AstraZeneca

STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: NA
ACTIVE INGREDIENT: NA

Study No: D3560L00089
Audit and screening study to determine the prevalence of peripheral arterial disease A cross-sectional multi-centre clinical study in subjects with cardiovascular disease risk factors.

Developmental Phase: NA
Study Completion Date: 29 October 2009
Date of Report: 21 April 2010

OBJECTIVES:

Primary objectives
The primary objective of this study was to establish the prevalence of lower extremity peripheral arterial disease, defined as an ankle-brachial index (ABI) ≤ 0.90, in subjects with at least two of the specified CVD risk factors and with no overt cardiovascular disease.

Secondary objectives
The secondary objectives were to establish the prevalence of cardiovascular risk factors in the target population; to establish the currently prescribed treatments (non-pharmacological and pharmacological) for cardiovascular risk factor management in the target population; to assess the cardiovascular risk level in the selected population according to the N.Z. Cardiovascular Risk Calculator; to identify physician approaches to patient management in subjects with at least two of the specified CVD risk factors, with no overt cardiovascular disease; to determine the change in physician approach to patient management pre and post study; to identify subject characteristics that are determinants of PAD diagnosis and to establish the additional interventions given to subjects following diagnosis of PAD.

METHODS:

Study Design

This was a cross-sectional, multi-centre clinical study in the primary care setting. Eligible subjects included male subjects aged ≥ 45 years or female subjects aged ≥ 55 years. Data collection for each subject took place at one visit during which the Investigator or designee completed a Case Report Form with the subject relevant data. The Investigator or designee performed the ABI measurement in order to detect the presence of lower extremity PAD in participating subjects.

Target Subject Population and Sample Size

Planned enrolment was 1000 subjects. Enrolment ceased after the 1000th patient was enrolled and the ITT analysis included data from 987 enrolled subjects.

Diagnosis and Main Criteria for Inclusion

In order to be enrolled in this study, male subjects aged ≥ 45 years or female subjects aged ≥ 55 years of any race who were able to give written informed consent and able to understand and complete a Subject Questionnaire in English had to have at least two of the specified CVD risk factors. To be eligible, subjects must have had no overt cardiovascular disease. Subjects were treated according to routine clinical practice, with the inclusion of an ABI screening test.

Variables

The primary variable was the number and percentage of subjects with lower extremity PAD, defined as an ABI of ≤ 0.90, in the target population.

The secondary variables were:

- The number and percentage of subjects with cardiovascular (CV) risk factors in the target population.
- The number and percentage of subjects on a prescribed treatment (non-pharmacological and pharmacological) for their CV risk factor in the target population.
- The physician approach to patient management.
- Subject characteristics associated with the diagnosis of PAD, including: demographic variables (age, sex, race), CVD risk factor variables (smoking habits, alcohol intake, physical activity, family history of premature CHD, hypertension, dysplipidaemia, increased waist circumference) and lipid management.
- The number and percentage of additional interventions given to subjects following a diagnosis of PAD.

Statistical Methods

Continuous data were described by their mean, standard deviation, median, minimum and maximum. All summaries were presented on all available data. Categorical data were

described by the number and percentage of subjects in each category. All statistical tests were interpreted at the 5% significance level (2-tailed), unless otherwise specified.

Logistic regression was used to determine the subject characteristics that are independently associated with development of PAD using a backwards stepwise logistic regression model. The dependent variable used in the model was a classification of PAD, and independent variables at the start of model development were: gender, age, smoking, diabetes, hypertension, low HDL, high LDL, family history of CHD, elevated waist circumference, physical activity, alcohol intake, use of statins, use of antihypertensive drugs and use of lipid-lowering drugs.

RESULTS:

Twenty-three sites actively participated in this study from all states across Australia. There were 1000 subjects enrolled into the study, 13 subjects were incorrectly enrolled leaving 987 as the evaluable subjects. There were just two major protocol violations in the evaluable subject dataset. There were 106 Investigators, of who 104 recruited patients.

The 987 subjects in the evaluable dataset were an average age of 64 years of age and had an elevated BMI, Table 2. All subjects had three or more risk factors present (including age), but most subjects had 4 or 5 risk factors – the most common being elevated waist circumference (94% of subjects), hypertension (88%) and dyslipidaemia (low HDL or high LDL, 44%). Just 13% of subjects were smokers and 28% had diabetes mellitus, Table 3. The stated levels of physical activity were moderate (49.0%) or active (27.0%), Table 4.

Table 1 Demographics (evaluable subject dataset)

Variable	All subjects n/N (%)
Gender	
Male	474/987 (48.0%)
Female	513/987 (52.0%)
Race	
White	927/987 (93.9%)
Black/ African American	6/987 (0.6%)
Asian	34/987 (3.4%)
Aboriginal / Other *	20/987 (2.0%)
Age group (years)	
45 - 49	33/987 (3.3%)
50 - 59	267/987 (27.1%)
60 - 69	446/987 (45.2%)
≥ 70	241/987 (24.4%)

Table 2 Vital signs (evaluable dataset)

Variable	N (N missing)	Mean (SD)	Median	Min	Max
Age	987 (0)	64.39 (7.96)	64.07	45.36	89.72
Systolic BP (sitting) – average	987 (0)	137.91 (15.94)	138.00	80.00	205.00
Diastolic BP (sitting) – average	987 (0)	79.00 (9.97)	80.00	40.00	114.00
Heart Rate (sitting)	987 (0)	74.80 (10.29)	75.00	47.00	120.00
Weight (kg)	987 (0)	85.94 (18.36)	84.00	40.00	175.00
Height (cm)	987 (0)	167.30 (9.90)	167.00	139.00	196.00
Body Mass Index	987 (0)	30.65 (5.78)	29.86	16.53	68.36
Waist Circumference (cm)	987 (0)	103.31 (13.52)	102.00	66.00	155.00

Table 3 Major risk factors (evaluable dataset)

Variable	All subjects n/N (%95%CI)
Age ≥ 45 (male), or age ≥ 55 (female)	987/987 (100.0%)
Smoking (current or within 12 months)	130/987 (13.2% (11.1,15.3))
Diabetes mellitus	277/987 (28.1% (25.3,30.9))
Hypertension	869/987 (88.0% (86.0,90.1))
Low HDL or high LDL	435/987 (44.1% (41.0,47.2))
Strong family history of CHD	182/987 (18.4% (16.0,20.9))
Elevated waist circumference	931/987 (94.3% (92.9,95.8))
Aboriginal / Torres Strait Islander	4/987 (0.4% (0.0,0.8))
Number of risk factors present	
3 risk factors	354/987 (35.9% (32.9,38.9))
4 risk factors	438/987 (44.4% (41.3,47.5))
5 risk factors	172/987 (17.4% (15.1,19.8))
6 risk factors	20/987 (2.0% (1.1,2.9))
More than 6 risk factors	3/987 (0.3% (0.0,0.6))

Table 4 Lifestyle factors (evaluable dataset)

Variable	All subjects n/N (%)
Physical Activity	
None	236/987 (23.9%)
Moderate	484/987 (49.0%)
Active	266/987 (27.0%)
Missing	1/987 (0.1%)
Alcohol Intake	
None	319/987 (32.3%)
Moderate (up to 2 units daily)	529/987 (53.6%)
Higher intake	138/987 (14.0%)
Missing	1/987 (0.1%)

Of the 987 evaluable subjects, twenty-nine had an ABI <= 0.90 and were diagnosed with PAD, giving a point prevalence of PAD of 2.9% (95% CIs 1.9% - 4.0%), Table 5. There were no significant differences in demographics (Table 6), vital signs (Table 7), lifestyle factors (Table 8) or laboratory values (Table 9) between PAD and the non-PAD populations.

Table 5 Ankle-Brachial Index (evaluable dataset)

Variable	All subjects n/N (% (CI))
PAD (ABI ≤ 0.90)	29/987 (2.9% (1.9, 4.0))
Non-PAD (ABI > 0.90)	958/987 (97.1% (96.0, 98.1))

Table 6 Subject Demographics (PAD vs non-PAD)

Variable	All subjects n/N (%)	PAD n/N (%)	Non-PAD n/N (%)	p-value
Gender				0.1385
Male	474/987 (48.0%)	10/29 (34.5%)	464/958 (48.4%)	
Female	513/987 (52.0%)	19/29 (65.5%)	494/958 (51.6%)	
Race				0.2237*
White	927/987 (93.9%)	27/29 (93.1%)	900/958 (93.9%)	
Black/ African American	6/987 (0.6%)	0/29	6/958 (0.6%)	
Asian	34/987 (3.4%)	0/29	34/958 (3.5%)	
Aboriginal / Other	20/987 (2.0%)	2/29 (6.9%)	18/958 (1.9%)	
Age group				0.3553
45-49	33/987 (3.3%)	1/29 (3.4%)	32/958 (3.3%)	
50-59	267/987 (27.1%)	4/29 (13.8%)	263/958 (27.5%)	
60-69	446/987 (45.2%)	14/29 (48.3%)	432/958 (45.1%)	
>=70	241/987 (24.4%)	10/29 (34.5%)	231/958 (24.1%)	

The p-values were calculated from the Chi-square statistic, except where marked with an asterisk (*) where Fisher's Exact Test was used (small numbers in some cells).

Table 7 Vital signs (PAD vs non-PAD)

All evaluable subjects

Variable	N (N missing)	Mean (SD)	95% CI	Median	Min	Max
Age	987 (0)	64.39 (7.96)	(63.90 , 64.89)	64.07	45.36	89.72
Systolic BP (sitting) - average	987 (0)	137.91 (15.94)	(136.91 , 138.90)	138.00	80.00	205.00
Diastolic BP (sitting) - average	987 (0)	79.00 (9.97)	(78.37 , 79.62)	80.00	40.00	114.00
Heart Rate (sitting)	987 (0)	74.80 (10.29)	(74.16 , 75.45)	75.00	47.00	120.00
Weight (kg)	987 (0)	85.94 (18.36)	(84.79 , 87.09)	84.00	40.00	175.00
Height (cm)	987 (0)	167.30 (9.90)	(166.68 , 167.92)	167.00	139.00	196.00
Body Mass Index	987 (0)	30.65 (5.78)	(30.29 , 31.01)	29.86	16.53	68.36
Waist Circumference (cm)	987 (0)	103.31 (13.52)	(102.46 , 104.15)	102.00	66.00	155.00

PAD Subjects

Variable	N (N missing)	Mean (SD)	95% CI	Median	Min	Max
Age	29 (0)	66.91 (7.33)	(64.12 , 69.70)	68.49	47.95	81.03
Systolic BP (sitting) - average	29 (0)	145.21 (21.00)	(137.22 , 153.20)	145.00	110.00	200.00
Diastolic BP (sitting) - average	29 (0)	79.78 (11.57)	(75.37 , 84.18)	80.00	55.00	105.00
Heart Rate (sitting)	29 (0)	75.24 (11.39)	(70.91 , 79.57)	76.00	55.00	96.00
Weight (kg)	29 (0)	91.17 (28.68)	(80.26 , 102.08)	94.00	40.00	168.00
Height (cm)	29 (0)	165.93 (12.19)	(161.29 , 170.57)	163.00	150.00	188.00
Body Mass Index	29 (0)	32.79 (8.62)	(29.51 , 36.07)	32.56	17.78	51.28
Waist Circumference (cm)	29 (0)	107.28 (19.62)	(99.81 , 114.74)	108.00	68.00	148.00

Non-PAD Subjects

Variable	N (N missing)	Mean (SD)	95% CI	Median	Min	Max
Age	958 (0)	64.32 (7.97)	(63.81 , 64.82)	63.95	45.36	89.72
Systolic BP (sitting) - average	958 (0)	137.69 (15.72)	(136.69 , 138.68)	137.50	80.00	205.00
Diastolic BP (sitting) - average	958 (0)	78.97 (9.92)	(78.34 , 79.60)	80.00	40.00	114.00
Heart Rate (sitting)	958 (0)	74.79 (10.26)	(74.14 , 75.44)	75.00	47.00	120.00
Weight (kg)	958 (0)	85.78 (17.95)	(84.64 , 86.92)	84.00	41.00	175.00
Height (cm)	958 (0)	167.34 (9.83)	(166.71 , 167.96)	167.00	139.00	196.00
Body Mass Index	958 (0)	30.59 (5.66)	(30.23 , 30.95)	29.76	16.53	68.36
Waist Circumference (cm)	958 (0)	103.19 (13.29)	(102.35 , 104.03)	102.00	66.00	155.00

t-tests were used to compare the PAD vs. Non-PAD groups. Differences are calculated as non-PAD minus PAD measures.

Variable	Difference in means	t-statistic	DF	p-value
Age	-2.59	-1.73	985	0.0845
Systolic BP (sitting) - average	-7.52	-1.91	29	0.0658*
Diastolic BP (sitting) - average	-0.80	-0.43	985	0.6689
Heart Rate (sitting)	-0.45	-0.23	985	0.8161
Weight (kg)	-5.39	-1.01	28.7	0.3226*
Height (cm)	1.41	0.75	985	0.4512
Body Mass Index	-2.20	-1.37	28.7	0.1821*
Waist Circumference (cm)	-4.09	-1.11	28.8	0.2745*

* Satterthwaite method used to calculate the p-value (the degrees of freedom were reduced) because the standard deviations for the groups were different

Table 8 Lifestyle factors (PAD vs non-PAD)

Variable	All subjects n/N (%)	PAD n/N (%)	Non-PAD n/N (%)	p-value
Physical Activity				0.4798
None	236/987 (23.9%)	10/29 (34.5%)	226/958 (23.6%)	
Moderate	484/987 (49.0%)	14/29 (48.3%)	470/958 (49.1%)	
Active	266/987 (27.0%)	5/29 (17.2%)	261/958 (27.2%)	
Missing	1/987 (0.1%)	0/29	1/958 (0.1%)	
Alcohol Intake				0.9961
None	319/987 (32.3%)	9/29 (31.0%)	310/958 (32.4%)	
Moderate (up to 2 units daily)	529/987 (53.6%)	16/29 (55.2%)	513/958 (53.5%)	
Higher intake	138/987 (14.0%)	4/29 (13.8%)	134/958 (14.0%)	
Missing	1/987 (0.1%)	0/29	1/958 (0.1%)	

Table 9 Laboratory measures (evaluable dataset)

All evaluable subjects

Variable	N (N missing)	Mean (SD)	Median	Min	Max
Total cholesterol (mmol/L)	987 (0)	5.07 (1.00)	5.00	2.40	8.30
High density lipoprotein cholesterol (mmol/L)	987 (0)	1.38 (0.41)	1.30	0.30	4.30
Low density lipoprotein cholesterol (mmol/L)	975 (12)	2.96 (0.91)	2.90	0.20	6.20
Triglycerides (mmol/L)	987 (0)	1.62 (0.87)	1.40	0.30	8.80
Fasting plasma glucose (mmol/L)	821 (166)	6.15 (1.94)	5.60	0.30	18.50
HbA_{1c} (%)	334 (653)	7.16 (1.41)	6.80	3.00	14.10
C-reactive protein (mg/L)	87 (900)	5.33 (9.19)	3.00	0.40	67.00
Apolipoprotein A-1 (g/L)	1 (986)	1.92 (.)	1.92	1.92	1.92
Apolipoprotein B (g/L)	1 (986)	1.21 (.)	1.21	1.21	1.21

PAD Subjects

Variable	N (N missing)	Mean (SD)	Median	Min	Max
Total cholesterol (mmol/L)	29 (0)	5.11 (1.01)	4.90	3.70	7.40
High density lipoprotein cholesterol (mmol/L)	29 (0)	1.43 (0.52)	1.40	0.30	2.50
Low density lipoprotein cholesterol (mmol/L)	28 (1)	2.89 (0.88)	2.98	0.80	4.70

Triglycerides (mmol/L)	29 (0)	1.68 (1.46)	1.50	0.50	8.80
Fasting plasma glucose (mmol/L)	23 (6)	6.14 (2.42)	5.70	0.30	13.10
HbA_{1c} (%)	11 (18)	7.53 (1.03)	7.90	5.60	9.20
C-reactive protein (mg/L)	1 (28)	0.90 (.)	0.90	0.90	0.90
Apolipoprotein A-1 (g/L)	0 (29)	.	.	.	.
Apolipoprotein B (g/L)	0 (29)	.	.	.	.

Non-PAD Subjects

Variable	N (N missing)	Mean (SD)	Median	Min	Max
Total cholesterol (mmol/L)	958 (0)	5.07 (1.00)	5.00	2.40	8.30
High density lipoprotein cholesterol (mmol/L)	958 (0)	1.38 (0.40)	1.30	0.60	4.30
Low density lipoprotein cholesterol (mmol/L)	947 (11)	2.96 (0.91)	2.90	0.20	6.20
Triglycerides (mmol/L)	958 (0)	1.62 (0.85)	1.40	0.30	7.20
Fasting plasma glucose (mmol/L)	798 (160)	6.15 (1.93)	5.60	3.30	18.50
HbA_{1c} (%)	323 (635)	7.15 (1.42)	6.80	3.00	14.10
C-reactive protein (mg/L)	86 (872)	5.38 (9.24)	3.00	0.40	67.00
Apolipoprotein A-1 (g/L)	1 (957)	1.92 (.)	1.92	1.92	1.92
Apolipoprotein B (g/L)	1 (957)	1.21 (.)	1.21	1.21	1.21

t-tests were used to compare the PAD vs. Non-PAD groups. Differences are calculated as Non-PAD minus PAD measures.

Variable	Difference in means	t-statistic	DF	p-value
Total cholesterol (mmol/L)	-0.04	-0.22	985	0.8228
High density lipoprotein cholesterol (mmol/L)	-0.05	-0.54	29	0.5954*
Low density lipoprotein cholesterol (mmol/L)	0.07	0.41	973	0.6853
Triglycerides (mmol/L)	-0.06	-0.21	28.6	0.8331*
Fasting plasma glucose (mmol/L)	0.01	0.02	819	0.9809
HbA_{1c} (%)	-0.38	-0.88	332	0.3803

* Satterthwaite method used to calculate the p-value (the degrees of freedom were reduced) because the standard deviations for the groups were different. Note that small numbers did not allow calculation of p-values for CRP, Apo-A1, and Apo-B

There were also significant differences in the secondary endpoints between the PAD and non-PAD populations - smoking and hypertension were significantly more likely to be present in PAD subjects than in those with non-PAD, Table 10. In addition, there were significant differences in the cardiovascular risk level, with subjects with PAD having a higher risk than those with non-PAD, Table 11.

Table 10 Major risk factors (PAD vs non-PAD)

Variable	All subjects n/N (%(95%CI))	PAD n/N (%(95%CI))	Non-PAD n/N (%(95%CI))	p-value
Age ≥ 45 (male), or age ≥ 55 (female)	987/987 (100.0%)	29/29 (100.0%)	958/958 (100.0%)	.
Smoking (current or within 12 months)	130/987 (13.2% (11.1,15.3))	9/29 (31.0% (14.2,47.9))	121/958 (12.6% (10.5,14.7))	0.0089*
Diabetes mellitus	277/987 (28.1% (25.3,30.9))	9/29 (31.0% (14.2,47.9))	268/958 (28.0% (25.1,30.8))	0.7179
Hypertension	869/987 (88.0% (86.0,90.1))	29/29 (100.0%)	840/958 (87.7% (85.6,89.8))	0.0397*
Low HDL or high LDL	435/987 (44.1% (41.0,47.2))	14/29 (48.3% (30.1,66.5))	421/958 (43.9% (40.8,47.1))	0.6436
Strong family history of CHD	182/987 (18.4% (16.0,20.9))	3/29 (10.3% (0.0,21.4))	179/958 (18.7% (16.2,21.2))	0.5121
Elevated waist circumference	931/987 (94.3% (92.9,95.8))	27/29 (93.1% (83.9,100.0))	904/958 (94.4% (92.9,95.8))	0.6777*
Aboriginal / Torres Strait Islander	4/987 (0.4% (0.0,0.8))	0/29	4/958 (0.4% (0.0,0.8))	1.0*
Number of risk factors present				0.0534
3 risk factors	354/987 (35.9% (32.9,38.9))	7/29 (24.1% (8.6,39.7))	347/958 (36.2% (33.2,39.3))	
4 risk factors	438/987 (44.4% (41.3,47.5))	11/29 (37.9% (20.3,55.6))	427/958 (44.6% (41.4,47.7))	
5 risk factors	172/987 (17.4% (15.1,19.8))	11/29 (37.9% (20.3,55.6))	161/958 (16.8% (14.4,19.2))	
6 risk factors	20/987 (2.0% (1.1,2.9))	0/29	20/958 (2.1% (1.2,3.0))	
More than 6 risk factors	3/987 (0.3% (0.0,0.6))	0/29	3/958 (0.3% (0.0,0.7))	

p-values calculated from the Chi-square statistic, except where marked with an asterisk (*) where Fisher's Exact Test was used

Table 11 New Zealand Cardiovascular Risk (all risk groups)

Variable	All subjects n/N (% (95%CI))	PAD n/N (% (95%CI))	Non-PAD n/N (% (95%CI))	p-value
5 year cardiovascular disease risk				0.0161*
Missing (some component missing)	33/987 (3.3% (2.2,4.5))	1/29 (3.4% (0.0,10.1))	32/958 (3.3% (2.2,4.5))	
Mild <2.5%	48/987 (4.9% (3.5,6.2))	1/29 (3.4% (0.0,10.1))	47/958 (4.9% (3.5,6.3))	
Mild 2.5-5%	251/987 (25.4% (22.7,28.1))	5/29 (17.2% (3.5,31.0))	246/958 (25.7% (22.9,28.4))	
Mild 5-10%	372/987 (37.7% (34.7,40.7))	5/29 (17.2% (3.5,31.0))	367/958 (38.3% (35.2,41.4))	
Moderate 10-15%	166/987 (16.8% (14.5,19.2))	11/29 (37.9% (20.3,55.6))	155/958 (16.2% (13.8,18.5))	
High 15-20%	71/987 (7.2% (5.6,8.8))	3/29 (10.3% (0.0,21.4))	68/958 (7.1% (5.5,8.7))	
Very high 20-25%	36/987 (3.6% (2.5,4.8))	3/29 (10.3% (0.0,21.4))	33/958 (3.4% (2.3,4.6))	
Very high 25-30%	9/987 (0.9% (0.3,1.5))	0/29	9/958 (0.9% (0.3,1.6))	
Very high >30%	1/987 (0.1% (0.0,0.3))	0/29	1/958 (0.1% (0.0,0.3))	

* The p-value was calculated from the Fisher's Exact test because of the small numbers in some cells, and excludes the subjects with missing data.

Note that according to the SAP, this table was to be recalculated excluding the Aboriginal and Torres Strait Islander subjects However, this was not done, as the number of these subjects was very small (n=4), and would not affect the results above. Of these 4 subjects, one was in the Mild (2.5-5%) risk group, and the remaining 3 subjects were in the Moderate (10-15%) group. None of them were classified as having PAD.

There were significant differences in the proportion of subjects taking statin medications and antihypertensive agents on entry and during the study – those with PAD were more likely to be taking statin and antihypertensive medications than those without PAD (Table 12) and the duration of antihypertensive therapy was significantly longer with those with PAD than without PAD, Table 13. A logistic regression model showed that subjects with PAD are more likely to be taking antihypertensive medication, have a BMI $\geq$ 33 and be current smokers.

Table 12 Lipid lowering agent and antihypertensive agent use on entry to the study (excluding drugs commenced on or after the date of visit)

Variable	All subjects n/N (%)	PAD n/N (%)	Non-PAD n/N (%)	p-value
Statin	491/987 (49.7%)	20/29 (69.0%)	471/958 (49.2%)	0.0356
Lipid lowering agent	577/987 (58.5%)	22/29 (75.9%)	555/958 (57.9%)	0.0536
Antihypertensive agent	759/987 (76.9%)	27/29 (93.1%)	732/958 (76.4%)	0.0356

Table 13 Duration of medications taken on entry to the study (excluding drugs commenced on or after the visit date)

All evaluable subjects

Variable	N (N missing)	Mean (SD)	Median	Min	Max
Statin	490 (459)	71.72 (167.08)	33.65	0.10	1316.8
Lipid lowering	576 (373)	71.83 (164.62)	33.35	0.10	1316.8
Antihypertensive medication	757 (192)	88.36 (177.62)	52.90	0.10	1316.8

PAD Subjects

Variable	N (N missing)	Mean (SD)	Median	Min	Max
Statin	20 (9)	103.36 (287.76)	24.80	1.10	1314.2
Lipid lowering	22 (7)	95.64 (274.89)	24.80	1.10	1314.2
Antihypertensive medication	27 (2)	47.41 (46.80)	20.80	1.00	128.50

Non-PAD Subjects

Variable	N (N missing)	Mean (SD)	Median	Min	Max
Statin	470 (450)	70.38 (160.34)	35.70	0.10	1316.8
Lipid lowering	554 (366)	70.89 (159.01)	33.85	0.10	1316.8
Antihypertensive medication	730 (190)	89.87 (180.49)	53.90	0.10	1316.8

t-tests were used to compare the PAD vs. Non-PAD groups. Differences are calculated as Non-PAD minus PAD measures.

Variable	Difference in means	t-statistic	DF	p-value (t-test)	p-value (Wilcoxon)
Statin	-33.0	-0.51	19.5	0.6163*	0.4374
Lipid lowering	-24.8	-0.42	21.6	0.6790	0.2118
Antihypertensive medication	42.5	3.79	61.8	0.0003	0.0303

* Satterthwaite method used to calculate the p-value (the degrees of freedom were reduced) because the standard deviations for the groups were different. The extra p-value column is calculated from the Wilcoxon 2-sample (non-parametric) test, because the data appeared to rather heavily skewed (non-Normal).

Most GPs use guidelines for the management of risk factors within the target population and GPs reported that they are routinely measuring lipid levels in assessing patients' CV risk. Participation in the study resulted in some changes to GP behaviour - the GPs stated that they would review the lipid profile of this patient group less often after the study than before, although once a patient reaches their target cholesterol level, the time in months until the first review of lipid profile did not change. However, GPs would use ABI for a number of different types of patients more often following this study.

The GPs stated that they generally inform their patients of the impact that the risk factors have on their prognosis when patients are first assessed for their CV risk. This was reinforced by the subject responses - most subjects report knowledge about the lipid levels and their relevant targets from their GPs. There were no significant differences between subject groups in the frequency of receiving information, and the quality of that information, from GPs about the risk of CVD and lipid management

There were no significant differences between subject groups in their beliefs about CVD risk factors, although more subjects with PAD believed that smoking did not increase risk of CVD than those without PAD – this may have failed to reach significance due to the small number of subjects with PAD.