AstraZeneca

STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: None
ACTIVE INGREDIENT: None

Study No: NIS-CES-DUM-2008/2

Treatment of Hypertension in Primary Care in Spain: Non-interventional , observational and retrospective study assessing the therapeutic and diagnostic attitude followed in primary care for a hypertensive patient depending on his degree of blood pressure control. (TAPAS Study)

Developmental phase: Phase IV
Study Completion Date: 01 July 2009
Date of Report: 1 June 2010

OBJECTIVES:

> The Primary objective was to assess the therapeutic and diagnostic attitude followed in primary care for a hypertensive patient depending on his degree of blood pressure (BP) control.
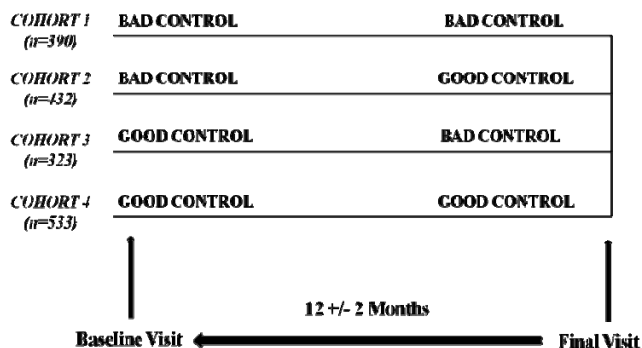
The Secondary objectives included:

- Assessment of the variation in the percentage of patients with blood pressure controlled and not controlled during a year of follow-up.

- Compare the clinical and total cardiovascular risk stratification according to the criteria of the European guide ESH-ESC 2007.

- Determine the percentage of patients poorly controlled on a visit in which treatment is unchanged and the possible causes of non-modification.

METHODS:

This was a retrospective study in hypertensive patients classified in 4 cohorts depending on their degree of BP control: cohort 1: BP not controlled in first and last visit: cohort 2: BP not controlled in first but controlled in last visit; cohort 3: BP controlled in first and lost control in the last visit; cohort 4: BP controlled in both visits. Good BP control was <140/90 mmHg and <130/80 mmHg in diabetics.

Study Design

COHORT 1 (n=390)	BAD CONTROL	BAD CONTROL
COHORT 2 (n=132)	BAD CONTROL	GOOD CONTROL
COHORT 3 (n=323)	GOOD CONTROL	BAD CONTROL
COHORT 4 (n=533)	GOOD CONTROL	GOOD CONTROL

Baseline Visit ◄───── 12 +/- 2 Months ─────► Final Visit

There were two more cohorts, cohort 5 and 6 determined only by their degree of SBP / DBP control in the medical history recorded 12 + / -2 months before inclusion, regardless of the value of SBP / DBP at inclusion.

Target Patient Population and Statistical Analysis:

The target patient population were patients of both genders aged 18 years or older with established diagnosis of essential or primary hypertension (criteria of ESH-ESC guide 2007), and / or drug treatment for hypertension for at least 1 year before inclusion in the study and of which data are available for BP 12 + / - two months before the current visit with a minimum of one year follow-up.

For the statistical analysis comparison of continuous variables in more than 2 groups was done using ANOVA or Kruskal-Wallis test. Comparison between 2 groups was done using T-Student. For comparisons of categorical variables Chi-square test was performed and in case of non-applicability of the above Fisher test was performed. Comparisons were made bilaterally and were considered statistically significant only when $p < 0.05$.

RESULTS:

Mean age was 64 years, with 53% males. In Table 1 are described the evolution of the SBP and DBP and their treatment before and after one year:

Table 1:

	Cohort 1	Cohort 2	Cohort 3	Cohort 4	p
SBP at baseline. Mean ± SD	158.7±13.9	154.4±13.9	132.6±11.8	131.0±10.8	<0.0001
SBP at last visit. Mean± SD	150.2±14.3	131.3±11.5	146.3±13.8	127.6±8.3	<0.0001
Change in SBP between visits. Mean± SD	-8.9±16.2	-23.5±14.7	14.3±16.9	-3.5±10.4	<0.0001
DBP at baseline. Mean± SD	89.2±9.2	89.3±9.3	78.1±8.4	76.7±7.5	<0.0001
SBP at last visit. Mean± SD	87.0±9.0	78.4±8.1	85.6±9.6	75.2±7.0	<0.0001
Change in DBP between visits. Mean± SD	-2.4±10.1	-10.7±10.5	8.3±9.9	-1.3±7.4	<0.0001
Mean number of antihypertensive treatments at baseline / last visit.	1.6/1,8	1.5/1,6	1.5/1,6	1.4/1,4	0.0382
Change between visits in the number of antihypertensive treatments Mean± SD	0.3±0.5	0.2±0.5	0.1±0.5	0.0±0.3	<0.0001
CI 95%	(0.2,0.3)	(0.1,0.2)	(0.1,0.2)	(0.0,0.1)	

Regarding their degree of BP control: 19.25% of hypertensive patients lost BP control in the last visit, and 23.24% were not controlled at baseline and at the last visit; 31.76% maintained a good control of their BP at baseline and a year later, and 25.74% achieved good BP control at both visits.

Regarding Cohort 5 and 6, in cohort 5 patients were poorly controlled the year before inclusion and in cohort 6 patients were well controlled the year before inclusion. The results regarding their degree of control after one year was for cohort 5: good control on 22.86% and 77.14% with poor control. For cohort 6, 56.86% had good control after a year and 43.14% poor control. Overall, 40.6% of all patients are controlled after a year and of them 73% were well controlled in the previous year. Among poorly controlled patients 38% are patients who have lost control.

The clinical and total cardiovascular risk stratification at baseline according to the criteria of the European guide ESH-ESC 2007 are showed in table 2.

Table 2:

Risk	Cohort 1 (N=390)	Cohort 2 (N=432)	Cohort 3 (N=323)	Cohort 4 (N=533)	Total (N=1678)	p-value
						<0.0001
Average risk	0(0.00%)	0(0.00%)	0(0.00%)	3(1.41%)	3(0.37%)	
Low added risk	0(0.00%)	2(0.91%)	20(15.15%)	53(24.88%)	75(9.14%)	
Moderate added risk	28(10.89%)	27(12.33%)	15(11.36%)	42(19.72%)	112(13.64%)	
High added risk	120(46.69%)	110(50.23%)	49(37.12%)	67(31.46%)	346(42.14%)	
Very high added risk	109(42.41%)	80(36.53%)	48(36.36%)	48(22.54%)	285(34.71%)	
Missing	133	213	191	320	857	

Factors associated with a change in the status of hypertension control are showed in table 3.

Table 3:

	Cohort 1	Cohort 2	Cohort 3	Cohort 4	
Diabetes, N(%)	152(39.48%)	120(28.17%)	121(37.81%)	127(24.10%)	<0.0001
Dyslipidemia N(%)	227(58.81%)	249(58.45%)	184(57.86%)	244(46.39%)	0.0001
Renal Impairment N(%)	31(7.99%)	29(6.81%)	21(6.62%)	15(2.84%)	0.0044
Smoker at baseline visit, N(%)	100(26.04%)	69(16.20%)	51(16.14%)	63(11.95%)	<0.0001
Smoker at final visit, N(%)	91(23.58%)	62(14.59%)	49(15.31%)	62(11.74%)	<0.0001
Alcohol consumption at baseline visit, N(%)	95(24.61%)	85(20.00%)	54(16.98%)	60(11.36%)	<0.0001
Alcohol consumption at final visit, N(%)	94(24.48%)	76(18.10%)	54(16.88%)	60(11.43%)	<0.0001
Urinary Albumin excretion rate (UAE) mg/g	88.7	160.7	153.9	27.4	0.0371
LVI at baseline, N(%)	56(18.98%)	49(14.29%)	29(11.89%)	39(9.63%)	0.0036
Ankle/Brachial Index (ABI) <0.9 at baseline, N(%)	32(42.11%)	20(22.22%)	14(24.14%)	30(37.50%)	0.0160
Change in BMI between visits	0,1	-0,2	0,4	0	0.0537
NSAIDs at baseline visit, N(%)	144(38.20%)	125(30.27%)	81(26.30%)	133(26.23%)	0.0006
NSAIDs at final visit, N(%)	125(33.33%)	115(28.75%)	89(29.28%)	120(23.76%)	0.0188
Cholesterol at baseline visit (mg/dl)	215	210	211	204	0.0003
LDL-cholesterol at baseline visit (mg/dl)	132	130	131	123	0.0002

A history of diabetes, dyslipidemia, renal impairment; organ damage expressed by LVH, UAE or pathological ABI; increased levels of total and LDL cholesterol; alcohol, tobacco, or NSAIDs consumption, all of these are factors associated with the lack or loss of control of Hypertension in the patients studied.