	7.2	6.3	0.9	47	Female	y	7
	IR: high	18.3%	167	7.2	6.3	0.9	47	Male	у	8
		21.7%	166	6.6	6.3	1.0	61	Female	у	9
		29.9%	165	6.6	6.3	1.0	61	Male	у	10
		28.6%	166	6.6	6.3	1.0	72	Female	у	11
		39.7%	165	6.6	6.3	1.0	72	Male	y	12
С	AR: high	15.4%	131	4.4	5.4	1.2	61	Male	у	36
	IR: lower	15.3%	132	4.5	5.5	1.2	73 [¶]	Female	y	37
		19.5%	129	3.6	5.2	1.5	72	Male	y	38
		15.5%	145	5.9	5.8	1.0	61	Female	ý	39
		21.3%	144	5.4	5.6	1.0	61	Male	y	40
		20.8%	145	6.0	6.0	1.0	72	Male	n	41
		20.0%	144	5.4	5.6	1.0	72	Female	у	42
		29.8%	143	5.4	5.6	1.0	72	Male	ý	43
D	AR: lower	1.4%	122	3.9	5.3	1.3	47	Female	n	1
	IR: lower	2.2%	123	3.8	5.1	1.3	47	Male	n	2
		3.4%	122	3.9	5.3	1.3	47	Female	n	3
		6.0%	122	3.8	5.1	1.3	61	Male	n	4
		5.5%	122	3.8	5.1	1.3	72	Female	n	5
		5.5%	122	5.0	5.1	1.0				

Appendix A: Overview of the different cases

AR=absolute cardiovascular disease risk, IR=individual risk factors, BP= systolic blood pressure

The shaded rows indicate control cases

§=(mmHg), #=(mmol/L)

[¶]Age was 73 in one case to ensure the correct threshold for absolute risk and individual risk factors.

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FINAL study protocol GP decision making about absolute cardiovascular disease (CVD) risk assessment and management

Date last amendments: July 29, 2013 (content), October 8, 2013 (lay out)

Investigators: Jesse Jansen, Carissa Bonner, Shannon McKinn, Les Irwig, Jenny Doust, Paul Glasziou, Armando Teixeira-Pinto, Andrew Hayen, Robin Turner, Kirsten McCaffery

Aim: To identify factors that influence clinician's decision making about absolute CVD risk assessment and management in the general population

Research questions:

For various scenarios: To what extent are GPs' decisions influenced by absolute risk
 (AR) or individual risk factors (IR)- blood pressure and cholesterol?

2. Are GPs' decisions about cardiovascular disease risk management consistent with the guidelines? In which situations are decisions per guideline and in which situations are they not per guideline?

3. How does patient age influence GPs' decisions about CVD management?

4. How do key factors (not included in the AR model such as BMI and family history) influence GPs' decision making about cardiovascular disease risk management?

Objectives and main analysis

All comparisons based on % of GPs who decide to treat the patient with medication (mix of within & between participants).

Primary outcome: any drug treatment (BP or cholesterol). At meeting January 23rd, we decided not to include aspirin in our primary analysis as it is not central to our research

question and may be confounded by the fact that the cases describes a family history of bowel cancer and the emerging evidence on the use of aspirin to prevent bowel cancer.

Secondary outcome:

- Specific treatment (for low/medium AR)
- Time to reassessment (analysis not included in first paper)

Objective 1: to investigate whether GPs' are more likely to treat <u>low/med</u> AR when patients have 'inconsistent' IR (<u>high</u> BP or cholesterol) than when they have 'consistent' IR (<u>low</u> BP and cholesterol).

- Control < high IR (across BP and chol; version 1-6 (n=219) vs 13-35 (n=846))
- Control < high BP (version 1-6 (n=219) vs 25-35 (n=430))
- Control < high cholesterol (version 1-6 (n=219) vs 13-24 (n=416))
- Additional analyses: do the above results differ for low vs med AR, age and gender

Objective 2: to investigate whether GPs' will be less likely to treat <u>high</u> AR when patients have 'inconsistent' IR (<u>low/med</u> BP and cholesterol) than when they have 'consistent' IR (<u>high</u> BP and cholesterol). *To reduce the total number of vignettes and because our main interest was in overprescribing of patients with high blood pressure/cholesterol but low/medium AR, we decided to look at objective 2 across BP/cholesterol only.*

- Control > low/med IR (across BP and chol; version 7-12 (n=220) vs 36-43 (n=299))
- Additional analyses: do the above results differ for low vs med IR, age and gender

Objective 3: to investigate (a) whether GPs' decision making will be influenced by patient age in general and (b) old-old (86 year old patient) age in particular (note: all analysis across BP and cholesterol):

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	1. More lil	kely to trea	at younge	r patie	nts who h	ave low/r	med AR	and 'incons	istent'
	IR (high	BP and ch	olesterol)						
	2. Less like	ely to treat	older pat	ients v	who have	high AR a	nd 'inco	nsistent' IR	
	(low/me	ed BP and	cholester	ol).					
					vc 72) fo	r objectiv	oc 1 and	2	
-									
-	Plus 7 addit	ional versi	ons for 86	o yo (di	scussed 2	/12/11 w	LI, AH a	nd CB) see	Table 1:
	• Low IR a	and high A	R (duplica	te vigr	nette 37&	38 with A	R recalc	ulated for 7	'4 year
	old = ve	rsion 46-4	7 (n=31)).						
	• Mediun	n IR and hi	gh AR (du	plicate	vignette	41-43 wit	h AR reo	calculated f	or 74
	year old	l = version	48-50 (n=	:67)).					
					dualicato	vignotto	11017,	with AD roc	alculated
						vignette	110121	WITH AR TEL	alculated
	for 74 y	ear old = v	ersion 44	-45 (n=	=46)).				
-	Additional a	inalyses: d	o the abo	ve resi	ults differ	for low ve	med Al	R and gend	er
Table 1	L. Overview o	of variable	levels for	absolu	te risk an	d individu	al risk fa	actors blood	k
nressu	re and choles	terol for t	he 72 vr o	ld and	86 vr old	natient ca	ises*		
Varia	ble levels	AR	(%)						
	IR (BP &				chol	total			
AR	Chol)	86 yo	72 уо	BP	ratio	chol	HDL	smoking	gender
high	high	29.9	28.6	166	6.6	6.3	1	yes	F
high	high	41.3	39.7	165	6.6	6.3	1	yes	М
high	moderate	22.1	20.8	145	6	6	1	no	М
high	moderate	21.1	20	144	5.4	5.6	1	ves	F
								-	
nign	moderate	31.3	29.8	143	5.4	5.0	1	yes	Μ
high	low	15.7	15.3	132	4.5	5.5	1.2	yes	F
	pressu Varia AR high high high high	IR (high 2. Less like (low/ma) 4. Covered by 9 Plus 7 addit 9 Low IR a old = ve 4. Medium year old 6. Control for 74 y 4. Control for 74 y 4. Additional a pressure and choles Variable levels IR (BP & AR Chol) high high high moderate high moderate	IR (high BP and ch 2. Less likely to treat (low/med BP and - Covered by age compa - Plus 7 additional versi - Low IR and high A old = version 46-4 - Medium IR and high year old = version - Control vignettes: for 74 year old = version - Additional analyses: d Table 1. Overview of variable pressure and cholesterol for th Variable levels AR IR (BP & AR Chol) 86 yo high high 41.3 high moderate 22.1 high moderate 21.1	IR (high BP and cholesterol) 2. Less likely to treat older pat (low/med BP and cholesterol 2. Less likely to treat older pat (low/med BP and cholesterol 3. Covered by age comparisons (4) 3. Plus 7 additional versions for 86 4. Low IR and high AR (duplicat old = version 46-47 (n=31)). 4. Medium IR and high AR (du year old = version 48-50 (n= 4. Control vignettes: high IR and for 74 year old = version 44 5. Additional analyses: do the about Table 1. Overview of variable levels for pressure and cholesterol for the 72 yr of Variable levels AR (%) IR (BP & AR Chol) 86 yo 72 yo high high 41.3 39.7 high moderate 22.1 20.8 high moderate 21.1 20	IR (high BP and cholesterol). 2. Less likely to treat older patients of (low/med BP and cholesterol). 3. Covered by age comparisons (47 vs 61) 4. Plus 7 additional versions for 86 vo (di 4. Low IR and high AR (duplicate vign old = version 46-47 (n=31)). 5. Medium IR and high AR (duplicate vign old = version 48-50 (n=67)). 5. Control vignettes: high IR and AR of for 74 year old = version 44-45 (n=100) analyses: do the above result of 74 year old = version 44-45 (n=100) analyses: do the above result of 74 year old = version 44-45 (n=100) analyses: do the above result of 74 year old = version 44-45 (n=100) analyses: do the above result of 74 year old = version 44-45 (n=100) analyses: do the above result of 74 year old = version 44-45 (n=100) analyses: do the above result of 74 year old = version 44-45 (n=100) analyses: do the above result of 74 year old = version 44-45 (n=100) analyses: do the above result of 74 year old = version 44-45 (n=100) analyses: do the above result of 74 year old = version 44-45 (n=100) analyses: do the above result of 74 year old = version 44-45 (n=100) analyses: do the above result of 74 year old = version 44-45 (n=100) analyses: do the above result of 74 year old = version 44-45 (n=100) analyses: do the above result of 74 year old = version 44-45 (n=100) analyses: do the above result of 74 year old = version 44-45 (n=100) analyses: do the above result of 74 year old = version 44-45 (n=100) analyses: do the above result of 74 year old = version 44-45 (n=100) analyses: do the above result of 74 year old = version 44-45 (n=100) analyses: do the above result of 74 year old = version 44-45 (n=100) analyses: do the above result of 74 year old = version 44-45 (n=100) analyses: do the above result of 74 year old = version 44-45 (n=100) analyses (n=100) analys	IR (high BP and cholesterol). 2. Less likely to treat older patients who have (low/med BP and cholesterol). 3. Covered by age comparisons (47 vs 61 vs 72) for 4. Plus 7 additional versions for 86 yo (discussed 24. Source of a version 46-47 (n=31)). 4. Low IR and high AR (duplicate vignette 37& old = version 46-47 (n=31)). 5. Medium IR and high AR (duplicate vignette 37& old = version 48-50 (n=67)). 5. Control vignettes: high IR and AR (duplicate for 74 year old = version 44-45 (n=46)). 5. Additional analyses: do the above results differ 4. Additional 4. Additi	IR (high BP and cholesterol). 2. Less likely to treat older patients who have high AR a (low/med BP and cholesterol). - Covered by age comparisons (47 vs 61 vs 72) for objective. Plus 7 additional versions for 86 yo (discussed 2/12/11 w - Low IR and high AR (duplicate vignette 37&38 with A old = version 46-47 (n=31)). - Medium IR and high AR (duplicate vignette 41-43 with year old = version 48-50 (n=67)). - Control vignettes: high IR and AR (duplicate vignette for 74 year old = version 44-45 (n=46)). - Additional analyses: do the above results differ for low version 44-45 (n=46)). - Additional analyses: do the above results differ for low version 44-45 (n=46)). - Kir (BP & Kortinal analyses: do the above results differ for low version 46-47 (n=31)). - R (BP & Kortinal analyses: do the above results differ for low version 44-45 (n=46)). - Table 1. Overview of variable levels for absolute risk and individuation pressure and cholesterol for the 72 yr old and 86 yr old patient cate of the for 100 moderate 22.1 20.8 146 6.6 6.3 6.3 1.3 1.3 39.7 165 6.6 6.3 1.3 1.3 1.4 1.4 1.4 1.4 1.4 1.4 1.4 1.4 1.4 1.4	IR (high BP and cholesterol). 2. Less likely to treat older patients who have high AR and 'incor (low/med BP and cholesterol). 3. Covered by age comparisons (47 vs 61 vs 72) for objectives 1 and Plus 7 additional versions for 86 vo (discussed 2/12/11 w LI, AH at • Low IR and high AR (duplicate vignette 37&38 with AR recall old = version 46-47 (n=31)). 4. Medium IR and high AR (duplicate vignette 41-43 with AR recall year old = version 48-50 (n=67)). 5. Control vignettes: high IR and AR (duplicate vignette 11&12 v for 74 year old = version 44-45 (n=46)). 5. Additional analyses: do the above results differ for low vs med AL Table 1. Overview of variable levels for absolute risk and individual risk for pressure and cholesterol for the 72 yr old and 86 yr old patient cases* Variable levels AR (%) Variable levels AR (%) K (MP) 86 yo 72 yo BP ratio chol HDL high high 41.3 39.7 165 6.6 6.3 1 high moderate 22.1 20.8 145 6 6 1 high moderate 21.1 20 144 5.4 5.6 1	IR (high BP and cholesterol). 2. Less likely to treat older patients who have high AR and 'inconsistent' IR (low/med BP and cholesterol). 3. Covered by age comparisons (47 vs 61 vs 72) for objectives 1 and 2 4. Plus 7 additional versions for 86 vo (discussed 2/12/11 w LI, AH and CB) see 4. Low IR and high AR (duplicate vignette 37&38 with AR recalculated for 7 5. old = version 46-47 (n=31)). 5. Medium IR and high AR (duplicate vignette 41-43 with AR recalculated for 7 5. old = version 48-50 (n=67)). 5. Control vignettes: high IR and AR (duplicate vignette 11&12 with AR recalculated for 74 year old = version 44-45 (n=46)). 5. Additional analyses: do the above results differ for low vs med AR and gender for 74 year old = version 44-45 (n=46)). 5. Additional analyses: do the above results differ for low vs med AR and gender for 74 year old = version 44-45 (n=46)). 5. Additional analyses: do the above results differ for low vs med AR and gender for 74 year old = version 44-45 (n=46)). 5. Additional analyses: do the above results differ for low vs med AR and gender for 74 year old = version 44-45 (n=46)). 5. Additional analyses: do the above results differ for low vs med AR and gender for the 72 yr old and 86 yr old patient cases* 5. Variable levels 6. AR (%) 6. Ra (hol) 7. Ra (%) 7. Ra (Pa) 7. Ra

high low 20.8 19.5 129 3.6 5.2 1.5 yes M

AR=absolute cardiovascular disease risk, IR=individual risk factors, BP= systolic bloodpressure, Chol=cholesterol *Shaded row describes case added to examine the effect of smoking/non smoking

To reduce the total number of vignettes, we have excluded the following hypothesis for now:

GPs' decision making will be influenced by factors that are not included in the absolute risk model, in particular family history and BMI.

Additional analysis: smoking and gender

Smoking comparison:

1. General rule: All low AR risk vignettes are non-smokers and all high AR risk vignettes are smokers. For the medium AR risk vignettes it was impossible to have all vignettes smokers or non-smokers so we have selected smoking or non-smoking based on whether there was a female as well as male version of the vignette possible within a given age.

2. In order to look at the effect of smoking/non-smoking on GP decision making, for each of the different age groups (when possible) we selected vignettes looking at:

- a. High IR medium AR and
- b. Medium IR high AR for the three different age groups,

For a) we selected high cholesterol/low BP vignettes, when possible.

a. We selected AR values as close to the AR value in the non-smoking/smoking equivalent as possible.

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To look at the effect of smoking, the following vignettes should be compared: non-smoker: vignette 19,22,30 vs smoker: 21,24,32 all in the medium AR category (see description of vignettes below).

General vignettes

Vignette 19: male, 61, non-smoker, medium AR, low BP, high chol Vignette 21: male, 61, smoker, medium AR, low BP, high chol Vignette 22: female, 72, non-smoker, medium AR, low BP, high chol, Vignette 24: female, 72, smoker, medium AR, low BP, high chol Vignette 30: male, 47, non-smoker, medium AR, high BP, med chol Vignette 32: male, 47, smoker, medium AR, high BP, med chol

Since all vignettes with patients 86 years old were high AR, we made additional smoking-non smoking comparison vignettes with patients 72 years old at high AR: non-smoker: 30, 48 vs smoker: 32, 50 (see description of vignettes below), we will exclude these vignettes from the smoking comparison analysis.

Age comparison (72-86 years)

Vignette 41: Male, 72, non-smoker, high AR, med BP, med chol Vignette 43: Male, 72, smoker, high AR, med BP, med chol Vignette 48: Male, 86, non-smoker, high AR, med BP, med chol Vignette 50: Male, 86, smoker, high AR, med BP, med chol

Methods

Design: paper based vignette study (controlled experiment) in which GPs will view different written vignettes describing patients who are at risk for developing CVD. The construction of the total set of vignettes, i.e. the relevant factors and appropriate factor levels, is based on the hypotheses as described above.

Selection of vignettes

A full factorial design although methodologically strongest is impossible in the current study because not all factor level combinations are clinically possible. We have selected vignettes that are a) directly relevant to our research questions, b) clinically possible, c) clinically relevant (face validity – expert clinicians). We decided at meeting 12/09 (JD, AH, JJ, CB, LI) that it is not necessary to cross check the data against AusDiab data. In addition:

- All low AR risk vignettes are non-smokers, all high AR risk vignettes are smokers. For the medium AR risk vignettes it was impossible to have all vignettes smokers or non-smokers so we have selected smoking or non-smoking based on whether there was a female as well as male version of the vignette possible within a given age.
- The ages we used in the vignettes are: 47 for the young age group, 61 for the middle age group and 72 for the older age group (apart from one vignette that was only possible for an adult aged 73). Added 86 year old comparison in December 2011.
- We have selected AR values that were middle of the range for the given age, IR and AR categories, used IR values around the middle of the category range where possible, and avoided using values that were at category thresholds.
- If possible, we have made a female version for each male version of a vignette. In order to look at the effect of smoking/non-smoking on GP decision making we selected vignettes looking at (a) high IR medium AR and (b) medium IR high AR for the three different age groups, if possible. For a) we selected high cholesterol/low BP vignettes, if

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oquis	ble. We selected AR valent as possible.			
- Wen	eed to give GPs sepa	arate TC & HI	DL values in additior	n to cholester
decid	led to us the median	total and HI	DL cholesterol value	s for each cho
want	to use in the vignet	tes based on	the NHANES data.	See appendix
comp	olete list of vignettes			
Table 2.	Variables and ideal	values for ea	ch level:	
		Level		
Variable		Low	Medium	High
Variable	s that will be manipu	ulated in the	first study (general j	population)
1	Absolute risk	<10%	10-15%	>15%
2	Blood pressure	121	144	167
3	Cholesterol/lipi	3.7	5.5	6.8
	ds			
	Smoking	No	Yes	
4			61	72
4 5	Patient age	47	61	
5	Patient age s that will be standa			
5				diabetic
5 Variable	s that will be standa		first study	

From an experimental point of view, we are most likely to find effects of the different factors if the low, medium and high categories are distinct from each other, with large gaps in between. However need to use a range of values across vignettes for each category to

ensure face validity of the vignettes. We have therefore defined a range around the ideal values (indicated in bold, inclusive, in Table 2).

Table 3. Variable categories:

	Blood	Chol Ratio	Total	HDL	Age
	pressure		Chol		
	Increment: 1	Increment: 0.1	Based on r	median for	Increment: 1
			ratio		year
Low	110- 121 -132	3- 3.7 -4.5	4.9- 5.2 -	1.6- 1.4 -1.2	45- 47 -49 (used
			5.5		47)
Medium	141- 144 -147	5- 5.5 -6	5.6- 6.0 -	1.1- 1.1 -1.0	58- 60 -62 (used
			6.0		61)
High	155- 167 -179	6.5- 6.8 -7.2	6.2- 6.1 -	1.0- 0.9 -0.9	70- 72 -74 (used
			6.3		72, except one
					case of 73)

Example of vignette format/style (High IR (BP) and low AR example - younger age, male)

Mr Johnson is 47 years old, with a systolic blood pressure of 167 mmHg. His total cholesterol is 5.13 mmol/L, HDL cholesterol is 1.34 mmol/L and cholesterol ratio is 3.8. He is a nonsmoker, not diabetic, has no family history of CVD, and his BMI is 26. His calculated 5-year general CVD risk score is 5.5%.

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<u>Pilot testing -</u> Time was a major issue and GPs did not like reading the above format multiple times. Decision made at CVD meeting 27/02/12 to use a generic patient scenario (see below) and use a table format for clinical values.

A regular patient of yours presents for a "check-up" and has no current symptoms. He/she has been trying to improve their diet and increase their physical activity levels. You have several previous blood pressure readings at approximately the same level as observed today. A recent test of electrolytes, liver function and renal function was normal.

- BMI: 27
- Past medical history: nil of note
- Family history: mother died of bowel cancer, nil family history of ischaemic heart

disease

- Social history: married, lives in own home
- Ethnicity: Caucasian

Sample: currently practicing GPs

Outcome measures: the main outcome measure will be the proportion of GPs that decide to

treat the patient with medication (%). We will ask the following questions:

How would you manage this patient?

- a) Prescribe a cholesterol lowering drug yes Y N
- b) Prescribe a blood pressure lowering drug Y
- c) Prescribe aspirin Y
- d) When would you reassess this patient?

Ν

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Pilot testing - Time was a major issue and GPs found the psychosocial questions confusing. Decision made at CVD meeting 27/02/12 to cut down questions and just have:

• Q1. For the cases you just read, how often did you use the absolute risk

score to inform your management decision?

• Q2. In your general practice, how often do you use absolute risk scores,

calculators or charts when assessing a patient's level of cardiovascular risk?

- Q3. What is your gender?
- Q4. What is your age?
- Q5. In what year did you qualify as a doctor?
- Q6. How many GPs work in your practice?

An additional question was added after CVD meeting 30/07/12:

Q7. In which state do you practice?

Recruitment

Paper-based conference recruitment was selected as the final recruitment strategy. A \$500

Red Balloon voucher was used as an incentive, as well as a stamp in the GPCE conference

passport for taking a survey at GPCE Sydney/Melbourne.

- GPCE Sydney (18-20 May): stall, n=49
- GPCE Brisbane (14-16 Sep): inserts , n=14
- RACGP Gold Coast (25-27 Oct): inserts, n=13
- GPCE Melbourne (16-18 Nov): stall + inserts, n=69
- Total n=145, minus 1 exclusion (not qualified as a GP) = 144

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Final set of vignettes and randomisation

We have a set of 25 different vignettes, with 1-3 versions of each vignette (male, female, smoking comparison), giving a total of 50 versions. Depending on the complexity of the vignettes, it is considered feasible to present respondents with up to 18 vignettes (Atzmuller et al., 2010). Piloting revealed that it was feasible to present GPs with 12 vignettes each with a shortened survey format. For the analyses, we will compare small subsets of vignettes to test hypotheses, for example, testing vignettes 1 and 2 versus vignettes 7 and 8. We will take into account any within-subject clustering in the analyses.

Participants will be presented with a random sample of 12 vignettes (i.e. approximately half of all vignettes) - 11 general population vignettes and 1 older adult vignette. We will then randomly selecting one of the 1-3 available versions for a specific vignette (i.e. every participant will only receive one version of each vignette). With a sample size of 150 GPs, we will therefore have a total of 1650 general population vignettes, with 75 on average for each different vignette. Each different vignette has between 1 and 3 versions; this means that for each individual version we will have between 25 and 75 responses. Most vignettes have 2 versions; therefore most versions of the vignettes will have 37.5 responses on average. Using randomly selected sets means that the analyses will be based on a mix of within and between subject comparisons.

Missing values

There were few surveys with missing values. In most instances the missing values occurred in questionnaires where only positive answers (i.e. GP would prescribe) were marked and it was therefore assumed that the missing values were negative answers (i.e. GP would not prescribe for that case). A sensitivity analysis was conducted excluding the surveys with missing values. The results did not change appreciably.

References

1. Atzmuller C, Steiner PM. Experimental Vignette Studies in Survey Research.

Methodology 2010;6(3):128-38.

2. Weiner M, Wells S, Kerse N. Perspectives of general practitioners towards

evaluation and treatment of cardiovascular diseases among older people. J Prim Health

Care 2009;1(3):198-206.

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Appendix A: Overview of the different vignettes Note: grey rows indicate additional vignette versions for the smoking comparison; responses are estimates based on n=150

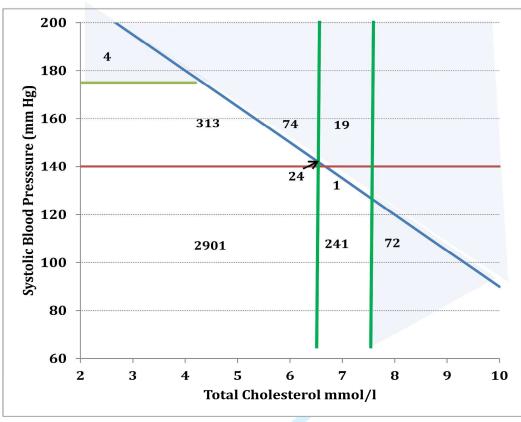
	B	С	D	E	F	G	Н		J	K		_ M	N	0	P	U	V	W	X	Y
1		Vignette	Responses				smoker	BP	chtottext			ratio Artext				smoke_cat			_	_
2	1 - low IR & AR	1	37.5		Female	47	No	122	5.3	1.3	3.9	1.4%	5.3	1.3		non-smoker	Low	Low	Low	Low
3	1 - low IR & AR	1	37.5		Male	47	No	123	5.1	_1.3	3.8	2.2%	5.1	1.3		non-smoker	Low	Low	Low	Low
4	1 - low IR & AR	2	37.5		Female	61	No	122	5.3	1.3	3.9	3.4%	5.3	1.3		non-smoker	Medium		Low	Low
5	1 · low IR & AR	2	37.5 37.5		Male	61 72	No	122	5.1 5.1	1.3	3.8	<u>6.0%</u> 5.5%	5.1 5.1	1.3		non-smoker		Low	Low	Low
6 7	1 - low IR & AR	3	37.5		Female	72	No No	119	5.1	1.3 1.5	3.8 3.3	5.5%	5.1	1.3		non-smoker non-smoker	High	Low	Low	Low
8	1 - low IR & AR	4	37.5		Male	47	Yes	177	6.3	0.9	7.2	15.6%	5.1				High	Low	Low	Low
	1 - high IR & AR				Female											smoker	Low	High	High	High
9 10	1 - high IR & AR	4	37.5		Male	47 61	Yes Yes	167 166	6.3 6.3	0.9	7.2	18.3%	6.3 6.3			smoker	Low	High	High	High
11	1 - high IR & AR	5	37.5		Female Male	61	Yes	165	6.3	1.0	6.6 6.6	21.7%	6.3			smoker smoker	Medium	High	High	High
12	1 - high IR & AR	6	37.5		Female	72	Yes	165	6.3	1.0	6.6	29.5%	6.3			smoker	Medium		High	High
3	1 - high IR & AR 1 - high IR & AR	6	37.5		Male	72	Yes	165	6.3	1.0	6.6	28.6%	6.3			smoker	High High	High High	High High	High High
		7	37.5		Female	47	No	114	6.2	0.9	6.7	2.2%	6.2	0.9		non-smoker			-	_
	2a/3a - high chol																Low	Low	High	Low
	2a/3a - high chol	7	37.5		Male	47	No	125	6.3	0.9	7.2	4.9%	6.3	0.9		non-smoker	Low	Low	High	Low
	2a/3a - high chol	8	37.5		Female	61	No	123	6.2	0.9 1 .0	6.8	6 .4% 8.9%	6.2	0.9		non-smoker	Medium	Low	High	Low
	2a/3a - high chol	8	37.5		Male	61	No	116	6.2		6.5		6.2	1.0		non-smoker	Medium		High	Low
	2a/3a - high chol	9	75		Female	72	No	118	6.3	1.0	6.6	8.6%	6.3	1.0		non-smoker	High	Low	High	Low
19	2a - high chol	10	75		Male	47	Yes	130	6.3	0.9	7.2	10.9%	6.3			smoker	Low	Low	High	Mediu
20	2a - high chol	11	25		Male	61	No	132	6.3	0.9	7.2	13.0%	6.3			non-smoker	Medium	Low	High	Mediu
21	2a - high chol	11	25		Female	61	Yes	123	6.2	0.9	6.8	12.4%	6.2			smoker		Low	High	Mediu
22	2a - high chol	11	25		Male	61	Yes	110	6.3	<u>1.0</u>	6.6	14.8%	6.3			smoker	Medium		High	Mediu
3	2a - high chol	12	25		Female	72	No	128	6.6	0.9	7.1	11.2%	6.6			non-smoker	High	Low	High	Mediu
24	2a - high chol	12	25		Male	72	No	112	6.2	0.9	6.8	13.9%	6.2			non-smoker	High	Low	High	Mediu
25	2a - high chol	12	25		Female	72	Yes	110	6.2	1.0	6.5	13.6%	6.2			smoker	High	Low	High	Mediu
26	2a/3a - high BP	13	37.5		Female	47	No	167	5.1	1.3	3.8	3.7%	5.1	1.3		non-smoker	Low	High	Low	Low
27	2a/3a - high BP	13	37.5		Male	47	No	167	5.1	1.3	3.8	5.5%	5.1	1.3		non-smoker	Low	High	Low	Low
28	2a/3a - high BP	14	37.5		Female	61	No	166	5.1	1.5	3.5	7.1%	5.1	1.5		non-smoker		High	Low	Low
29	2a/3a - high BP	14	37.5		Male	61	No	156	4.9	1.6	3.0	8.9%	4.9			non-smoker		High	Low	Low
30	2a/3a - high BP	15	75		Female	72	No	156	4.9	1.6	3.1	8.4%	4.9	1.6		non-smoker	High	High	Low	Low
31	2a - high BP	16	25		Male	47	No	179	6.0	1.0	6.0	10.2%	6.0			non-smoker	Low	High	Medium	Mediu
32	2a - high BP	16	25		Female	47	Yes	169	6.0	1.0	5.8	11.9%	6.0			smoker	Low	High	Medium	
33	2a - high BP	16	25		Male	47	Yes	157	5.8	1.1	5.2	12.6%	5.8			smoker	Low	High	Medium	Mediu
34	2a - high BP	17	37.5		Female	61	No	169	6.0	1.0	5.8	11.8%	6.0			non-smoker		High	Low	Mediu
35	2a - high BP	17	37.5		Male	61	No	147	5.9	1.0	5.7	13.5%	5.9			non-smoker		High	Low	Mediu
36	2a - high BP	18	75		Female	72	No	158	5.6	1.1	5.0	13.2%	5.6			non-smoker	High	High	Medium	Mediu
37	2b/3b	19	75		Male	61	Yes	131	5.4	1.2	4.4	15.4%	5.4			smoker	Medium	Low	Low	High
38	2b/3b	20	37.5	37	Female	73	Yes	132	5.5	1.2	4.5	15.3%	5.5			smoker	High	Low	Low	High
39	2b/3b	20	37.5	38	Male	72	Yes	129	5.2	1.5	3.6	19.5%	5.2	1.5	19.5%	smoker	High	Low	Low	High
0	3c	21	37.5	39	Female	61	Yes	145	5.8	1.0	5.9	15.5%	5.8	1.0	15.5%	smoker	Medium	Medium	Medium	High
11	3c	21	37.5	40	Male	61	Yes	144	5.6	1 .0	5.4	21.3%	5.6	1.0	21.3%	smoker	Medium	Medium	Medium	High
12	3c	22	25	41	Male	72	No	145	6.0	1.0	6.0	20.8%	6.0	1.0	20.8%	non-smoker	High	Medium	Medium	High
13	3c	22	25	42	Female	72	Yes	144	5.6	1 .0	5.4	20.0%	5.6	1.0	20.0%	smoker	High	Medium	Medium	High
4	3c	22	25	43	Male	72	Yes	143	5.6	1 .0	5.4	29.8%	5.6	1.0	29.8%	smoker	High	Medium	Medium	High
15	1 - high IR & AR	23	37.5	44	Female	86	Yes	166	6.3	1.0	6.6	29.9%	6.3	1.0	29.9%	smoker	High	High	High	High
16	1 - high IR & AR	23	37.5		Male	86	Yes	165	6.3	1.0	6.6	41.3%	6.3			smoker	High	High	High	High
17	2b/3b	24	37.5		Female	86	Yes	132	5.5	1.2	4.5	15.7%	5.5			smoker	High	Low	Low	High
18	2b/3b	24	37.5		Male	86	Yes	129	5.2	1.5	3.6	20.8%	5.2			smoker	High	Low	Low	High
19	30	25	25		Male	86	No	145	6.0	1.0	6.0	22.1%	6.0			non-smoker	High	Medium	Medium	High
50	30	25	25		Female	86	Yes	144	5.6	1.0	5.4	21.1%	5.6			smoker	High	Medium	Medium	High
51	30	25	25		Male	86	Yes	143	5.6	1.0	5.4	31.3%	5.6			smoker	High		Medium	

Appendix B: Responses and missing data by version and vignette

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Appendix D: Conceptual treatment diagram (Jenny Doust)

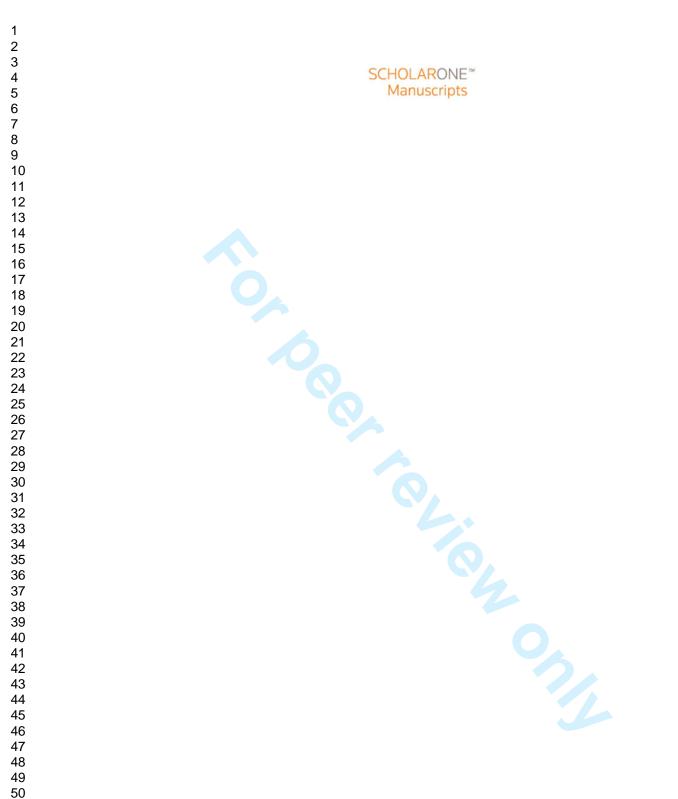


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General Practitioners' use of absolute risk versus individual risk factors in cardiovascular disease prevention: An experimental study

Journal:	BMJ Open
Manuscript ID:	bmjopen-2014-004812.R1
Article Type:	Research
Date Submitted by the Author:	14-Apr-2014
Complete List of Authors:	Jansen, Jesse; The University of Sydney, Screening and Test Evaluation Program (STEP), School of Public Health; The University of Sydney, Centre for Medical Psychology & Evidence-based Decision-making (CeMPED) Bonner, Carissa; The University of Sydney, Screening and Test Evaluation Program (STEP), School of Public Health; The University of Sydney, Centre for Medical Psychology & Evidence-based Decision-making (CeMPED) McKinn, Shannon; The University of Sydney, Screening and Test Evaluation Program (STEP), School of Public Health; The University of Sydney, Centre for Medical Psychology & Evidence-based Decision-making (CeMPED) Irwig, Les ; The University of Sydney, Screening and Test Evaluation Program (STEP), School of Public Health; The University of Sydney, Centre for Medical Psychology & Evidence-based Decision-making (CeMPED) Irwig, Les ; The University of Sydney, Screening and Test Evaluation Program (STEP), School of Public Health Glasziou, Paul; The University of Sydney, Screening and Test Evaluation Program (STEP), School of Public Health; Bond University, Centre for Research in Evidence Based Practice, Faculty of Health Sciences and Medicine Doust, Jenny; The University of Sydney, Screening and Test Evaluation Program (STEP), School of Public Health; Bond University, Centre for Research in Evidence Based Practice, Faculty of Health Sciences and Medicine Teixeira-Pinto, Armando; The University of Sydney, Screening and Test Evaluation Program (STEP), School of Public Health Hayen, Andrew; University of New South Wales, School of Public Health and Community Medicine Turner, Robin; The University of Sydney, Screening and Test Evaluation Program (STEP), School of Public Health McCaffery, Kirsten; The University of Sydney, Screening and Test Evaluation Program (STEP), School of Public Health McCaffery, Kirsten; The University of Sydney, Screening and Test Evaluation Program (STEP), School of Public Health; The University of Sydney, Centre for Medical Psychology & Evidence-based Decision-making (CeMPED)
Primary Subject Heading :	Cardiovascular medicine
Secondary Subject Heading:	General practice / Family practice, Evidence based practice
Keywords:	CARDIOLOGY, GENERAL MEDICINE (see Internal Medicine), PUBLIC HEALTH



General Practitioners' use of absolute risk versus individual risk factors in cardiovascular disease prevention: An experimental study

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Word count: 3375

Key words: cardiovascular disease, primary care, general practice, prevention, risk assessment

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ABSTRACT

Objective: To understand general practitioners' (GPs) use of individual risk factors (blood pressure and cholesterol levels) versus absolute risk in cardiovascular disease (CVD) risk management decision-making.

Design: Randomised experiment. Absolute risk, systolic blood pressure (SBP), cholesterol ratio (TC/HDL), and age were systematically varied in hypothetical cases. High absolute risk was defined as 5 year risk of a cardiovascular event > 15%, high blood pressure levels varied between SBP 147 and 179 mmHg and high cholesterol (TC/HDL ratio) between 6.5 and 7.2 mmol/L.

Setting: 4 GP conferences in Australia.

Participants: 144 Australian GPs.

Outcomes: GPs indicated whether they would prescribe cholesterol and/or blood pressure lowering medication. Analyses involved logistic regression.

Results: For patients with high blood pressure: 93% (95%CI=86-96%) of high absolute risk patients and 83% (95%CI=76-88%) of lower absolute risk patients were prescribed blood pressure medication. Conversely, 30% (95%CI=25-36%) of lower blood pressure patients were prescribed blood pressure medication if absolute risk was high and 4% (95%CI=3-5%) if lower. 69% of high cholesterol/high absolute risk patients were prescribed cholesterol medication (95%CI=61-77%) versus 34% of high cholesterol/lower absolute risk patients (95%CI=28-41%). 36% of patients with lower cholesterol (95%CI=30-43%) were prescribed cholesterol medication if absolute risk was high versus 10% if lower (95%CI=8-13%).

Conclusions: GPs' decision making was more consistent with management of individual risk factors than an absolute risk approach, especially when prescribing blood pressure medication. The results suggest medical treatment of lower risk patients (5 year risk of CVD event < 15%) with mildly

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elevated blood pressure or cholesterol levels is likely to occur even when an absolute risk assessment is specifically provided. The results indicate a need for improving uptake of absolute risk

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STRENGTHS AND LIMITATIONS

- This study uses a rigorous experimental design to systematically investigate how GPs use individual risk factors (blood pressure and cholesterol) versus the absolute risk of a CVD event in their decision making about CVD preventive medication. International guidelines are based on absolute risk, but are used inconsistently.
- The results show that GPs' decision making was more consistent with management of individual risk factors than an absolute risk approach, especially when prescribing blood pressure lowering medication.
- Our findings have important clinical implications, suggesting that medical treatment of lower risk patients (5 year risk of CVD event < 15%) with mildly elevated blood pressure or cholesterol is likely to occur even when an absolute risk assessment is specifically provided to GPs.
- The results may over-estimate the use of absolute risk in clinical practice due to: 1) a low response rate that is typical of such GP studies but may have favoured those more interested and positive about absolute risk, 2) reliance on self-reported intentions, which was necessary to enable an experimental design, and 3) explicitly providing GPs with an absolute risk score for each case, since absolute risk is often not assessed in practice.

INTRODUCTION

International guidelines for cardiovascular disease (CVD) prevention encourage the use of absolute risk to guide treatment with blood pressure and cholesterol lowering medication.[1-6] Several risk prediction models exist that differ in the duration over which they calculate CVD risk (typically 5 or 10 years) and the variables they base the risk on.[7-8] One of the most commonly used absolute risk models is the Framingham Risk Equation (FRE)[9], which estimates the risk of a cardiovascular event based on sex, age, smoking status, diabetes, systolic blood pressure, and cholesterol ratio. The Australian guidelines classify patients with a 5 year risk of > 15% as high risk and recommend that they should be simultaneously treated with cholesterol and blood pressure lowering medication in addition to lifestyle intervention unless contraindicated or clinically inappropriate.[10-11] For lower risk patients < 15% without additional risk factors such as family history, lifestyle intervention is recommended as the primary management approach. Adults with very high individual risk factors (systolic blood pressure ≥180 mmHg or diastolic blood pressure ≥110 mmHg or total cholesterol >7.5 mmol/L) do not require absolute CVD risk assessment because they are already considered to be at high risk of CVD.[10-11]

Using absolute risk is a major shift from the traditional approach of treating high blood pressure and high cholesterol individually. An absolute risk approach is likely to achieve the best balance between preventing CVD events and avoiding unnecessary treatment with medication. It has the potential to reduce overtreatment of people who have an elevated individual risk factor (e.g. blood pressure) but low or moderate overall risk of a CVD event and reducing under treatment of people with slightly elevated individual risk factors but a combined high overall risk.[12-13] The first Framingham risk equation was published in 1976[14] and New Zealand was the first country to introduce an absolute risk approach in 1993[15]. More than twenty years have passed since then and the absolute risk approach has been shown to reduce short-term CVD risk without causing clinical harms.[14]

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However, research suggests that General Practitioners (GPs) often do not use absolute risk to guide their decision making about CVD prevention.[15-19] Past research includes studies exploring barriers to GP's use of absolute risk[19-22] and studies quantifying treatment gaps using clinical databases[12, 16-17, 23-24] but individual decision making about absolute risk has not been comprehensively examined quantitatively. In this study we applied a method based on judgments of hypothetical patient cases to analyse GPs' decisions about CVD risk management and their use of absolute risk. Hypothetical patient cases (also called vignettes) have been widely used to measure decision processes in a range of clinical settings,[25] including GP decision making about cardiovascular disease.[26-28] Indeed, three recent studies using patient cases suggest that clinicians might not base treatment decisions on absolute risk thresholds (e.g. only treat patients > 15% for 5 year FRE based absolute risk or > 20% for 10 year risk); instead they focus on the levels of the individual risk factors blood pressure and cholesterol.[26-28] However, these studies did not systematically assess different combinations of absolute risk and individual risk factor levels. Therefore, they provide limited interpretation of how GPs use absolute risk versus individual risk factors in decision making.

In the current study we used hypothetical patient cases (from here on referred to as cases) in which the levels of absolute risk and three individual risk factors (systolic blood pressure, cholesterol (TC/HDL ratio), and age) were systematically varied in order to evaluate their respective influence on GPs' decision making about CVD risk management. Absolute risk levels were derived from the FRE.[9]

In line with the literature suggesting that GPs tend to use an individual risk factor approach, we hypothesized that:

- GPs are more likely to treat lower absolute risk with medication when individual risk factors (blood pressure, cholesterol) are high than when individual risk factors are lower; and conversely:
- GPs are less likely to treat high absolute risk with medication when individual risk factors (blood pressure, cholesterol) are lower than when individual risk factors are high

METHOD

Recruitment

GPs currently practicing in Australia were recruited between May and November 2012 at four general practice conferences in New South Wales, Victoria and Queensland. All participants were asked when they became a GP and whether they were currently practicing in Australia through survey questions, and the eligibility of returned questionnaires was verified before data analysis. Ethical approval was obtained from the University of Sydney Human Research Ethics Committee.

Data collection and measurement

Respondents viewed a generic patient scenario (see Box 1) followed by a table with the relevant values for absolute risk, systolic blood pressure, TC/HDL ratio, HDL, total cholesterol, and age, as well as patient gender and smoking status (i.e. the cases). GPs were asked how they would manage the patient in the case: prescribe cholesterol medication, prescribe blood pressure medication, and/or prescribe aspirin (yes/no for each). In addition, they were asked when they would reassess the patient (open ended). The aspirin and reassessment results are reported separately. We collected information regarding GP characteristics: gender, age, years in practice, practice size. We asked GPs two questions about their use of absolute risk as follows: *"For the cases you just read, how often did you use the absolute risk score to inform your management decision?"* and *"In your"*

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general practice, how often do you use absolute risk scores, calculators or charts when assessing a patient's level of cardiovascular risk?" (5 point Likert scale; 1 never – 5 always). The survey was piloted with nine GPs.

Different sets of cases

We developed four sets of cases (also see Table 1):

A) High IR/lower AR with high individual risk factors (blood pressure only) and lower absolute risk
Aii) High IR/lower AR with high individual risk factors (cholesterol only) and lower absolute risk
B) High IR/high AR with high individual risk factors and high absolute risk,

C) Lower IR/high AR with lower individual risk factors and high absolute risk, and

D) Lower IR/lower AR with lower individual risk factors and lower absolute risk.

Cases were designed to be clinically plausible and relevant. Only the sets of cases B and C were eligible for treatment with cholesterol and blood pressure lowering medication according to the Australian absolute risk guidelines.[10-11] In all cases except high IR/lower AR (Ai and Aii) the levels of individual risk factors were the same across blood pressure and cholesterol (i.e. both lower or both high). For cases with high IR/lower AR (Ai and Aii) blood pressure was high and cholesterol was lower, or vice versa, to enable exploration of their independent effects on GP decision making. This resulted in a core set of 25 cases with different combinations of absolute and individual risk factor levels (see Appendix 1 for the complete set of cases).

Gender and smoking status

We constructed a female and male equivalent of each core case (where possible, given the restraints of the FRE and the individual and absolute risk levels defined above). We made all high absolute risk cases smokers and all lower absolute risk cases non-smokers, and we constructed an additional set of cases to test for the potential confounding effect of smoking. Table 1. The levels for absolute risk and individual risk factors blood pressure (SBP) and cholesterol

(TC/HDL ratio) plus the relevant case numbers and number of cases $(n=144 \text{ GPs})^{\dagger}$

Category Figure 2/ Appendix 1	Absolute risk	Individual risk factors [‡]					
Арреник т		SBP (mmHg)	TC/HDL ratio (<i>mmol/L</i>)	N	Case #		
Ai	Lower	High	Lower	431	25-35		
Aii	Lower	Lower	High	415	13-24		
В*	High	High	High	221	7-12		
C*	High	Lower	Lower	298	36-43		
D	Lower	Lower	Lower	219	1-6		

[†]See Appendix 1 for the actual values used in these cases

 *Only the sets of cases B and C were eligible for treatment with cholesterol and blood pressure lowering medication according to the Australian absolute risk guidelines[10-11]

Levels of absolute risk and individual risk factor levels

The levels used to describe elevated absolute risk and the individual risk factors (see Table 1) were based on the 2012 Australian absolute risk guidelines[11] (using the FRE) and informed by practicing GPs (JD, PG). We defined patients with a risk of a cardiovascular event over 5 years greater than 15% as high absolute risk, for whom preventive medication is recommended. The Australian absolute risk guidelines recommend that adults with systolic blood pressure ≥180 mmHg or total cholesterol >7.5 mmol/L do not require absolute CVD risk assessment because they are already known to be at clinically determined high risk of CVD.[5, 11] We ensured that the individual risk factor levels remained below these thresholds and, where possible, we avoided values that were close to the cut off. High blood pressure levels varied between SBP 147 and 179 mmHg and high cholesterol (TC/HDL ratio) between 6.5 and 7.2 mmol/L. Lower blood pressure levels varied between SBP of 110 and 145 mmHg and lower TC/HDL ratio between 3.0 and 6.0 mmol/L. We defined three age categories within the target population for CVD risk assessment: 47, 61, and 72 years. Previous Australian guidelines for cholesterol (2005)[29] and hypertension management (2010)[30] are consistent with the 2012

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guidelines recommendations for the commencement of cholesterol lowering and/or blood pressure lowering drug treatment in patients with an absolute risk > 15% of a CVD event in the next 5 years, or those with an absolute risk of 10-15% with the presence of additional risk factors but have now been replaced with the 2012 guidelines.

Randomisation

There were 25 core cases with systematically varied levels of absolute risk, cholesterol, blood pressure, and age. Each case had between one and three versions to enable male/female and smoking/non-smoking comparisons, depending on clinical plausibility. 11 of the core cases were randomly selected for each survey to reduce response burden, and only one version of the selected case was used (e.g. only the female, non-smoking version). The 11 selected cases were presented in random order. This process generated a total of 43 clinically possible cases (see Appendix 1 for details of each case).

Box 1: General patient scenario

'A regular patient of yours presents for a "check-up" and has no current symptoms. He/she has been trying to improve their diet and increase their physical activity levels. You have several previous blood pressure readings at approximately the same level as observed today. A recent test of electrolytes, liver function and renal function was normal.'

BMI: 27

Past medical history: nil of note

Family history: mother died of bowel cancer, nil family history of ischaemic heart disease

Social history: married, lives in own home

Ethnicity: Caucasian

Analysis

GPs' decisions on risk management for the different cases were summarized as the percentage of cases in which the GPs would prescribe cholesterol or blood pressure medication. We analysed how the chances of prescribing medication changed according to the risk profiles of the cases (i.e. levels of absolute and individual risk factors). This was done using Generalised Estimation Equations (GEEs) with a logit link (logistic regression) and an exchangeable working correlation matrix to take into account the clustering of cases per GP.

The outcome was whether the GP would prescribe medication for the case, and the covariates were the levels of absolute risk and individual risk factors (i.e. blood pressure and cholesterol levels) presented in the cases. More specifically, four sets of cases were compared: A) high individual risk factors and lower absolute risk, B) high individual risk factors and high absolute risk, C) lower individual risk factors and high absolute risk, and D) lower individual risk factors and lower absolute risk. The 95% confidence intervals for the percentages presented in the results section and Figure 2 were obtained from the GEEs.

We performed exploratory analyses to examine 1) how risk management changed according to GP characteristics (i.e. age, gender, years in practice, practice size, and self-reported use of absolute risk in practice and in the cases); and 2) how risk management changed according to specific characteristics of the cases presented (i.e. age, gender, and smoking status). This was achieved by testing the interaction between each characteristic and the four sets of cases with different risk profiles in separate GEEs (one for each characteristic). The statistical analysis was performed with the software SPSS version 21.

Missing data handling

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Five participants completed only half of the survey (1 out of 2 pages). For those participants, only the completed part of the survey was included in the analysis. Additionally, there was an average of 5 missing responses per case. In most instances the missing values occurred in questionnaires where only positive responses were marked (i.e. GP only gave a response for cases where he/she would prescribe) and it was therefore assumed that the missing values were negative responses (i.e. GP would not prescribe for that case). A sensitivity analysis was conducted to check this assumption by excluding the surveys with missing values. The pattern of results did not change.

RESULTS

Response rate

Over the four General Practice conferences, we had a 30% response rate for surveys that were handed out at a stall (90 surveys completed from 304 distributed at two conferences) and a 3% response rate for surveys that were inserted into GPs' conference packs (55 surveys completed from 1803 surveys inserted into GPs' conference packs at three conferences). One returned survey was excluded due to participant ineligibility (not currently practicing). A total of 144 GPs participated in this study.

GP characteristics

The median age of the GPs who participated in the study was 53 (IQR= 47 to 59) and 58% were female. They had been practicing medicine for a median of 28 years (IQR=21 to 35) with a median practice size of five GPs (IQR= 3 to 8). Figure 1 shows GPs' self-reported use of absolute risk in their usual practice and the cases.

<Please insert Figure 1>

Prescription of blood pressure lowering medication

For cases in the high blood pressure group (SBP ≥147 mmHg) GPs stated that they would prescribe blood pressure medication for 93% (95%CI=86-96%) of the cases with high absolute risk (5 year risk of a CVD event > 15%) and 83% (95%CI=76-88%) of the cases with lower absolute risk. See Figure 2(I) and Appendix 1, Ai and B. Conversely, 30% (95%CI=25-36%) of cases in the lower blood pressure group were prescribed blood pressure medication if absolute risk was high and 4% (95%CI=3-5%) of the cases if absolute risk was lower. See Figure 2(I) and Appendix 1, C and D.

<Please insert Figure 2>

Prescription of cholesterol lowering medication

GPs stated they would prescribe cholesterol medication for 69% of cases with high cholesterol (TC/HDL ratio \geq 6.5) and high absolute risk (95%Cl=61-77%; Figure 2b, B). In contrast, a smaller percentage of cases with high cholesterol but lower absolute risk were prescribed cholesterol medication (34%, 95%Cl=28-41%; Figure 2(II) and Appendix 1, Aii). The prescribing pattern for cholesterol medication in cases with lower cholesterol was similar to blood pressure medication. GPs indicated that they would prescribe cholesterol medication in just over a third of cases (36%, 95%Cl=30-43%; Figure 2(II) and Appendix 1, C) if absolute risk was high and 10% of cases if absolute risk was lower (95%Cl=8-13%; Figure 2(II) and Appendix 1, D).

Prescription and patients' characteristics

There were no differences in the pattern of prescribing cholesterol medication for cases of different age groups at similar risk (p=0.331). However, 61 year old cases were twice as likely (OR=2.00, p<0.001, 95%CI=1.52-2.65) to be prescribed blood pressure medication than 72 year old cases with the same risk profile. GPs were also more likely to indicate that they would prescribe cholesterol medication (OR=1.27, p=0.025, 95%CI=1.03-1.56) but not blood pressure medication for male cases

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(OR=1.24, p=0.212, 95%CI=0.89-1.72). Smoking status was not associated with the prescription of cholesterol or blood pressure medication (OR=0.66, p=0.077, 95%CI=0.42-1.05).

Prescription and GP characteristics

Older GPs were less likely to prescribe cholesterol medication (OR=0.77, p=0.039, 95%CI=0.60-0.99, per 10 years of age). A similar trend was found for years of practice (OR=0.80, p=0.052, 95%CI=0.65-1.00, per 10 years of practice). GP age and years of practice were not associated with stated prescribing of blood pressure medication (OR=0.81, p=0.160, 95%CI=0.61-1.09, per 10 years of age; OR=0.84, p=0.191, 95%CI=0.65-1.09, per 10 years of practice).

Stated prescribing was not significantly associated with self-reported use of the absolute risk approach in practice or GP gender. However, GPs who reported using absolute risk in the cases were more likely to prescribe blood pressure and cholesterol medication for cases with high absolute risk (blood pressure medication: OR=1.29, p=0.042, 95%Cl=1.01-1.64; cholesterol medication: OR=1.61, p=0.001, 95%Cl=1.22-2.12). For the cases with lower absolute risk these GPs also prescribed more, but this was not statistically significant (blood pressure medication: OR=1.07, p=0.654, 95%Cl=0.81-1.41; cholesterol medication: OR=1.22, p=0.077, 95%Cl=0.98-1.52).

DISCUSSION

Our analysis of the prescribing decisions for 144 general practitioners (GPs) over a range of systematically varied cases suggests that GPs focus more on the levels of individual CVD risk factors blood pressure and cholesterol than on absolute risk, especially when prescribing blood pressure lowering medication. The results suggest that, inconsistent with the Australian guidelines,[10-11] GPs are likely to prescribe blood pressure and cholesterol lowering medication to lower risk patients (5 year risk of CVD event < 15%) if these risk factors are elevated, even when an absolute risk

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assessment is specifically provided to GPs. Conversely, GPs did not always prescribe medication to higher risk cases when blood pressure or cholesterol were not elevated. These results are in line with our hypotheses, and previous studies of patient records showing overtreatment of low risk patients and undertreatment of high risk patients, and that individual risk factors influence prescribing.[26-28, 31-33] Age appeared to be largely ignored as a risk factor, and GPs prescribed less blood pressure lowering medication for 72 year old cases in comparison with 61 year olds despite similar descriptions in the scenarios (a relatively healthy fit x year old). This finding is worthy of further exploration, given that age is one of the strongest risk factors for CVD, as it runs counter to the concept of absolute CVD risk and proposals based solely on an age cut off. [34-35] We acknowledge that in clinical practice GPs may have various and valid reasons for deviating from the guidelines, and strict adherence to guidelines and/or treatment thresholds may undermine the shared decision making (SDM) approach that is now considered gold standard.[36-37] SDM in the current context would entail that a GP assesses absolute CVD risk, explains this and the recommended management approach to the patient, discusses the benefits and harms of the different management options with the patient, and makes a shared decision with the patient. Our study and previous work suggests that many GPs do not based their recommendations on absolute risk, so it is unlikely that they can adequately inform their patients about the benefits and harms of CVD risk management and engage them in shared decision making.

Prescribing patterns were different for cholesterol and blood pressure medication. Although explanatory factors were not investigated in this study, historically, anti-hypertensive prescribing dates back to the late 1950s; hypertension was the first major CVD risk factor successfully treated.[38] In contrast, there was controversy over the treatment of cholesterol until the largescale trials of statins reported in the mid-1990s,[39] which coincided with the emergence of ideas and methods using absolute CVD risk. This history may have influenced the language used for these risk factors; "hypertension" is more commonly used than its lipid analogues such as "hypercholesterolaemia".

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The strengths of this study include the heterogeneity of the GPs who participated, and the systematic variation of cases, but there are also some limitations: First, the response rate was disappointing though typical for such GP studies.[27] However, any bias in our sample is likely to favour GPs more interested and positive about absolute risk, although almost 15% of GPs in our study stated that they never use absolute risk in practice. Second, to keep cases simple and clear we were restrictive in the range of clinical variables and management options presented, excluding lifestyle modification although space was provided for comments. Third, we relied solely on self-reported intentions to prescribe in the different cases rather than actual prescribing behaviour. This allowed an experimental design, but the results may not reflect what is actually happening in clinical practice. However, our results are likely to be an over-estimate of the use of absolute risk in actual practice as the cases explicitly provided GPs with an absolute risk score. We know from our qualitative work that absolute risk is often not assessed in practice.[19]

In conclusion, GPs' decision making was more consistent with an individual risk factor approach than absolute risk, especially when prescribing blood pressure lowering medication. While more research to explore the cognitions behind these reported behaviours would be worthwhile, our study identifies a clear need to improve guideline recommendations about how GPs should integrate individual risk factor assessment with a management that is guided by absolute CVD risk.

ACKNOWLEDGEMENTS

The authors would like to thank the General Practitioners who participated in the study, and Adam McSorley for assistance with data management.

FUNDING

The study was funded by the National Health and Medical Research Council (NHMRC) project grant 511217. Jesse Jansen and Kirsten McCaffery are supported by NHMRC fellowships. Carissa Bonner was supported by an Australian Postgraduate Award. Robin Turner and Armando Teixeira-Pinto were supported by NHMRC program grant 633003 to the Screening & Test Evaluation Program. Jenny Doust was supported by the NHMRC project grant 511217.

AUTHOR CONTRIBUTIONS

All authors included on the paper fulfill the criteria of authorship, and there was no one else who fulfils the criteria. JJ contributed to study design, analysis, interpretation, drafting and revising the manuscript. CB contributed to study design, recruitment, data collection, analysis, interpretation, and revising the manuscript. SM contributed to recruitment, data collection, analysis, interpretation, and revising the manuscript. LI contributed to study design, interpretation, and revising the manuscript. LI contributed to study design, interpretation, and revising the manuscript. PG contributed to study design, interpretation, and revising the manuscript. PG contributed to study design, and revising the manuscript. ATP contributed to analysis, and revising the manuscript. RT contributed to study design, and revising the manuscript. AH contributed to study design, and revising the manuscript. KM contributed to study design, analysis and interpretation, and revising the manuscript. All authors approved the final version of the manuscript and all authors are guarantors.

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COMPETING INTERESTS

All authors have completed the Unified Competing Interest form at www.icmje.org/coi disclosure.pdf (available on request from the corresponding author) and declare: no financial relationships with any organisations that might have an interest in the submitted work in the previous three years, and no other relationships or activities that could <text> appear to have influenced the submitted work.

ETHICAL APPROVAL

The University of Sydney human research ethics committee approved this study (No 11-

2011/14379).

DATA SHARING

No additional data available.

FIGURE LEGENDS

Figure 1. Self-reported use of absolute risk in practice and in the hypothetical cases (n=144 GPs).

Figure 2. Percentages of cases in which the General practitioners would prescribe a blood pressure or cholesterol lowering drugs according to different combination of absolute (horizontal axis) and individual risk factors (vertical axis).

The error bars represent the 95% confidence intervals for the percentage of cases (controlled for clustering)

Ai) High IR/lower AR with high individual risk factors (blood pressure only) and lower absolute risk

Aii) High IR/lower AR with high individual risk factors (cholesterol only) and lower absolute risk

B) High IR/high AR with high individual risk factors and high absolute risk*,

C) Lower IR/high AR with lower individual risk factors and high absolute risk*, and

D) Lower IR/lower AR with lower individual risk factors and lower absolute risk.

See Appendix 1 for exact AR and IR values

*Only the sets of cases B and C were eligible for treatment with cholesterol and blood pressure

lowering medication according to the Australian absolute risk guidelines[10-11]

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General Practitioners' use of absolute risk versus individual risk factors in cardiovascular disease prevention: An experimental study

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Word count: 3375

Key words: cardiovascular disease, primary care, general practice, prevention, risk assessment

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ABSTRACT

Objective: To understand general practitioners' (GPs) use of individual risk factors (blood pressure and cholesterol levels) versus absolute risk in cardiovascular disease (CVD) risk management decision-making.

Design: Randomised experiment. Absolute risk, systolic blood pressure (SBP), cholesterol ratio (TC/HDL), and age were systematically varied in <u>hypothetical cases</u>. High absolute risk was defined as 5 year risk of a cardiovascular event > 15%, high blood pressure levels varied between SBP 147 and 179 mmHg and high cholesterol (TC/HDL ratio) between 6.5 and 7.2 mmol/L.

Setting: 4 GP conferences in Australia.

Participants: 144 Australian GPs.

Outcomes: GPs indicated whether they would prescribe cholesterol and/or blood pressure lowering medication. Analyses involved logistic regression.

Results: For patients with high blood pressure: 93% (95%CI=86-96%) of high absolute risk patients and 83% (95%CI=76-88%) of lower absolute risk patients were prescribed blood pressure medication. Conversely, 30% (95%CI=25-36%) of lower blood pressure patients were prescribed blood pressure medication if absolute risk was high and 4% (95%CI=3-5%) if lower. 69% of high cholesterol/high absolute risk patients were prescribed cholesterol medication (95%CI=61-77%) versus 34% of high cholesterol/lower absolute risk patients (95%CI=28-41%). 36% of patients with lower cholesterol (95%CI=30-43%) were prescribed cholesterol medication if absolute risk was high versus 10% if lower (95%CI=8-13%).

Conclusions: GPs' decision making was more consistent with management of individual risk factors than an absolute risk approach, especially when prescribing blood pressure medication. The results suggest medical treatment of lower risk patients (5 year risk of CVD event < 15%) with mildly

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elevated blood pressure or cholesterol levels is likely to occur even when an absolute risk assessment is specifically provided. The results indicate a need for improving uptake of absolute risk

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STRENGTHS AND LIMITATIONS

- This study uses a rigorous experimental design to systematically investigate how GPs use individual risk factors (blood pressure and cholesterol) versus the absolute risk of a CVD event in their decision making about CVD preventive medication. International guidelines are based on absolute risk, but are used inconsistently.
- The <u>results</u> show that GPs' decision making was more consistent with management of individual risk factors than an absolute risk approach, especially when prescribing blood pressure lowering medication.
- Our findings have important clinical implications, suggesting that medical treatment of lower risk patients (5 year risk of CVD event < 15%) with mildly elevated blood pressure or cholesterol is likely to occur even when an absolute risk assessment is specifically provided to GPs.
- The results may over-estimate the use of absolute risk in clinical practice due to: 1) a low response rate that is typical of such GP studies but may have favoured those more interested and positive about absolute risk, 2) reliance on self-reported intentions, which was necessary to enable an experimental design, and 3) explicitly providing GPs with an absolute risk score for each case, since absolute risk is often not assessed in practice.

INTRODUCTION

International guidelines for cardiovascular disease (CVD) prevention encourage the use of absolute risk to guide treatment with blood pressure and cholesterol lowering medication.[<u>1-6</u>] Several risk prediction models exist that differ in the duration over which they calculate CVD risk (typically 5 or 10 years) and the variables they base the risk on.[7-8] One of the most commonly used absolute risk models is the Framingham Risk Equation (FRE)[9], which estimates the risk of a cardiovascular event based on sex, age, smoking status, diabetes, systolic blood pressure, and cholesterol ratio. The Australian guidelines classify patients with a 5 year risk of > 15% as high risk and recommend that they should be simultaneously treated with cholesterol and blood pressure lowering medication in addition to lifestyle intervention unless contraindicated or clinically inappropriate.[10-11] For lower risk patients < 15% without additional risk factors such as family history, lifestyle intervention is recommended as the primary management approach. Adults with very high individual risk factors (systolic blood pressure ≥180 mmHg or diastolic blood pressure ≥110 mmHg or total cholesterol >7.5 mmol/L) do not require absolute CVD risk assessment because they are already considered to be at high risk of CVD.[10-11]

Using absolute risk is a major shift from the traditional approach of treating high blood pressure and high cholesterol individually. An absolute risk approach is likely to achieve the best balance between preventing CVD events and avoiding unnecessary treatment with medication. It has the potential to reduce overtreatment of people who have an elevated individual risk factor (e.g. blood pressure) but low or moderate overall risk of a CVD event and reducing under treatment of people with slightly elevated individual risk factors but a combined high overall risk.[12-13] <u>The first Framingham risk</u> equation was published in 1976[14] and New Zealand was the first country to introduce an absolute risk approach in 1993[15]. More than twenty years have passed since then and the absolute risk approach has been shown to reduce short-term CVD risk without causing clinical harms.[14]

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However, research suggests that General Practitioners (GPs) often do not use absolute risk to guide their decision making about CVD prevention.[15-19] Past research includes studies exploring barriers to GP's use of absolute risk[19-22] and studies quantifying treatment gaps using clinical databases[12, 16-17, 23-24] but individual decision making about absolute risk has not been comprehensively examined quantitatively. In this study we applied a method based on judgments of hypothetical patient cases to analyse GPs' decisions about CVD risk management and their use of absolute risk. Hypothetical patient cases (also called vignettes) have been widely used to measure decision processes in a range of clinical settings,[25] including GP decision making about cardiovascular disease.[26-28] Indeed, three recent studies using patient cases suggest that clinicians might not base treatment decisions on absolute risk thresholds (e.g. only treat patients > 15% for 5 year FRE based absolute risk or > 20% for 10 year risk); instead they focus on the levels of the individual risk factors blood pressure and cholesterol.[26-28] However, these studies did not systematically assess different combinations of absolute risk and individual risk factor levels. Therefore, they provide limited interpretation of how GPs use absolute risk versus individual risk factors in decision making.

In the current study we used hypothetical patient cases <u>(from here on referred to as cases)</u> in which the l<u>evels of</u> absolute risk and three individual risk factors (systolic blood pressure, cholesterol (TC/HDL ratio), and age) were systematically varied in order to evaluate their respective influence on GPs' decision making about CVD risk management. Absolute risk levels were derived from the FRE.[9]

In line with the literature suggesting that GPs tend to use an individual risk factor approach, we hypothesized that:

- <u>GPs are more likely to treat lower absolute risk with medication when individual risk factors</u> (blood pressure, cholesterol) are high than when individual risk factors are lower; and conversely:
- <u>GPs are less likely to treat high absolute risk with medication when individual risk factors</u>
 (blood pressure, cholesterol) are lower than when individual risk factors are high

METHOD

Recruitment

GPs <u>currently practicing in Australia</u> were recruited between May and November 2012 at four general practice conferences in <u>New South Wales, Victoria and Queensland</u>. All participants were <u>asked when they became a GP and whether they were currently practicing in Australia through</u> <u>survey questions, and the eligibility of returned questionnaires was verified before data analysis</u>. Ethical approval was obtained from the University of Sydney Human Research Ethics Committee.

Data collection and measurement

Respondents viewed a generic patient scenario (see Box 1) followed by a table with the relevant values for absolute risk, systolic blood pressure, TC/HDL ratio, HDL, total cholesterol, and age, as well as patient gender and smoking status (i.e. the cases). GPs were asked how they would manage the patient in the <u>case</u>: prescribe cholesterol medication, prescribe blood pressure medication, and/or prescribe aspirin (yes/no for each). In addition, they were asked when they would reassess the patient (open ended). The aspirin and reassessment results are reported separately. We collected information regarding GP characteristics: gender, age, years in practice, practice size. We asked GPs two questions about their use of absolute risk as follows: *"For the cases you just read, how often did you use the absolute risk score to inform your management decision?"* and *"In your"*

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general practice, how often do you use absolute risk scores, calculators or charts when assessing a patient's level of cardiovascular risk?" (5 point Likert scale; 1 never – 5 always). The survey was piloted with nine GPs.

Different sets of cases

We developed four sets of <u>cases</u> (also see Table 1):

A) High IR/lower AR with high individual risk factors (blood pressure only) and lower absolute risk

Aii) High IR/lower AR with high individual risk factors (cholesterol only) and lower absolute risk

B) High IR/high AR with high individual risk factors and high absolute risk,

C) Lower IR/high AR with lower individual risk factors and high absolute risk, and

D) Lower IR/lower AR with lower individual risk factors and lower absolute risk.

<u>Cases</u> were designed to be clinically plausible and relevant. <u>Only the sets of cases B and C were</u> <u>eligible for treatment with cholesterol and blood pressure lowering medication according to the</u> <u>Australian absolute risk guidelines.[10-11]</u> In all <u>cases</u> except high IR/lower AR (Ai and Aii) the levels of individual risk factors were the same across blood pressure and cholesterol (i.e. both lower or both high). For cases with high IR/lower AR (Ai and Aii) blood pressure was high and cholesterol was lower, or vice versa, to enable exploration of their independent effects on GP decision making. This resulted in a core set of 25 <u>cases</u> with different combinations of absolute and individual risk factor levels (see Appendix 1 for the complete set of <u>cases</u>).

Gender and smoking status

We constructed a female and male equivalent of each core <u>case</u> (where possible, given the restraints of the FRE and the individual and absolute risk levels defined above). We made all high absolute risk <u>cases</u> smokers and all lower absolute risk cases non-smokers, and we constructed an additional set of cases to test for the potential confounding effect of smoking.

Table 1. The levels for absolute risk and individual risk factors blood pressure (SBP) and cholesterol

(TC/HDL ratio) plus the relevant case numbers and number of cases $(n=144 \text{ GPs})^{\dagger}$

Category Figure 2/ Appendix 1	Absolute risk	Individual risk factors [‡]						
Appendix 1		SBP (mmHg)	TC/HDL ratio (mmol/L)	N	Case #			
Ai	Lower	High	Lower	431	25-35			
Aii	Lower	Lower	High	415	13-24			
<u>B*</u>	High	High	High	221	7-12			
<u>C*</u>	High	Lower	Lower	298	36-43			
D	Lower	Lower	Lower	219	1-6			

[†]See Appendix 1 for the actual values used in these cases

 *Only the sets of cases B and C were eligible for treatment with cholesterol and blood pressure lowering medication according to the Australian absolute risk guidelines[10-11]

Levels of absolute risk and individual risk factor levels

The levels used to describe elevated absolute risk and the individual risk factors (see Table 1) were based on the 2012 Australian absolute risk guidelines[11] (using the FRE) and informed by practicing GPs (JD, PG). We defined patients with a risk of a cardiovascular event over 5 years greater than 15% as high absolute risk, for whom preventive medication is recommended. The Australian absolute risk guidelines recommend that adults with systolic blood pressure ≥180 mmHg or total cholesterol >7.5 mmol/L do not require absolute CVD risk assessment because they are already known to be at clinically determined high risk of CVD.[5, 11] We ensured that the individual risk factor levels remained below these thresholds and, where possible, we avoided values that were close to the cut off. High blood pressure levels varied between SBP 147 and 179 mmHg and high cholesterol (TC/HDL ratio) between 6.5 and 7.2 mmol/L. Lower blood pressure levels varied between SBP of 110 and 145 mmHg and lower TC/HDL ratio between 3.0 and 6.0 mmol/L. We defined three age categories within the target population for CVD risk assessment: 47, 61, and 72 years. <u>Previous Australian guidelines</u> for cholesterol (2005)[29] and hypertension management (2010)[30] are consistent with the 2012

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guidelines recommendations for the commencement of cholesterol lowering and/or blood pressure lowering drug treatment in patients with an absolute risk > 15% of a CVD event in the next 5 years, or those with an absolute risk of 10-15% with the presence of additional risk factors but have now been replaced with the 2012 guidelines.

Randomisation

There were 25 core cases with systematically varied levels of absolute risk, cholesterol, blood pressure, and age. Each case had between one and three versions to enable male/female and smoking/non-smoking comparisons, depending on clinical plausibility. 11 of the core cases were randomly selected for each survey to reduce response burden, and only one version of the selected case was used (e.g. only the female, non-smoking version). The 11 selected cases were presented in random order. This process generated a total of 43 clinically possible cases (see Appendix 1 for details of each case).

Box 1: General patient scenario

'A regular patient of yours presents for a "check-up" and has no current symptoms. He/she has been trying to improve their diet and increase their physical activity levels. You have several previous blood pressure readings at approximately the same level as observed today. A recent test of electrolytes, liver function and renal function was normal.'

BMI: 27

Past medical history: nil of note

Family history: mother died of bowel cancer, nil family history of ischaemic heart disease

Social history: married, lives in own home

Ethnicity: Caucasian

Analysis

GPs' decisions on risk management for the different <u>cases</u> were summarized as the percentage of <u>cases</u> in which the GPs would prescribe cholesterol or blood pressure medication. We analysed how the chances of prescribing medication changed according to the <u>risk profiles</u> of the <u>cases</u> (i.e. levels of absolute and individual risk factors). This was done using Generalised Estimation Equations (GEEs) with a logit link (logistic regression) and an exchangeable working correlation matrix to take into account the clustering of cases per GP.

The outcome was whether the GP would prescribe medication for the <u>case</u>, and the covariates were the levels of absolute risk and individual risk factors (i.e. blood pressure and cholesterol levels) presented in the cases. More specifically, four sets of <u>cases</u> were compared: A) high individual risk factors and lower absolute risk, B) high individual risk factors and high absolute risk, C) lower individual risk factors and high absolute risk, and D) lower individual risk factors and lower absolute risk. The 95% confidence intervals for the percentages presented in the results section and Figure 2 were obtained from the GEEs.

We performed exploratory analyses to examine 1) how risk management changed according to GP characteristics (i.e. age, gender, years in practice, practice size, and self-reported use of absolute risk in practice and in the cases); and 2) how risk management changed according to specific characteristics of the <u>cases</u> presented (i.e. age, gender, and smoking status). <u>This was achieved by testing the interaction between each characteristic and the four sets of cases with different risk profiles in separate GEEs (one for each characteristic).</u> The statistical analysis was performed with the software SPSS version 21.

Missing data handling

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Five participants completed only half of the survey (1 out of 2 pages). For those participants, only the completed part of the survey was included in the analysis. Additionally, there was an average of 5 missing responses per case. In most instances the missing values occurred in questionnaires where only positive responses were marked (i.e. GP only gave a response for cases where he/she would prescribe) and it was therefore assumed that the missing values were negative responses (i.e. GP would not prescribe for that case). A sensitivity analysis was conducted to check this assumption by excluding the surveys with missing values. The pattern of results did not change.

RESULTS

Response rate

Over the four General Practice conferences, we had a 30% response rate for surveys that were handed out at a stall (90 surveys completed from 304 distributed at two conferences) and a 3% response rate for surveys that were inserted into GPs' conference packs (55 surveys completed from 1803 surveys inserted into GPs' conference packs at three conferences). One returned survey was excluded due to participant ineligibility (not currently practicing). A total of 144 GPs participated in this study.

GP characteristics

The median age of the GPs who participated in the study was 53 (IQR= 47 to 59) and 58% were female. They had been practicing medicine for a median of 28 years (IQR=21 to 35) with a median practice size of five GPs (IQR= 3 to 8). Figure 1 shows GPs' self-reported use of absolute risk in their usual practice and the <u>cases</u>.

<Please insert Figure 1>

Prescription of blood pressure lowering medication

 For <u>cases</u> in the high blood pressure group (SBP \geq 147 mmHg) GPs stated that they would prescribe blood pressure medication for 93% (95%CI=86-96%) of the <u>cases</u> with high absolute risk (5 year risk of a CVD event > 15%) and 83% (95%CI=76-88%) of the <u>cases</u> with lower absolute risk. See Figure 2(I) and Appendix 1, Ai and B. Conversely, 30% (95%CI=25-36%) of <u>cases</u> in the lower blood pressure group were prescribed blood pressure medication if absolute risk was high and 4% (95%CI=3-5%) of the <u>cases</u> if absolute risk was lower. See Figure 2(I) and Appendix 1, C and D.

<Please insert Figure 2>

Prescription of cholesterol lowering medication

GPs stated they would prescribe cholesterol medication for 69% of <u>cases</u> with high cholesterol (TC/HDL ratio \geq 6.5) and high absolute risk (95%Cl=61-77%; Figure 2b, B). In contrast, a smaller percentage of <u>cases</u> with high cholesterol but lower absolute risk were prescribed cholesterol medication (34%, 95%Cl=28-41%; Figure 2(II) and Appendix 1, Aii). The prescribing pattern for cholesterol medication in <u>cases</u> with lower cholesterol was similar to blood pressure medication. GPs indicated that they would prescribe cholesterol medication in just over a third of <u>cases</u> (36%, 95%Cl=30-43%; Figure 2(II) and Appendix 1, C) if absolute risk was high and 10% of <u>cases</u> if absolute risk was lower (95%Cl=8-13%; Figure 2(II) and Appendix 1, D).

Prescription and patients' characteristics

There were no differences in the pattern of prescribing cholesterol medication for <u>cases</u> of different age groups at similar risk (p=0.331). However, 61 year old cases were twice as likely (OR=2.00, p<0.001, 95%CI=1.52-2.65) to be prescribed blood pressure medication than 72 year old <u>cases</u> with the same risk profile. GPs were also more likely to indicate that they would prescribe cholesterol medication (OR=1.27, p=0.025, 95%CI=1.03-1.56) but not blood pressure medication for male cases

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(OR=1.24, p=0.212, 95%CI=0.89-1.72). Smoking status was not associated with the prescription of cholesterol or blood pressure medication (OR=0.66, p=0.077, 95%CI=0.42-1.05).

Prescription and GP characteristics

Older GPs were less likely to prescribe cholesterol medication (OR=0.77, p=0.039, 95%CI=0.60-0.99, per 10 years of age). A similar trend was found for years of practice (OR=0.80, p=0.052, 95%CI=0.65-1.00, per 10 years of practice). GP age and years of practice were not associated with stated prescribing of blood pressure medication (OR=0.81, p=0.160, 95%CI=0.61-1.09, per 10 years of age; OR=0.84, p=0.191, 95%CI=0.65-1.09, per 10 years of practice).

Stated prescribing was not significantly associated with self-reported use of the absolute risk approach in practice or GP gender. However, GPs who reported using absolute risk in the <u>cases</u> were more likely to prescribe blood pressure and cholesterol medication for cases with high absolute risk (blood pressure medication: OR=1.29, p=0.042, 95%Cl=1.01-1.64; cholesterol medication: OR=1.61, p=0.001, 95%Cl=1.22-2.12). For the <u>cases</u> with lower absolute risk these GPs also prescribed more, but this was not statistically significant (blood pressure medication: OR=1.07, p=0.654, 95%Cl=0.81-1.41; cholesterol medication: OR=1.22, p=0.077, 95%Cl=0.98-1.52).

DISCUSSION

Our analysis of the prescribing decisions for 144 general practitioners (GPs) over a range of systematically varied cases suggests that GPs focus more on the levels of individual CVD risk factors blood pressure and cholesterol than on absolute risk, especially when prescribing blood pressure lowering medication. The results suggest that, inconsistent with the Australian guidelines,[10-11] GPs are likely to prescribe blood pressure and cholesterol lowering medication to lower risk patients (5 year risk of CVD event < 15%) if these risk factors are elevated, even when an absolute risk

assessment is specifically provided to GPs. <u>Conversely, GPs did not always prescribe medication to</u> higher risk cases when blood pressure or cholesterol were not elevated. These results are in line with our hypotheses, and previous studies of patient records showing overtreatment of low risk patients and undertreatment of high risk patients, and that individual risk factors influence prescribing.[26-28, 31-33] Age appeared to be largely ignored as a risk factor, and GPs prescribed less blood pressure lowering medication for 72 year old cases in comparison with 61 year olds despite similar descriptions in the scenarios (a relatively healthy fit x year old). This finding is worthy of further exploration, given that age is one of the strongest risk factors for CVD, as it runs counter to the concept of absolute CVD risk and proposals based solely on an age cut off. [34-35] We acknowledge that in clinical practice GPs may have various and valid reasons for deviating from the guidelines, and strict adherence to guidelines and/or treatment thresholds may undermine the shared decision making (SDM) approach that is now considered gold standard.[36-37] SDM in the current context would entail that a GP assesses absolute CVD risk, explains this and the recommended management approach to the patient, discusses the benefits and harms of the different management options with the patient, and makes a shared decision with the patient. Our study and previous work suggests that many GPs do not based their recommendations on absolute risk, so it is unlikely that they can adequately inform their patients about the benefits and harms of CVD risk management and engage them in shared decision making.

Prescribing patterns were different for cholesterol and blood pressure medication. Although explanatory factors were not investigated in this study, historically, anti-hypertensive prescribing dates back to the late 1950s; hypertension was the first major CVD risk factor successfully treated.[38] In contrast, there was controversy over the treatment of cholesterol until the largescale trials of statins reported in the mid-1990s,[39] which coincided with the emergence of ideas and methods using absolute CVD risk. This history may have influenced the language used for these risk factors; "hypertension" is more commonly used than its lipid analogues such as "hypercholesterolaemia".

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The strengths of this study include the heterogeneity of the GPs who participated, and the systematic variation of cases, but there are also some limitations: First, the response rate was disappointing though typical for such GP studies.[27] However, any bias in our sample is likely to favour GPs more interested and positive about absolute risk, although almost 15% of GPs in our study stated that they never use absolute risk in practice. Second, to keep cases simple and clear we were restrictive in the range of clinical variables and management options presented, excluding lifestyle modification although space was provided for comments. Third, we relied solely on self-reported intentions to prescribe in the different <u>cases</u> rather than actual prescribing behaviour. This allowed an experimental design, but the results may not reflect what is actually happening in clinical practice. However, our results are likely to be an over-estimate of the use of absolute risk in actual practice as the <u>cases</u> explicitly provided GPs with an absolute risk score. We know from our qualitative work that absolute risk is often not assessed in practice.[19]

In conclusion, GPs' decision making was more consistent with an individual risk factor approach than absolute risk, especially when prescribing blood pressure lowering medication. While more research to explore the cognitions behind these reported behaviours would be worthwhile, our study identifies a clear need to improve guideline recommendations about how GPs should integrate individual risk factor assessment with a management that is guided by absolute CVD risk.

ACKNOWLEDGEMENTS

The authors would like to thank the General Practitioners who participated in the study, and Adam McSorley for assistance with data management.

COMPETING INTERESTS

All authors have completed the Unified Competing Interest form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare: no financial relationships with any organisations that might have an interest in the submitted work in the previous three years, and no other relationships or activities that could appear to have influenced the submitted work.

FUNDING

The study was funded by the National Health and Medical Research Council (NHMRC) project grant 511217. Jesse Jansen and Kirsten McCaffery are supported by NHMRC fellowships. Carissa Bonner was supported by an Australian Postgraduate Award. Robin Turner and Armando Teixeira-Pinto were supported by NHMRC program grant 633003 to the Screening & Test Evaluation Program. Jenny Doust was supported by the NHMRC project grant 511217.

ETHICAL APPROVAL

The University of Sydney human research ethics committee approved this study (No 11-2011/14379).

DATA SHARING

No additional data available.

AUTHOR CONTRIBUTIONS

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All authors included on the paper fulfill the criteria of authorship, and there was no one else who fulfils the criteria. JJ contributed to study design, analysis, interpretation, drafting and revising the manuscript. CB contributed to study design, recruitment, data collection, analysis, interpretation, and revising the manuscript. SM contributed to recruitment, data collection, analysis, interpretation, and revising the manuscript. LI contributed to study design, interpretation, and revising the manuscript. JD contributed to study design, interpretation, and revising the manuscript. JD contributed to study design, interpretation, and revising the manuscript. PG contributed to study design, interpretation, and revising the manuscript. ATP contributed to analysis, and revising the manuscript. RT contributed to study design, and revising the manuscript. AH contributed to study design, and revising the manuscript. KM contributed to study design, analysis and interpretation, and revising the manuscript. All authors approved the final version of the manuscript and all authors are guarantors.

FIGURE LEGENDS

Figure 1. Self-reported use of absolute risk in practice and in the hypothetical cases (n=144 GPs).

Figure 2. Percentages of cases in which the General practitioners would prescribe a blood pressure or cholesterol lowering drugs according to different combination of absolute (horizontal axis) and individual risk factors (vertical axis).

The error bars represent the 95% confidence intervals for the percentage of <u>cases</u> (controlled for clustering)

Ai) High IR/lower AR with high individual risk factors (blood pressure only) and lower absolute risk

Aii) High IR/lower AR with high individual risk factors (cholesterol only) and lower absolute risk

B) High IR/high AR with high individual risk factors and high absolute risk*,

C) Lower IR/high AR with lower individual risk factors and high absolute risk*, and

D) Lower IR/lower AR with lower individual risk factors and lower absolute risk.

See Appendix 1 for exact AR and IR values

*Only the sets of cases B and C were eligible for treatment with cholesterol and blood pressure

lowering medication according to the Australian absolute risk guidelines[10-11]

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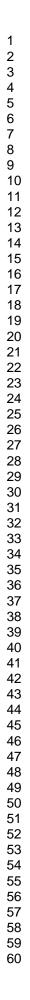
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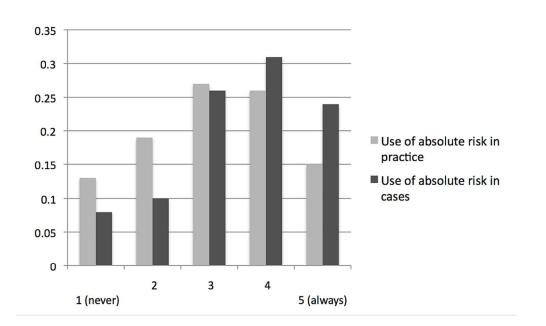


Figure 1. Self-reported use of absolute risk in practice and in the hypothetical cases (n=144 GPs). 90x55mm (300 x 300 DPI)

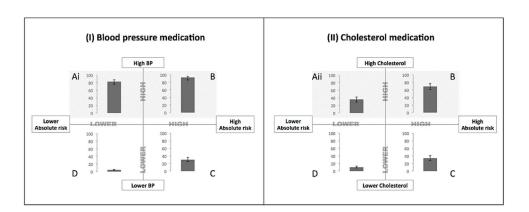


Figure 2. Percentages of cases in which the General practitioners would prescribe a blood pressure or cholesterol lowering drugs according to different combination of absolute (horizontal axis) and individual risk factors (vertical axis).

The error bars represent the 95% confidence intervals for the percentage of cases (controlled for clustering)

Ai) High IR/lower AR with high individual risk factors (blood pressure only) and lower absolute risk Aii) High IR/lower AR with high individual risk factors (cholesterol only) and lower absolute risk

B) High IR/high AR with high individual risk factors and high absolute risk*,

C) Lower IR/high AR with lower individual risk factors and high absolute risk*, and

D) Lower IR/lower AR with lower individual risk factors and lower absolute risk.

See Appendix 1 for exact AR and IR values

*Only the sets of cases B and C were eligible for treatment with cholesterol and blood pressure lowering medication according to the Australian absolute risk guidelines[10-11]

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Appendix 1: Overview of the different cases

	Case type	AR B	BP [§]	Cholesterol			Age	Gender	Smoker	Case #
				TC/HDL [#]	Total [#]	HDL [#]	_			
Α	(i)	3.7%	167	3.8	5.1	1.3	47	Female	n	25
	AR: lower	5.5%	167	3.8	5.1	1.3	47	Male	n	26
	IR: high	7.1%	166	3.5	5.1	1.5	61	Female	n	27
	(BP only)	8.9%	156	3.0	4.9	1.6	61	Male	n	28
		8.4%	156	3.1	4.9	1.6	72	Female	n	29
		10.2%	179	6.0	6.0	1.0	47	Male	n	30
		11.9%	169	5.8	6.0	1.0	47	Female	у	31
		12.6%	157	5.2	5.8	1.1	47	Male	у	32
		11.8%	169	5.8	6.0	1.0	61	Female	n	33
		13.5%	147	5.7	5.9	1.0	61	Male	n	34
		13.2%	158	5.0	5.6	1.1	72	Female	n	35
	(i)	2.2%	114	6.7	6.2	0.9	47	Female	n	13
	AR: lower	4.9%	125	7.2	6.3	0.9	47	Male	n	14
	IR: high	6.4%	123	6.8	6.2`	0.9	61	Female	n	15
	(chol only)	8.9%	116	6.5	6.2	1.0	61	Male	n	16
		8.6%	118	6.6	6.3	1.0	72	Female	n	17
		10.9%	130	7.2	6.3	0.9	47	Male	у	18
		13.0%	132	7.2	6.3	0.9	61	Male	n	19
		12.4%	123	6.8	6.2	0.9	61	Female	у	20
		14.8%	110	6.6	6.3	1.0	61	Male	ý	21
		11.2%	128	7.1	6.6	0.9	72	Female	n	22
		13.9%	112	6.8	6.2	0.9	72	Male	n	23
		13.6%	110	6.5	6.2	1.0	72	Female	у	24
В	AR: high	15.6%	177	7.2	6.3	0.9	47	Female	y	7
	IR: high	18.3%	167	7.2	6.3	0.9	47	Male	у	8
		21.7%	166	6.6	6.3	1.0	61	Female	у	9
		29.9%	165	6.6	6.3	1.0	61	Male	y	10
		28.6%	166	6.6	6.3	1.0	72	Female	y	11
		39.7%	165	6.6	6.3	1.0	72	Male	y	12
С	AR: high	15.4%	131	4.4	5.4	1.2	61	Male	y	36
	IR: lower	15.3%	132	4.5	5.5	1.2	73 [¶]	Female	ý	37
		19.5%	129	3.6	5.2	1.5	72	Male	y	38
		15.5%	145	5.9	5.8	1.0	61	Female	ý	39
		21.3%	144	5.4	5.6	1.0	61	Male	y	40
		20.8%	145	6.0	6.0	1.0	72	Male	'n	41
		20.0%	144	5.4	5.6	1.0	72	Female	у	42
		29.8%	143	5.4	5.6	1.0	72	Male	ý	43
D	AR: lower	1.4%	122	3.9	5.3	1.3	47	Female	n	1
	IR: lower	2.2%	123	3.8	5.1	1.3	47	Male	n	2
		3.4%	122	3.9	5.3	1.3	47	Female	n	3
		6.0%	122	3.8	5.1	1.3	61	Male	n	4
		5.5%	122	3.8	5.1	1.3	72	Female	 n	5
		8.5%	119	3.3	5.1	1.5	72	Male	n	6

AR=absolute cardiovascular disease risk, IR=individual risk factors, BP= systolic blood pressure

The shaded rows indicate control cases

§=(mmHg), #=(mmol/L)

[¶]Age was 73 in one case to ensure the correct threshold for absolute risk and individual risk factors.