STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: None
ACTIVE INGREDIENT: None

Study No: NIS-CCH-DUM-2008/2 (NCT00848380)
This observational study is a retrospective collection of data regarding cardiovascular risk factors of patients with cardiovascular diseases in usual daily practice in Switzerland

Developmental Phase: Observational Study (NIS)
Study Completion Date: 23-Dec-2009
Date of Report: 02-Dec-2010

OBJECTIVES:

The primary objective of this observational study was an evaluation of the development of the risk profile of cardiovascular patients with simultaneous treatment of hypertension and hyperlipidemia in clinical daily practice in Switzerland.

METHODS:

The survey was retrospective with visit 1 at day 0 when the physician selected the patient. The data available in the patient dossier 6 to 9 months before visit 1 were considered visit 2, and the data available in the patient dossier 9 to 15 months before visit 1 were considered visit 3.

The inclusion criteria for the patients were patients with known cardiovascular risk factors receiving:

- hypertension treatment in addition to cholesterol lowering treatment in the observation period
- cholesterol lowering treatment in addition to hypertension treatment in the observation period
- new cholesterol lowering and/or hypertension treatment in the observation period

The exclusion criteria for the patients were patients with not fulfilling any of the inclusion criteria
No simple size calculation was performed.

CRITERIA FOR EVALUATION (MAIN VARIABLES)
The AGLA score for cardiovascular risk factors and Swiss Society Hypertension (SSH) target values for hypertension (BP <140/90 mmHg; diabetes BP <130/80 mmHg) were the primary variables.

The AGLA risk score was based on following variables: gender, age, BMI, family anamnesis, smoking, level of hypertension, lipid profile: elevated total cholesterol, low HDL, elevated LDL, elevated triglycerides, systolic BP. Missing values were not replaced and the corresponding score not computed.

Parameters

Following parameter could be provided by the physician when available in the patient dossier:

Visit 1

- Demographic data; anamnesis with CV risk factors (smoking, diabetes, family anamnesis and hyperlipidemia), primary or secondary prevention, current hypertension and hyperlipidemia treatment, blood pressure, cholesterol (total, HDL, LDL) and triglycerides.

Visits 2 and 3

- Current and new hypertension and hyperlipidemia treatment, blood pressure, cholesterol (total, HDL, LDL) and triglycerides.

Stratification

Following *a posteriori* stratifications were performed by:

- Three Swiss language regions: SG: German; SF: French; IS: Italian
- Prevention type: primary, secondary
- Treatment at the first available visit: hypertension treatment, cholesterol lowering treatment, hypertension treatment + cholesterol lowering treatment

The survey was not formally designed for strata comparison (no randomization in patient segment/strata). Therefore, when performed, comparisons were only indicative.

Population Analysis Sets:

Definition of the target population

A total of 1753 questionnaires provided by 193 participating physicians were available and were entered in the database. The distribution by region is described in **Table 1**.

Table 1 Patient distribution by region and physician

Region	GS	FS	IS	Total
Patient	877	637	239	1753
Patient % region	50%	36.3%	13.6%	100%
Physicians	98	71	24	193
Physician % region	50.8%	36.8%	12.4%	100%

Of the available 1753 questionnaires, 1492 (85.1%) were fulfilling the inclusion criteria. 261 were not included in the analysis. Table 2 shows the number of included and excluded patients by region. In 231 cases, no hypertension treatment & lipid treatment could be found before visit 1. In 28 cases, the sequence of visits was not evaluable or prospective. In two cases, both reasons applied.

Table 2 Patient distribution by region and inclusion

Included

Region	GS	FS	IS	Total
Patient	710	569	213	1492
Patient % region	47.6%	38.1%	14.3%	100%
Physicians	97	71	24	192
Physician % region	50.5%	37.0%	12.5%	100%

Excluded

Region	GS	FS	IS	Total
Patient	167	68	26	261
Patient % region	64.0%	26.1%	10.0%	100%
Physicians	57	36	12	105
Physician % region	54.3%	34.3%	11.4%	100%

RESULTS:

Statistical Analysis Results

Descriptive Analysis:

The gender distribution by region is shown in Table 3. Overall, 62.8% of the included patients were males for 35.9% of females and 1.3% with unreported gender.

Table 3 Gender distribution by region

Gender * Region Crosstabulation

			Region			
			DS	FS	IS	**Total**
Gender	male	Count	454	342	141	**937**
		Row %	48.5%	36.5%	15.0%	**100.0%**
		Column %	63.9%	60.1%	66.2%	**62.8%**
	female	Count	248	217	71	**536**
		Row %	46.3%	40.5%	13.2%	**100.0%**
		Column %	34.9%	38.1%	33.3%	**35.9%**
	unk.	Count	8	10	1	**19**
		Row %	42.1%	52.6%	5.3%	**100.0%**
		Column %	1.1%	1.8%	.5%	**1.3%**
Total		Count	**710**	**569**	**213**	**1492**
		Row %	**47.6%**	**38.1%**	**14.3%**	**100.0%**
		Column %	**100.0%**	**100.0%**	**100.0%**	**100.0%**

The mean age at visit 1 of the male patients was 63.3 ± 10.5 years (28 – 97) and 67.0 ± 10.7 years (35 – 94) for females (Table 4). The overall mean age was 64.7 ± 10.7 years (28 – 97). Irrespective of region, males were significantly younger, taller and heavier than females. Irrespective of gender, no clear difference in age, weight and height was found between regions.

Table 4 Demographic data by region

Case Summaries

Gender: Total

Region		Year of birth	Year of v1	Age at v1	Height (cm) v1	Weight (kg) v1	BMI at v1
DS	N	705	708	704	708	704	702
	Mean	1943.99	2009.00	65.006	169.73	81.75	28.326
	Median	1944.00	2009.00	65.000	170.00	81.00	27.700
	Std. Deviation	10.881	.084	10.8910	8.904	15.087	4.5392
	Minimum	1912	2007	30.0	146	49	18.8
	Maximum	1979	2009	97.0	193	160	48.3
FS	N	567	569	567	565	559	555
	Mean	1944.20	2008.98	64.776	169.06	81.77	28.529
	Median	1944.00	2009.00	65.000	170.00	80.00	27.739
	Std. Deviation	10.803	.138	10.8049	9.030	15.606	4.7322
	Minimum	1918	2008	28.0	146	45	18.6
	Maximum	1981	2009	91.0	193	144	56.3
IS	N	212	212	211	212	212	211
	Mean	1945.70	2008.97	63.251	169.10	81.25	28.436
	Median	1945.00	2009.00	64.000	170.00	79.50	27.636
	Std. Deviation	9.866	.179	9.9023	8.550	14.984	4.7783
	Minimum	1923	2008	37.0	148	52	17.6
	Maximum	1972	2009	86.0	190	134	43.8
Total	N	1484	1489	1482	1485	1475	1468
	Mean	1944.31	2008.99	64.668	169.39	81.68	28.419
	Median	1944.00	2009.00	65.000	170.00	80.00	27.701
	Std. Deviation	10.720	.124	10.7317	8.903	15.262	4.6454
	Minimum	1912	2007	28.0	146	45	17.6
	Maximum	1981	2009	97.0	193	160	56.3

At visit 1, mean weight was 81.7 ± 15.3 kg (45-160) and mean BMI 28.4 ± 4.6 kg/m^2 (17.6-56.3). At visit 2, mean weight was 82.1 ± 15.5 kg (45-147) and mean BMI 28.6 ± 4.7 kg/m^2 (18-56.7). At visit 3, mean weight was 82.6 ± 15.8 kg (46-160) and mean BMI 28.7 ± 4.9 kg/m^2 (17.9-56.9).

Prevention status

The physician could check whether the patient had primary or secondary prevention. In 7 cases, both primary and secondary prevention was checked. Primary prevention was reported for 942 (63.1%) of the patients and secondary prevention for 483 (32.4%). The prevention was unknown for 61 (4.1%) patients.

Female patients had more primary prevention (70.5%) compared to male patients (58.8%), and conversely male patients more secondary prevention (36.9%) compared to female patients (25%). The detail by gender is shown in Table 5.

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Table 5 Prevention by gender

Crosstab

			Gender			Total
			male	female	unk.	
Prevention	primary prevention	Count	551	378	13	942
		% within Prevention	58.5%	40.1%	1.4%	100.0%
		% within Gender	58.8%	70.5%	68.4%	63.1%
	secondary prevention	Count	346	134	3	483
		% within Prevention	71.6%	27.7%	.6%	100.0%
		% within Gender	36.9%	25.0%	15.8%	32.4%
	I+II prevent.	Count	5	1	0	6
		% within Prevention	83.3%	16.7%	.0%	100.0%
		% within Gender	.5%	.2%	.0%	.4%
	unk.	Count	35	23	3	61
		% within Prevention	57.4%	37.7%	4.9%	100.0%
		% within Gender	3.7%	4.3%	15.8%	4.1%
Total		Count	937	536	19	1492
		% within Prevention	62.8%	35.9%	1.3%	100.0%
		% within Gender	100.0%	100.0%	100.0%	100.0%

Table 6 shows that the figures by region are different. The proportion of patients with primary prevention was 63.1% ranging between 59.2% in IS and 64.5% in FS. The proportion of patients with secondary prevention was 32.4% ranging between 31.3% in FS and 33.8% in IS.

Table 6 Prevention by region

Crosstab

			Region			Total
			DS	FS	IS	
Prevention	primary prevention	Count	449	367	126	942
		% within Prevention	47.7%	39.0%	13.4%	100.0%
		% within Region	63.2%	64.5%	59.2%	63.1%
	secondary prevention	Count	233	178	72	483
		% within Prevention	48.2%	36.9%	14.9%	100.0%
		% within Region	32.8%	31.3%	33.8%	32.4%
	I+II prevent.	Count	2	0	4	6
		% within Prevention	33.3%	.0%	66.7%	100.0%
		% within Region	.3%	.0%	1.9%	.4%
	unk.	Count	26	24	11	61
		% within Prevention	42.6%	39.3%	18.0%	100.0%
		% within Region	3.7%	4.2%	5.2%	4.1%
Total		Count	710	569	213	1492
		% within Prevention	47.6%	38.1%	14.3%	100.0%
		% within Region	100.0%	100.0%	100.0%	100.0%

Risk factors

Risk factor - smoking

As shown in Table 7, the number of smoking patients at visit 1 was 421 (28.2%) including 0.7% of ex-smokers that the physician considered smokers. The number of non-smokers was

1055 (70.7%) including 1.0% of ex-smokers that the physician considered non-smokers. The smoking status was unknown in 0.7% or not reported in 0.4% of the cases.

The proportion of male smokers was 29.8% for 25.2% of females. The proportion of males ex-smoker was 2.4% compared to 0.6% for females. The proportion of smokers was 24.9% in DS, 29% in FS and 37.1% in IS.

Table 7 Risk factors by gender and region

		Gender									Group Total	
		male				female				unk.		
		Count	Row %	Col %	Layer %	Count	Row %	Col %	Layer %	Count	Count	Col %
Smoking v1	yes	270	65.7%	28.8%	18.1%	134	32.6%	25.0%	9.0%	7	411	27.5%
	yes (ex-smoker)	9	90.0%	1.0%	.6%	1	10.0%	.2%	.1%		10	.7%
	no	636	61.2%	67.9%	42.6%	393	37.8%	73.3%	26.3%	11	1040	69.7%
	no (ex-smoker)	13	86.7%	1.4%	.9%	2	13.3%	.4%	.1%		15	1.0%
	unknown	5	50.0%	.5%	.3%	5	50.0%	.9%	.3%		10	.7%
	no answer	4	66.7%	.4%	.3%	1	16.7%	.2%	.1%	1	6	.4%
Group Total		937	62.8%	100.0%	62.8%	536	35.9%	100.0%	35.9%	19	1492	100.0%
Smoking (binary)	yes	279	66.3%	29.8%	18.7%	135	32.1%	25.2%	9.0%	7	421	28.2%
	no	649	61.5%	69.3%	43.5%	395	37.4%	73.7%	26.5%	11	1055	70.7%
	no answer	9	56.3%	1.0%	.6%	6	37.5%	1.1%	.4%	1	16	1.1%
Group Total		937	62.8%	100.0%	62.8%	536	35.9%	100.0%	35.9%	19	1492	100.0%
Diabetes mellitus	yes	334	62.1%	35.6%	22.4%	197	36.6%	36.8%	13.2%	7	538	36.1%
	no	588	63.0%	62.8%	39.4%	333	35.7%	62.1%	22.3%	12	933	62.5%
	unk.	3	60.0%	.3%	.2%	2	40.0%	.4%	.1%		5	.3%
	no answer	12	75.0%	1.3%	.8%	4	25.0%	.7%	.3%		16	1.1%
Group Total		937	62.8%	100.0%	62.8%	536	35.9%	100.0%	35.9%	19	1492	100.0%
Family anamnesis positive	yes	398	65.1%	42.5%	26.7%	208	34.0%	38.8%	13.9%	5	611	41.0%
	no	406	62.5%	43.3%	27.2%	234	36.0%	43.7%	15.7%	10	650	43.6%
	unk.	123	56.4%	13.1%	8.2%	91	41.7%	17.0%	6.1%	4	218	14.6%
	no answer	10	76.9%	1.1%	.7%	3	23.1%	.6%	.2%		13	.9%
Group Total		937	62.8%	100.0%	62.8%	536	35.9%	100.0%	35.9%	19	1492	100.0%
Family anamnesis positive: M1/CI in 1st degre relative	<55 yrs	68	70.1%	7.3%	4.6%	28	28.9%	5.2%	1.9%	1	97	6.5%
	<65 yrs	168	62.7%	17.9%	11.3%	100	37.3%	18.7%	6.7%		268	18.0%
	unk.	701	62.2%	74.8%	47.0%	408	36.2%	76.1%	27.3%	18	1127	75.5%
Group Total		937	62.8%	100.0%	62.8%	536	35.9%	100.0%	35.9%	19	1492	100.0%
Familiar hyperlipidemia	yes	284	67.5%	30.3%	19.0%	133	31.6%	24.8%	8.9%	4	421	28.2%
	no	373	60.3%	39.8%	25.0%	236	38.1%	44.0%	15.8%	10	619	41.5%
	unk.	269	62.3%	28.7%	18.0%	158	36.6%	29.5%	10.6%	5	432	29.0%
	no answer	11	55.0%	1.2%	.7%	9	45.0%	1.7%	.6%		20	1.3%
Group Total		937	62.8%	100.0%	62.8%	536	35.9%	100.0%	35.9%	19	1492	100.0%

		Region												Group Total		
		DS				FS				IS						
		Count	Row %	Col %	Layer %	Count	Row %	Col %	Layer %	Count	Row %	Col %	Layer %	Count	Col %	Layer %
Smoking v1	yes	171	41.6%	24.1%	11.5%	161	39.2%	28.3%	10.8%	79	19.2%	37.1%	5.3%	411	27.5%	27.5%
	yes (ex-smoker)	6	60.0%	.8%	.4%	4	40.0%	.7%	.3%					10	.7%	.7%
	no	516	49.6%	72.7%	34.6%	394	37.9%	69.2%	26.4%	130	12.5%	61.0%	8.7%	1040	69.7%	69.7%
	no (ex-smoker)	9	60.0%	1.3%	.6%	6	40.0%	1.1%	.4%					15	1.0%	1.0%
	unknown	5	50.0%	.7%	.3%	1	10.0%	.2%	.1%	4	40.0%	1.9%	.3%	10	.7%	.7%
	no answer	3	50.0%	.4%	.2%	3	50.0%	.5%	.2%					6	.4%	.4%
Group Total		710	47.6%	100.0%	47.6%	569	38.1%	100.0%	38.1%	213	14.3%	100.0%	14.3%	1492	100.0%	100.0%
Smoking (binary)	yes	177	42.0%	24.9%	11.9%	165	39.2%	29.0%	11.1%	79	18.8%	37.1%	5.3%	421	28.2%	28.2%
	no	525	49.8%	73.9%	35.2%	400	37.9%	70.3%	26.8%	130	12.3%	61.0%	8.7%	1055	70.7%	70.7%
	no answer	8	50.0%	1.1%	.5%	4	25.0%	.7%	.3%	4	25.0%	1.9%	.3%	16	1.1%	1.1%
Group Total		710	47.6%	100.0%	47.6%	569	38.1%	100.0%	38.1%	213	14.3%	100.0%	14.3%	1492	100.0%	100.0%
Diabetes mellitus	yes	226	42.0%	31.8%	15.1%	231	42.9%	40.6%	15.5%	81	15.1%	38.0%	5.4%	538	36.1%	36.1%
	no	473	50.7%	66.6%	31.7%	331	35.5%	58.2%	22.2%	129	13.8%	60.6%	8.6%	933	62.5%	62.5%
	unk.	3	60.0%	.4%	.2%	1	20.0%	.2%	.1%	1	20.0%	.5%	.1%	5	.3%	.3%
	no answer	8	50.0%	1.1%	.5%	6	37.5%	1.1%	.4%	2	12.5%	.9%	.1%	16	1.1%	1.1%
Group Total		710	47.6%	100.0%	47.6%	569	38.1%	100.0%	38.1%	213	14.3%	100.0%	14.3%	1492	100.0%	100.0%
Family anamnesis positive	yes	284	46.5%	40.0%	19.0%	230	37.6%	40.4%	15.4%	97	15.9%	45.5%	6.5%	611	41.0%	41.0%
	no	292	44.9%	41.1%	19.6%	267	41.1%	46.9%	17.9%	91	14.0%	42.7%	6.1%	650	43.6%	43.6%
	unk.	129	59.2%	18.2%	8.6%	68	31.2%	12.0%	4.6%	21	9.6%	9.9%	1.4%	218	14.6%	14.6%
	no answer	5	38.5%	.7%	.3%	4	30.8%	.7%	.3%	4	30.8%	1.9%	.3%	13	.9%	.9%
Group Total		710	47.6%	100.0%	47.6%	569	38.1%	100.0%	38.1%	213	14.3%	100.0%	14.3%	1492	100.0%	100.0%
Family anamnesis positive: M1/CI in 1st degre relative	<55 yrs	41	42.3%	5.8%	2.7%	45	46.4%	7.9%	3.0%	11	11.3%	5.2%	.7%	97	6.5%	6.5%
	<65 yrs	111	41.4%	15.6%	7.4%	116	43.3%	20.4%	7.8%	41	15.3%	19.2%	2.7%	268	18.0%	18.0%
	unk.	558	49.5%	78.6%	37.4%	408	36.2%	71.7%	27.3%	161	14.3%	75.6%	10.8%	1127	75.5%	75.5%
Group Total		710	47.6%	100.0%	47.6%	569	38.1%	100.0%	38.1%	213	14.3%	100.0%	14.3%	1492	100.0%	100.0%
Familiar hyperlipidemia	yes	171	40.6%	24.1%	11.5%	173	41.1%	30.4%	11.6%	77	18.3%	36.2%	5.2%	421	28.2%	28.2%
	no	258	41.7%	36.3%	17.3%	271	43.8%	47.6%	18.2%	90	14.5%	42.3%	6.0%	619	41.5%	41.5%
	unk.	268	62.0%	37.7%	18.0%	120	27.8%	21.1%	8.0%	44	10.2%	20.7%	2.9%	432	29.0%	29.0%
	no answer	13	65.0%	1.8%	.9%	5	25.0%	.9%	.3%	2	10.0%	.9%	.1%	20	1.3%	1.3%
Group Total		710	47.6%	100.0%	47.6%	569	38.1%	100.0%	38.1%	213	14.3%	100.0%	14.3%	1492	100.0%	100.0%

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Laboratory data and blood pressure

The laboratory statistics displayed for all patients are only descriptive since not weighted for treatment and baseline (**Table 8**, excluded = missing data).

Table 8 Lab values at visit 1

Case Processing Summary

	Cases					
	Included		Excluded		Total	
	N	Percent	N	Percent	N	Percent
BP systolic v1 (mmHg) * Gender * Region	1482	99.3%	10	.7%	1492	100.0%
BP diastolic v1 (mmHg) * Gender * Region	1480	99.2%	12	.8%	1492	100.0%
Cholesterol total (mmol/l) v1 * Gender * Region	1358	91.0%	134	9.0%	1492	100.0%
Cholesterol HDL (mmol/l) v1 * Gender * Region	1254	84.0%	238	16.0%	1492	100.0%
Cholesterol LDL (mmol/l) v1 * Gender * Region	1159	77.7%	333	22.3%	1492	100.0%
Triglyceride (mmol/l) v1 * Gender * Region	1292	86.6%	200	13.4%	1492	100.0%

Lab values at visit 1

Region: Total

Gender		BP systolic v1 (mmHg)	BP diastolic v1 (mmHg)	Cholesterol total (mmol/l) v1	Cholesterol HDL (mmol/l) v1	Cholesterol LDL (mmol/l) v1	Triglyceride (mmol/l) v1
male	N	930	928	855	799	736	819
	Mean	134.47	81.20	4.6795	1.2753	2.6084	1.8997
	Median	132.00	80.00	4.6900	1.2000	2.5350	1.6500
	Std. Deviation	13.748	8.803	.98848	.41567	.87623	1.17464
	Minimum	100	50	2.26	.40	.15	.25
	Maximum	209	130	8.26	4.20	6.75	10.00
female	N	533	533	487	440	410	458
	Mean	135.95	80.54	4.9343	1.4500	2.7357	1.7598
	Median	135.00	80.00	4.8000	1.4000	2.6550	1.6000
	Std. Deviation	13.129	8.229	.93615	.47561	.83500	.88527
	Minimum	90	50	1.29	.26	.70	.28
	Maximum	195	110	8.10	5.65	5.60	6.30
unk.	N	19	19	16	15	13	15
	Mean	130.16	81.95	5.3013	1.4347	3.1400	2.2640
	Median	130.00	80.00	5.2150	1.4600	3.0900	1.5000
	Std. Deviation	9.275	9.560	.98574	.27116	.88963	2.64339
	Minimum	115	69	3.04	.80	1.20	.63
	Maximum	150	110	7.30	1.80	4.27	11.40
Total	N	1482	1480	1358	1254	1159	1292
	Mean	134.95	80.97	4.7782	1.3385	2.6594	1.8543
	Median	134.00	80.00	4.7900	1.2500	2.6000	1.6200
	Std. Deviation	13.503	8.611	.97859	.44400	.86492	1.11080
	Minimum	90	50	1.29	.26	.15	.25
	Maximum	209	130	8.26	5.65	6.75	11.40

Treatment data

Drugs for the treatment of hypertension were the first prescribed (36.7%), than LIPID lowering drug (12.2%) followed by a combination of antihypertensive and lipid lowering drugs (51.1%).

Antihypertensive drugs (HTA)

At visit 1, as per definition, all patients had antihypertensive treatment. Table **9** shows that 59.1% of the patients had treatment with one drug class, 29.3% with two drug classes.

Table 9 Number of antihypertensive treatment per patient at visit 1

Crosstab

			Gender			Total
			male	female	unk.	
HTA drug at v1 count	1	Count	532	337	13	882
		% within HTA drug at v1 count	60.3%	38.2%	1.5%	100.0%
		% within Gender	56.8%	62.9%	68.4%	59.1%
	2	Count	294	140	3	437
		% within HTA drug at v1 count	67.3%	32.0%	.7%	100.0%
		% within Gender	31.4%	26.1%	15.8%	29.3%
	3	Count	93	44	3	140
		% within HTA drug at v1 count	66.4%	31.4%	2.1%	100.0%
		% within Gender	9.9%	8.2%	15.8%	9.4%
	4	Count	15	13	0	28
		% within HTA drug at v1 count	53.6%	46.4%	.0%	100.0%
		% within Gender	1.6%	2.4%	.0%	1.9%
	5	Count	3	2	0	5
		% within HTA drug at v1 count	60.0%	40.0%	.0%	100.0%
		% within Gender	.3%	.4%	.0%	.3%
Total		Count	937	536	19	1492
		% within HTA drug at v1 count	62.8%	35.9%	1.3%	100.0%
		% within Gender	100.0%	100.0%	100.0%	100.0%

The most frequent treatment was a drug combination prescribed to 40.8% of the patients, followed by beta-blockers (32.6%) and Angiotensin II inhibitors (28.8%) (Table 10).

Table 10 Number of patients by antihypertensive drug classes at visit 1

HTA treatments at visit1

		Region												Table Total		
		DS				FS				IS						
		Count	Row %	Col %	Layer %	Count	Row %	Col %	Layer %	Count	Row %	Col %	Layer %	Count	Col %	Layer %
Angiotensin II: yes v1	no	545	51.3%	76.8%	36.5%	366	34.5%	64.3%	24.5%	151	14.2%	70.9%	10.1%	1062	71.2%	71.2%
	yes	165	38.4%	23.2%	11.1%	203	47.2%	35.7%	13.6%	62	14.4%	29.1%	4.2%	430	28.8%	28.8%
Group Total		710	47.6%	100.0%	47.6%	569	38.1%	100.0%	38.1%	213	14.3%	100.0%	14.3%	1492	100.0%	100.0%
ACE inhibitor: yes v1	no	548	45.1%	77.2%	36.7%	502	41.3%	88.2%	33.6%	166	13.7%	77.9%	11.1%	1216	81.5%	81.5%
	yes	162	58.7%	22.8%	10.9%	67	24.3%	11.8%	4.5%	47	17.0%	22.1%	3.2%	276	18.5%	18.5%
Group Total		710	47.6%	100.0%	47.6%	569	38.1%	100.0%	38.1%	213	14.3%	100.0%	14.3%	1492	100.0%	100.0%
Calcium antagonist: yes v1	no	589	48.7%	83.0%	39.5%	454	37.6%	79.8%	30.4%	166	13.7%	77.9%	11.1%	1209	81.0%	81.0%
	yes	121	42.8%	17.0%	8.1%	115	40.6%	20.2%	7.7%	47	16.6%	22.1%	3.2%	283	19.0%	19.0%
Group Total		710	47.6%	100.0%	47.6%	569	38.1%	100.0%	38.1%	213	14.3%	100.0%	14.3%	1492	100.0%	100.0%
Beta Blocker: yes v1	no	445	44.2%	62.7%	29.8%	423	42.0%	74.3%	28.4%	138	13.7%	64.8%	9.2%	1006	67.4%	67.4%
	yes	265	54.5%	37.3%	17.8%	146	30.0%	25.7%	9.8%	75	15.4%	35.2%	5.0%	486	32.6%	32.6%
Group Total		710	47.6%	100.0%	47.6%	569	38.1%	100.0%	38.1%	213	14.3%	100.0%	14.3%	1492	100.0%	100.0%
Diuretic: yes v1	no	620	47.3%	87.3%	41.6%	492	37.6%	86.5%	33.0%	198	15.1%	93.0%	13.3%	1310	87.8%	87.8%
	yes	90	49.5%	12.7%	6.0%	77	42.3%	13.5%	5.2%	15	8.2%	7.0%	1.0%	182	12.2%	12.2%
Group Total		710	47.6%	100.0%	47.6%	569	38.1%	100.0%	38.1%	213	14.3%	100.0%	14.3%	1492	100.0%	100.0%
Combination HTA drug: yes v1	no	430	48.7%	60.6%	28.8%	314	35.6%	55.2%	21.0%	139	15.7%	65.3%	9.3%	883	59.2%	59.2%
	yes	280	46.0%	39.4%	18.8%	255	41.9%	44.8%	17.1%	74	12.2%	34.7%	5.0%	609	40.8%	40.8%
Group Total		710	47.6%	100.0%	47.6%	569	38.1%	100.0%	38.1%	213	14.3%	100.0%	14.3%	1492	100.0%	100.0%
Other HTA drug: yes v1	no	688	47.6%	96.9%	46.1%	547	37.9%	96.1%	36.7%	210	14.5%	98.6%	14.1%	1445	96.8%	96.8%
	yes	22	46.8%	3.1%	1.5%	22	46.8%	3.9%	1.5%	3	6.4%	1.4%	.2%	47	3.2%	3.2%
Group Total		710	47.6%	100.0%	47.6%	569	38.1%	100.0%	38.1%	213	14.3%	100.0%	14.3%	1492	100.0%	100.0%
Table Total		710	47.6%	100.0%	47.6%	569	38.1%	100.0%	38.1%	213	14.3%	100.0%	14.3%	1492	100.0%	100.0%

Lipid lowering drugs (LIPID)

At visit 1, as per definition, all patients had a lipid lowering drug. Of the included 1492 patients, 96.9% received only one lipid lowering drug, 3% two and 1 patient 3 lipid lowering drugs. As shown in Table 11, statins were prescribed to 91.3% of the patients. Of the 104 patients with a “lipid combination” 98 received Inegy and 6 Caduet.

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Table 11 Number of patients by lipid drug classes at visit 1

Lipid treatments at visit1

		Region												Table Total	
		DS				FS				IS					
		Count	Row %	Col %	Layer %	Count	Row %	Col %	Layer %	Count	Row %	Col %	Layer %	Count	Col %
Statin: yes v1	no	53	40.8%	7.5%	3.6%	58	44.6%	10.2%	3.9%	19	14.6%	8.9%	1.3%	130	8.7%
	yes	657	48.2%	92.5%	44.0%	511	37.5%	89.8%	34.2%	194	14.2%	91.1%	13.0%	1362	91.3%
Group Total		710	47.6%	100.0%	47.6%	569	38.1%	100.0%	38.1%	213	14.3%	100.0%	14.3%	1492	100.0%
Fibrate: yes v1	no	704	47.8%	99.2%	47.2%	560	38.0%	98.4%	37.5%	209	14.2%	98.1%	14.0%	1473	98.7%
	yes	6	31.6%	.8%	.4%	9	47.4%	1.6%	.6%	4	21.1%	1.9%	.3%	19	1.3%
Group Total		710	47.6%	100.0%	47.6%	569	38.1%	100.0%	38.1%	213	14.3%	100.0%	14.3%	1492	100.0%
Ezetimib: yes v1	no	693	48.0%	97.6%	46.4%	540	37.4%	94.9%	36.2%	211	14.6%	99.1%	14.1%	1444	96.8%
	yes	17	35.4%	2.4%	1.1%	29	60.4%	5.1%	1.9%	2	4.2%	.9%	.1%	48	3.2%
Group Total		710	47.6%	100.0%	47.6%	569	38.1%	100.0%	38.1%	213	14.3%	100.0%	14.3%	1492	100.0%
Nicotinic acid: yes v1	no	708	47.5%	99.7%	47.5%	569	38.2%	100.0%	38.1%	213	14.3%	100.0%	14.3%	1490	99.9%
	yes	2	100.0%	.3%	.1%									2	.1%
Combination dyslipid. drug: yes v1	no	663	47.8%	93.4%	44.4%	525	37.8%	92.3%	35.2%	200	14.4%	93.9%	13.4%	1388	93.0%
	yes	47	45.2%	6.6%	3.2%	44	42.3%	7.7%	2.9%	13	12.5%	6.1%	.9%	104	7.0%
Table Total		710	47.6%	100.0%	47.6%	569	38.1%	100.0%	38.1%	213	14.3%	100.0%	14.3%	1492	100.0%

Primary Objective: change of AGLA score

AGLA sum score and % risk at 10 years

AGLA score could only be computed for 63.8% of the patients at v1, 52.2% at v2 and 54.7% at v3. When considering the first available AGLA score, a value was available only for 67.4% of the patients. Due to the large proportion of missing AGLA data, the values are only of descriptive value. Results focused on the data at the 1st available visit, at v1 and their paired difference.

The median AGLA score was 47 at the first available visit and 41 at v1. The median paired difference between the first available visit and visit 1 was 6 (-28 to +42) indicating a decrease in AGLA score for the 58.2% patients with paired data (Table 12).

By first available treatment

The median AGLA sum score at the first available visit was 50 in the antihypertensive treatment group, 45 in the LIPID lowering group and 46 in the antihypertensive & LIPID lowering group. Figure 1 shows that the treatment groups are not comparable at the first available visit.

The median change between the 1st available visit and visit 1 was 9 in the antihypertensive group, 5.1 in the LIPID lowering group and 4 in the antihypertensive & LIPID lowering group (Table 12 and Figure 2). Therefore the higher the value at the 1st available visit, the greater the decrease (reduction to the mean effect cannot be excluded).

The overall proportion of patients with 10% to > 20 % risk at 10 years at the first available visit was 28.9% compared to 12.4% at visit 1 (Table 13 and Figure 3). In the antihypertensive group theses proportions were 37.1% versus 13.3%. In the LIPID lowering group theses proportions were 25.8% versus 10.4%. In the antihypertensive &LIPID lowering group theses proportions were 23.7% versus 12.2%.

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Table 12 AGAL sum score by 1st available treatment

AGLA sum score and difference by 1st available treatment

Treatment at first available visit		AGLA score at v1	AGLA score at v2	AGLA score at v3	AGLA score at 1st available visit	AGLA: diff first available - v1
HTA	N	361	318	291	386	338
	Mean	41.238	47.112	50.052	50.160	9.371
	Median	41.000	46.000	50.000	50.000	9.000
	Std. Deviation	10.3388	10.8974	10.9383	11.0695	8.4434
	Minimum	6.3	5.0	5.8	5.8	-19.0
	Maximum	71.0	72.0	81.0	81.0	37.0
Lipid	N	120	101	114	132	110
	Mean	38.275	41.656	43.853	44.176	6.505
	Median	38.500	43.000	44.500	45.000	5.125
	Std. Deviation	11.0465	10.9317	12.7725	12.2900	8.6481
	Minimum	5.3	4.3	4.8	4.8	-27.8
	Maximum	67.0	64.0	71.0	71.0	26.0
HTA+Lipid	N	471	360	411	487	420
	Mean	41.636	43.901	46.526	46.179	4.802
	Median	41.000	43.000	46.000	46.000	4.000
	Std. Deviation	9.8975	10.5362	12.4521	11.9834	9.7806
	Minimum	2.0	7.3	5.8	5.8	-28.0
	Maximum	70.0	72.0	81.0	81.0	42.0
Total	N	952	779	816	1005	868
	Mean	41.061	44.921	47.410	47.445	6.797
	Median	41.000	45.000	47.000	47.000	6.000
	Std. Deviation	10.2617	10.8996	12.1594	11.8838	9.3736
	Minimum	2.0	4.3	4.8	4.8	-28.0
	Maximum	71.0	72.0	81.0	81.0	42.0

Figure 1 AGLA sum score by 1st treatment – boxplot

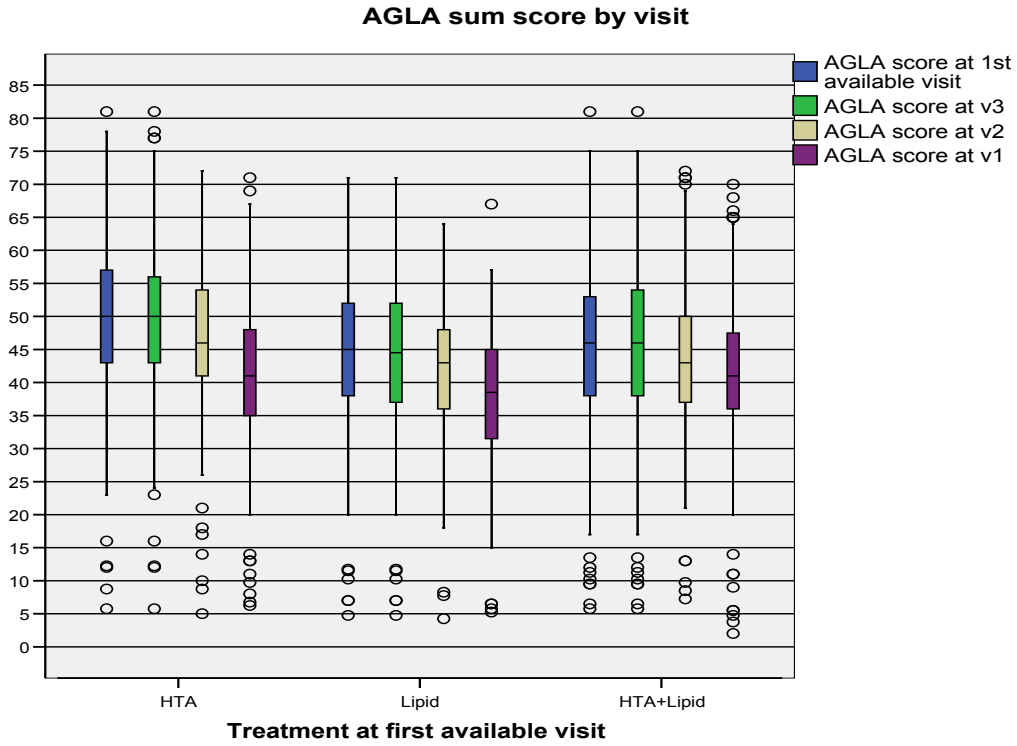


Figure 2 AGLA change in sum scores by 1st available treatment

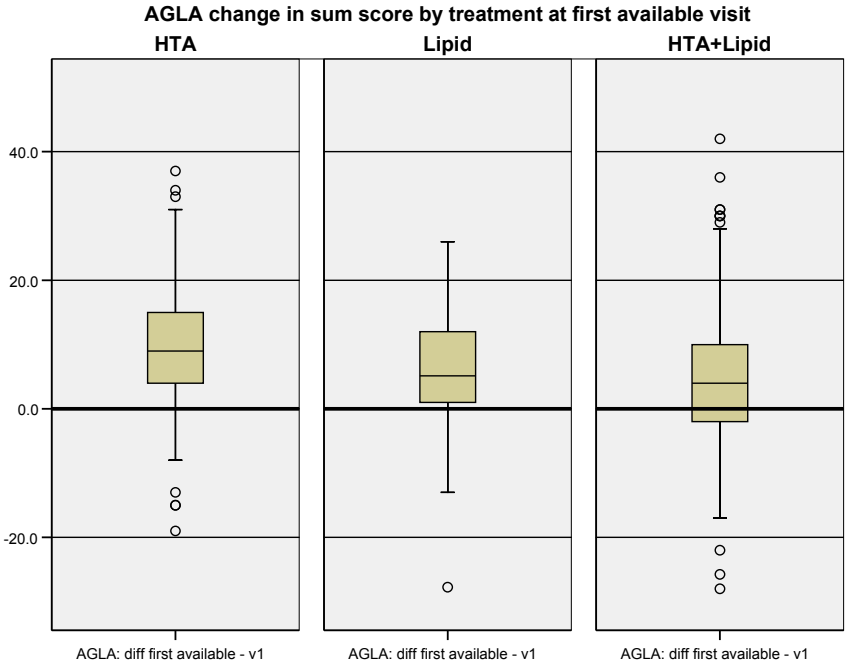
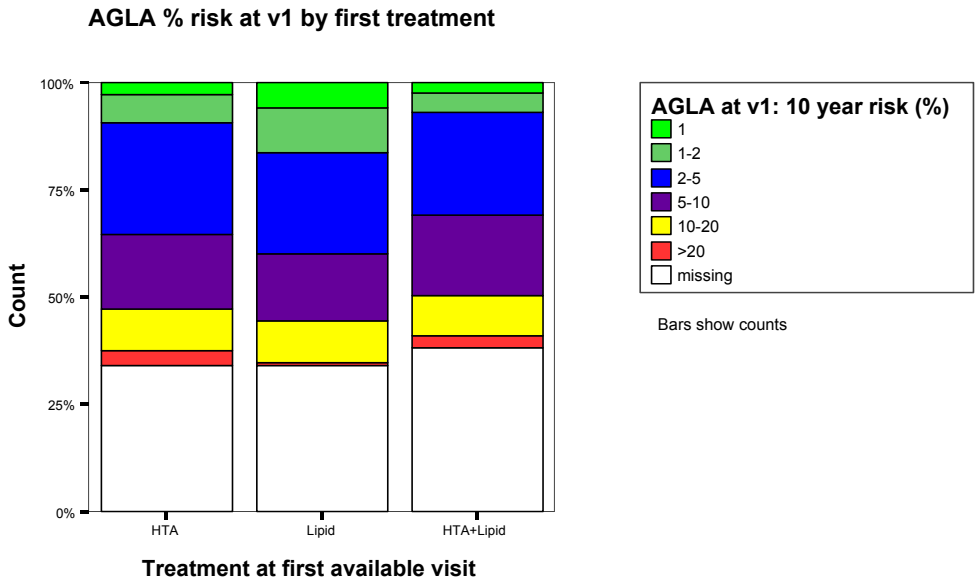


Table 13 AGLA % risk at 10 years by first available treatment

AGLA % risk at 10 years

		Treatment at first available visit									Table Total	
		HTA			Lipid			HTA+Lipid				
		Count	Row %	Col %	Count	Row %	Col %	Count	Row %	Col %	Count	Col %
AGLA at v1: 10 year risk (%)	1	15	33.3%	2.7%	11	24.4%	6.0%	19	42.2%	2.5%	45	3.0%
	1-2	36	40.0%	6.6%	19	21.1%	10.4%	35	38.9%	4.6%	90	6.0%
	2-5	142	38.7%	26.0%	43	11.7%	23.6%	182	49.6%	23.9%	367	24.6%
	5-10	95	35.8%	17.4%	28	10.6%	15.4%	142	53.6%	18.6%	265	17.8%
	missing	186	34.4%	34.0%	62	11.5%	34.1%	292	54.1%	38.3%	540	36.2%
	10-20	53	36.8%	9.7%	18	12.5%	9.9%	73	50.7%	9.6%	144	9.7%
	>20	20	48.8%	3.7%	1	2.4%	.5%	20	48.8%	2.6%	41	2.7%
AGLA at v2: 10 year risk (%)	1	7	33.3%	1.3%	5	23.8%	2.7%	9	42.9%	1.2%	21	1.4%
	1-2	12	24.5%	2.2%	10	20.4%	5.5%	27	55.1%	3.5%	49	3.3%
	2-5	62	30.2%	11.3%	30	14.6%	16.5%	113	55.1%	14.8%	205	13.7%
	5-10	118	44.5%	21.6%	35	13.2%	19.2%	112	42.3%	14.7%	265	17.8%
	missing	229	32.1%	41.9%	81	11.4%	44.5%	403	56.5%	52.8%	713	47.8%
	10-20	70	47.9%	12.8%	15	10.3%	8.2%	61	41.8%	8.0%	146	9.8%
	>20	49	52.7%	9.0%	6	6.5%	3.3%	38	40.9%	5.0%	93	6.2%
AGLA at v3: 10 year risk (%)	1	6	24.0%	1.1%	8	32.0%	4.4%	11	44.0%	1.4%	25	1.7%
	1-2	2	6.1%	.4%	7	21.2%	3.8%	24	72.7%	3.1%	33	2.2%
	2-5	45	26.3%	8.2%	25	14.6%	13.7%	101	59.1%	13.2%	171	11.5%
	5-10	85	36.0%	15.5%	35	14.8%	19.2%	116	49.2%	15.2%	236	15.8%
	missing	256	37.9%	46.8%	68	10.1%	37.4%	352	52.1%	46.1%	676	45.3%
	10-20	95	43.8%	17.4%	30	13.8%	16.5%	92	42.4%	12.1%	217	14.5%
	>20	58	43.3%	10.6%	9	6.7%	4.9%	67	50.0%	8.8%	134	9.0%
AGLA at 1st available visit: 10 year risk (%)	1	7	25.9%	1.3%	8	29.6%	4.4%	12	44.4%	1.6%	27	1.8%
	1-2	4	10.3%	.7%	7	17.9%	3.8%	28	71.8%	3.7%	39	2.6%
	2-5	65	29.0%	11.9%	32	14.3%	17.6%	127	56.7%	16.6%	224	15.0%
	5-10	107	37.7%	19.6%	38	13.4%	20.9%	139	48.9%	18.2%	284	19.0%
	missing	161	33.1%	29.4%	50	10.3%	27.5%	276	56.7%	36.2%	487	32.6%
	10-20	119	44.9%	21.8%	36	13.6%	19.8%	110	41.5%	14.4%	265	17.8%
	>20	84	50.6%	15.4%	11	6.6%	6.0%	71	42.8%	9.3%	166	11.1%
Table Total		547	36.7%	100.0%	182	12.2%	100.0%	763	51.1%	100.0%	1492	100.0%

Figure 3 AGLA % risk at 10 years by first treatment



SAFETY

No safety data were collected