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Title: Improved cardiovascular risk profile in patients referred to a specialised vascular outpatient clinic: a cohort study.

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Keywords: Cardiovascular risk profile; Specialised vascular outpatient clinic; Framingham Heart Risk Score; Heart SCORE

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Abstract: We carried out a retrospective cohort study in patients referred to our vasculair outpatient clinic to see how their cardiovascular riskprofile developed. The classical riskfactors were compared at first visit and one year later. The adapted Framingham Heart Risk Score (FHRS) and the Heart SCORE (HS) were used to compare the cardiovascular risks.
There was a decline of 9 and 5 mmHg in mean systolic bloodpressure in the hypertension group and in the group with atherosclerotic disease, respectively. On average 0.6 and 0.8 antihypertensive agents were added. In the hypertension group mean LDL-level decreased from 3.2 to 2.4mmol/l. For the secondary prevention group mean LDL-cholesterol decreased from 3.3 to 2.1mmol/l. In the hypertension group, the 10-year relative risk of myocardial infarction (FHRS) decreased with 28% (95%CI 25-30). The 10-year relative risk on a fatal cardiovascular event (HS) decreased with 33% (95%CI 31-36). The absolute risk decreased with 3,3% (95%CI 2,0-4,6) and 1,4% (95%CI 0,5-2,3) by using the HS.
We conclude that the cardiovascular risk profile of our patients significantly improved as shown by the FHRS or the HS. These benefits were reached by a decreasing number of smokers, better blood pressure control and a lower LDL-cholesterol.

Gouda, 8-4-2009

Dear Editor,

Please find enclosed our manuscript entitled “Improved cardiovascular risk profile in patients referred to a specialised vascular outpatient clinic: a cohort study”, which we would like you to consider for publication in the journal.
It is only recently that many hospitals nowadays have a special outpatient clinic for cardiovascular risk management, where several specialists and vascular nurses work together. The effect of these outpatient clinics on patient outcomes has never been evaluated or published. We showed that already after one year of intervention in our outpatient setting there was a significant improvement of the cardiovascular risk profile in referred patients.
We hope that you will find this paper suitable for publication from a scientific point of view. Also, we hope that this outcome can be used in discussions with hospital boards and insurance companies to underline the importance and necessity of these kinds of vascular outpatient clinics.
The final manuscript has been seen and approved by all authors. There are no conflicts of interest.

With kind regards

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Improved cardiovascular risk profile in patients referred to a specialised vascular outpatient clinic: a cohort study.

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Abstract

We carried out a retrospective cohort study in patients referred to our vasculair outpatient clinic to see how their cardiovascular riskprofile developed. The classical riskfactors were compared at first visit and one year later. The adapted Framingham Heart Risk Score (FHRS) and the Heart SCORE (HS) were used to compare the cardiovascular risks.

There was a decline of 9 and 5 mmHg in mean systolic bloodpressure in the hypertension group and in the group with atherosclerotic disease, respectively. On average 0.6 and 0.8 antihypertensive agents were added. In the hypertension group mean LDL-level decreased from 3.2 to 2.4mmol/l. For the secondary prevention group mean LDL-cholesterol decreased from 3.3 to 2.1mmol/l. In the hypertension group, the 10-year relative risk of myocardial infarction (FHRS) decreased with 28% (95%CI 25-30). The 10-year relative risk on a fatal cardiovascular event (HS) decreased with 33% (95%CI 31-36). The absolute risk decreased with 3,3% (95%CI 2,0-4,6) and 1,4% (95%CI 0,5-2,3) by using the HS.

We conclude that the cardiovascular risk profile of our patients significantly improved as shown by the FHRS or the HS. These benefits were reached by a decreasing number of smokers, better blood pressure control and a lower LDL-cholesterol.

Keywords:

Cardiovascular risk profile

Specialised vascular outpatient clinic

Framingham Heart Risk Score

Heart SCORE

Introduction

Cardiovascular diseases rank number one in mortality in the Dutch population.[1] In 2005 43.350 people died of cardiovascular disease. The risk factors for cardiovascular disease can be divided in non-treatable risk factors (age, gender, heredity) and treatable risk factors (high blood pressure, elevated serum cholesterol, smoking, obesity, glucose intolerance/Diabetes Mellitus). The risk factors for cardiovascular disease are prevalent: among the Dutch population aged 35-70 years almost 50% has a blood pressure >140/90 mmHg and the prevalence of a serum Total Cholesterol >6,5 mmol/l is about 25%, and almost 30% is a current smoker.[2,3] From the literature is known that in a substantial proportion of these patients the cardiovascular risk factors are not treated or are not treated optimally. Therefore in 2003 we started our specialised vascular outpatient clinic to optimize treatment in these patients.

Our aim was to analyse and treat all cardiovascular risk factors in a structured programme, for all patients referred with hypertension, dyslipidaemia or (premature) atherosclerotic vascular diseases (stroke, transient ischaemic attack, peripheral arterial obstructive diseases, central retinal vein thrombosis or myocardial infarction). In this study we investigate the development of the cardiovascular risk profile in these patients during one year of treatment and follow-up.

Materials and methods

The investigation conforms with the principles outlined in the Declaration of Helsinki.
All consecutive patients who were referred to our specialised vascular outpatient clinic during September 2003 until 31 December 2004 were included. The patient population consisted of patients referred by general practitioners primarily for analyses and treatment of their hypertension and of patients referred for treatment of cardiovascular risk factors after an atherosclerotic event (stroke, transient ischaemic attack, peripheral arterial obstructive diseases, central retinal vein thrombosis or myocardial infarction). The latter patients were primarily referred by other specialists within the Groene Hart Ziekenhuis, which is a mid-sized general teaching hospital in the southwest of the Netherlands (450 in-patient beds).
At first visit (t=0) a standardised history was taken and physical examination was done by the vascular nurses. After that, blood was drawn from the antecubital vein for standard laboratory measurements, an ECG was made and ultrasonography of the kidney's and abdominal aorta was performed. At second visit patients were seen by the treating physician, the cardiovascular risk profile was made up and therapy initiated or adapted. After 3,6 and 12 months patients were seen for follow-up at the outpatient clinic and when necessary therapy was adjusted. At 12-15 month (t=1) data on the cardiovascular risk profile were collected again in the same manner and were used for comparison with the data at entry. For the analyses, the following data were extracted from the files: medical (family) history on vascular events, medication, current and past smoking behaviour, length, weight, waist circumference, blood pressure, fasting lipid profile (total cholesterol, triglyceride, HDL-cholesterol, LDL-cholesterol), fasting glucose and the amount of micro-albuminuria (all at t=0 and t=1).

Blood pressure. For every patient several blood pressure measurements were available, manual or automatic, two-hour blood pressure measurements and 24-hour ambulant blood pressure registrations. For the analysis we used the first measurement of a two-hour blood pressure registration in our clinic. In this situation patients were comfortably seated for some time before start of the measurements.

Cutt-off points. The target blood pressure was <140/90 mmHg for patients with hypertension without extra cardiovascular risk factors and <130/80 mmHg for patients with cardiovascular risk factors or end-organ damage. [2,6,7]

Cholesterol. In the group treated for secondary prevention, the target fasting LDL-cholesterol was 2.5 mmol/l or less. In the hypertension group we did prescribe statins following the algorithm of the ASCOT trial. [8]

Smoking status. Patients were classified as a current smoker when smoking at the time of the examination or when they stopped smoking less then nine months before.

Family history. This was regarded positive when first line relatives < 60 years old or at least three relatives in the second line were diagnosed with cardiovascular events, hypertension or diabetes mellitus.

Framingham Heart Risk Score. A number of instruments have been developed to calculate the risk of future cardiovascular diseases. Most commonly used is the algorithm from the Framingham Heart Study of 1968. [5] In the analysis we used the last version of the Framingham Heart Risk Score.

Heart SCORE. An alternative for the Framingham Heart Risk Score is the Heart SCORE [7]. The Heart SCORE calculates the risk of dying from any cardiovascular disease in the next ten years for patients aged 40-65 years. For patients aged younger than 40 or elder than 65 we extrapolated the age respectively to 40 and 65 years of age. We used the version based on national (Dutch) data for mortality, smoking, blood pressure and cholesterol.

Analysis. All data were analysed with SPSS. We used the paired-samples t-test to compare means, for the several parameters on t=0 and t=1.

Missing data: on t=1 we had to replace the smoking status for four patients. If a patient did not smoke at t=0 we assumed he did not at t=1 as well. If the patient was a current smoker at t=0 or had stopped smoking less than nine months before we assumed he was still smoking at t=1. When the first measurement of a two-hour blood pressure registration in our outpatient clinic was not available we took the first blood pressure reading at the office (n=15 patients at t=1).

Results

Complete data sets (t=0 and t=1) were available for 87 patients with hypertension and 58 patients with atherosclerotic vascular disease. (Figure 1).

Table 1 shows the baseline characteristics of the patients referred for treatment of hypertension and for the patients referred for cardiovascular risk management after an episode of an atherosclerotic disease.

Table 2 shows the effect of one-year treatment on the blood pressure and serum cholesterol levels. Also the change in smoking behaviour is presented.

In the hypertension group the average systolic blood pressure decreases with 9 mmHg and diastolic blood pressure with 4 mmHg. The lower blood pressure was achieved by adding an average of 0.6 antihypertensive agents and in many cases titrating to the maximum approved doses for the used antihypertensives. In the group patients with atherosclerotic vascular disease the average systolic and diastolic blood pressure decreased with 5 mmHg. This was achieved by adding 0,8 antihypertensive agents on average. In both groups there was a decrease of current smokers (7% versus 11%).

In the hypertension group the number of patients with cholesterol lowering therapy increased from 13% to 53% and in the group with atherosclerotic disease from 32% to 90%.

Table 3 shows the Framingham Heart Risk Score and the Heart Score at t=0 and t=1 for both groups. For the patients referred for hypertension treatment the 10-year risk on myocardial infarction according to the Framingham Heart Risk Score decreased significantly with 28% (95% CI 25-30). For the Heart SCORE the relative risk reduction on the 10-year risk of dying due to cardiovascular disease decreased by 33% (95% CI 31-36). The absolute risk reduction was respectively 3,3% and 1,4%. When the group was confined to patients 40-65 year of age the outcomes were essentially the same.

Discussion

In our cohort study we observed that the cardiovascular risk profile of patients referred with hypertension or atherosclerotic vascular disease significantly improved as shown by the Framingham Heart Risk Score or the Heart SCORE. These substantial benefits were reached by a decreasing number of smokers, better blood pressure control and an evident decrease in serum LDL-cholesterol.

In the data analyses the risk reduction of myocardial infarction in the hypertension group was for a substantial part caused by the decrease of serum cholesterol. Although we recognise the importance of strict blood pressure regulation, in practice it is often hard to fulfil the pre-specified targets of <130/80 mmHg. Three agents of different classes, each with its own side effects, are often needed for adequate blood pressure lowering. In contrast, cholesterol lowering is nowadays more easily achieved. In most cases one tablet is enough to get an LDL-cholesterol below 2.5 mmol/l. Also the side effects of these tablets seems less when compared to blood pressure lowering agents. In this theoretical approach with the 10-year risk on myocardial infarction according to the Framingham Hears Risk Score as a starting-point, one should consider not to add a third or fourth antihypertensive agent, but instead to start a cholesterol lowering agent. However, there is no scientific evidence for this kind of therapeutical decision making from the epidemiological armchair.

The use of statins in the group with atherosclerotic vascular disease on t=1 did not reach 100%. The main reason for this is the inclusion of 10 patients with ocular vein thrombosis. In these patients statins are not routinely applied.

In our retrospective study there were a number of patients with incomplete data sets for t=0 and t=1. The main reason for this were missing laboratory data (with high serum triglyceride,

for example, HDL-cholesterol could not be determined and the total cholesterol/HDL-cholesterol ratio could not be determined and used for the risk scores).

On t=1 the main cause of loss were patients who did not show up for the outpatient clinic visits (Figure 1). It might be so that these were patients who reached their target blood pressure <130/80 mmHg in a relative short time (within 1-2 visits). For them, there was less urge to come to the outpatient clinic any longer. If true, our study results would even be more positive.

A point of criticism are the missing data of the 2-hours blood pressure measurement at t=1. These missing data were replaced by the first office blood pressure measurement. There is prove from other studies that the mean office blood pressure is higher. If this is true for our study, this could imply that the decrease in blood pressure at t=1 in reality is greater. By analysing the data with the exception of the 10 and respectively 5 blood pressure replacements at t=1, the average blood pressure and the reported results did not essentially change.

There are a number of limitations to the use of the Framingham Heart Risk Score and the Heart SCORE; in routine practice the most important restriction is that the Framingham Heart Risk Score and the Heart Score are not validated for using at two different moments in time in the same population as a tool for evaluation of medical interventions. Furthermore, the use of the Heart SCORE is restricted to the category of age 40-65 years old. Also the different methods for blood pressure measurements in our study did not correspond with the definitions used in the Framingham Heart Study or in the Heart SCORE. However in our opinion, the risk scores can be used in clinical practice to show patients their cardiovascular risk profile and the potential development in time.

In conclusion we found that after one year of treatment in a specialised vascular outpatient clinic of a mid-size general hospital there is a significant improvement of the cardiovascular risk profile of patients referred with hypertension or atherosclerotic vascular diseases.

Acknowledgement

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Figure 1. Patients summary September 2003-December 2004

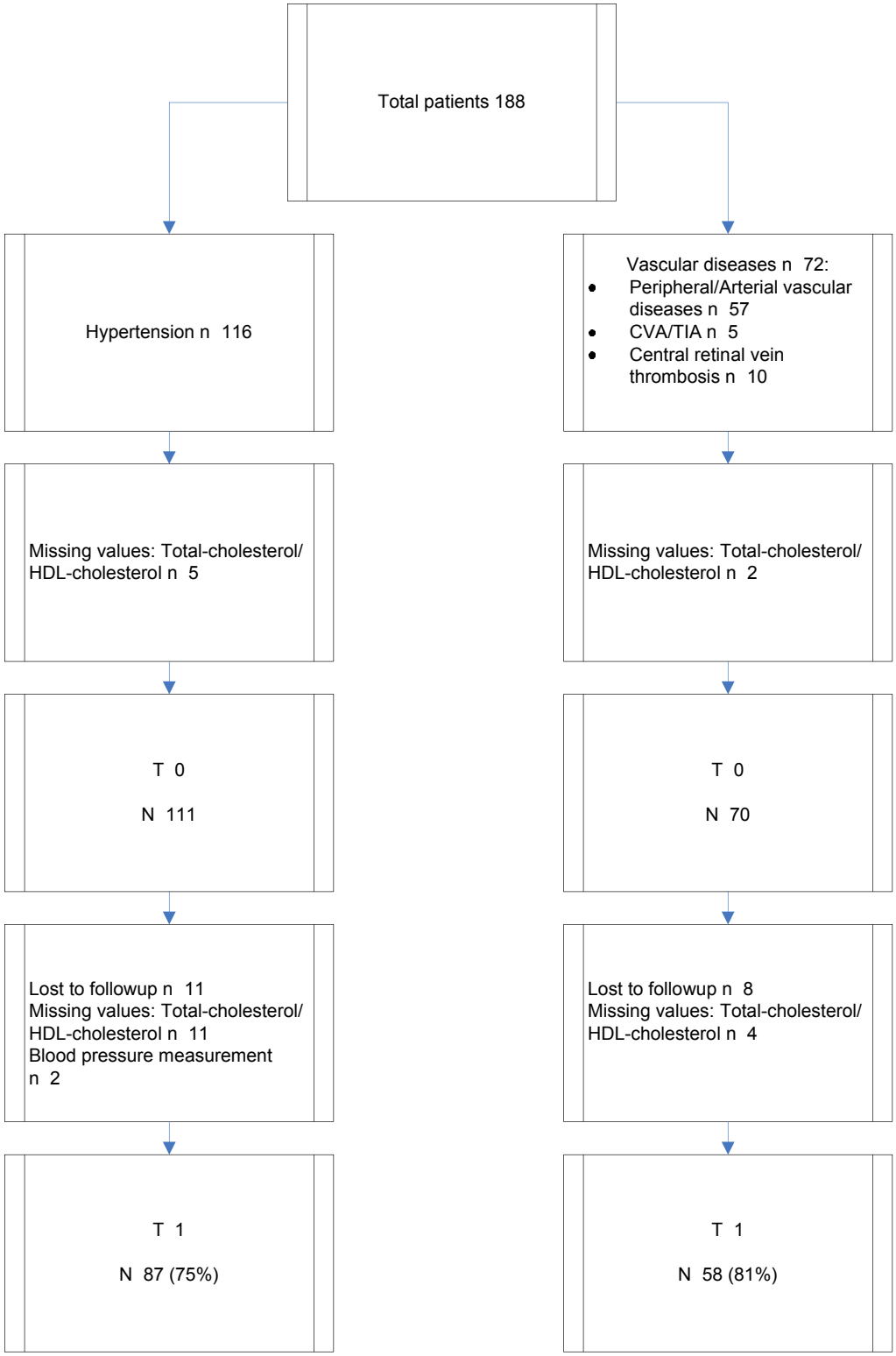

Table 1 Baseline characteristics of the patients at t = 0

Characteristic	Hypertension group (n=87)	Atherosclerotic vascular disease (n=58)
Sex		
Male	n=40(47%)	n=36(61%)
Average age in years (range)	52 (20-78)	58 (30-76)
Average BMI (range) kg/m^2	28 (19-42)	26 (19-46)
Fasting serum glucose <6.0 mmol/l	66.3%	56%
6-7 mmol/l	28.8%	35.7%
>7 mmol/l	8.4%	8.5%
Current smoker*	n=27(31%)	n=28(48%)
Average Total cholesterol (mmol/l)†		
non cholesterol lowering treatment	5.6	5.8
cholesterol lowering treatment	4.4	4.6
Average LDL-cholesterol (mmol/l)†		
non cholesterol lowering treatment	3.3	3.7
cholesterol lowering treatment	2.4	2.4
Average HDL-cholesterol (mmol/l)†		
non cholesterol lowering treatment	1.5	1.4
cholesterol lowering treatment	1.6	1.5
Micro-albuminuria > 3.0 mg/mmolkreatinine	8(9.6%)	8(13.6%)
Familial anamnesis of cardiovascular disease ‡	31(36%)	29(49%)
Familial history of hypertension ‡	56(65%)	28(48%)
Familial history of Diabetes mellitus ‡	23(27%)	14(24%)
Earlier diagnosis of Vascular atherosclerotic event §	10(12%)	58(100%)
Diabetes mellitus	7(8%)	7(12%)
Hypertension	87(100%)	29(49%)
Dyslipidaemia	20(23%)	16(27%)

* definition of a current smoker: active smoking or stopped < 9 months

† On T0, 15% of all hypertension patients were treated with cholesterol lowering therapy. In the group patients with peripheral arterial obstructive diseases 31% was treated with cholesterol lowering therapy at entry.

‡ definition of familial predisposition: 1^e line relative < 60 years old or at least 3 relatives in the second line [1]

§ definition of vascular event; central- or peripheral vascular disease, cerebro vascular accident / transcient ischemic attack, heart faillure/ myocardial infarction, arterial retinal vein thrombosis.

Table 2 Mean blood pressure, cholesterol levels and smoking status at entry (T=0) and at one year follow-up (T=1).

	Hypertension group (n=87)			Atherosclerotic disease group (n=58)		
	T=0	T=1	p-value	T=0	T=1	p-value
Mean SBP	156	147	0,002	138	133	0,065
Mean DBP	90	86	0,026	81	76	0,000
Mean TC	5,5	4,6	0,000	5,5	4,3	0,000
Mean HDL	1,5	1,5	0,970	1,5	1,6	0,001
Mean LDL	3,2	2,4	0,000	3,3	2,1	0,000
Smoking	31%	24%	0,033	47%	36%	0,007

PAOD: peripheral arterial obstructive disease; SBD: systolic blood pressure;
DBD: diastolic blood pressure; TC: total serum cholesterol; HDL: High-density lipoproteins;
LDL: Low-density lipoproteins

Table 3. Framingham Heart Risk Score and Heart SCORE in patients referred for hypertension on T=0 and T=1

		T0	**T1**	**ARR** (95% CI)	**RRR** (95% CI)
All patients (n=87)	**Framingham (%)**	12	8.8	3.2 (2.0- 4.6)	28 (25-30)
	Heart SCORE (%)	4.2	2.8	1.4 (0.5-2.3)	33 (31-36)
Patients 40-65 yrs (n=42)	**Framingham (%)**	11	8.5	2.8 (1.1-4.5)	25 (24-26)
	Heart SCORE (%)	3.1	2.6	0.6 (-0.1-1.2)	19 (18-20)

ARR: absolute risk reduction; RRR: relative risk reduction

*** Referee Suggestions**

Reviewers:
No suggestions