AstraZeneca

STUDY REPORT SUMMARY

Asthma control and clinical practice in Hungary 2009

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: No specific study drug
ACTIVE INGREDIENT: N/A
STUDY CODE: NIS-RHU-DUM-2009/1
Developmental Phase: Non-Interventional Study
Study Completion Date: 2009 November 16 (Last Subject Last Visit)
Date of Report: 2010 November 2

OBJECTIVES:

To evaluate the asthma control level of patients on monosteroid or bronchodilatator treatment

Clinical practice: non controlled or partially controlled patients' therapy change based on GINA and national guidelines.

METHODS:

Observational study using probability methods for assessment of patient's percent rate achieving guideline defined asthma control level.

Control level based on GINA criteria. QoL measured by Visual Analogue Scale.

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RESULTS:

The study was undertaken over a three months period with 2017 randomly selected patients; patient who met the inclusion criteria was enrolled to the study; subjects over aged 18 years with a clinical diagnosis of asthma made by a chest physician of differing severity. Exclusion criteria were the if patients had COPD or TBC

In the study a total of 1832 patient's data were analysed, 275 (13.1%) had to be excluded from the analysis from which 241 received a combination therapy and 43 had missing data. Patients characteristics are summarised on table 1.

Table 1. Patient Characteristics

Age	46.76±16	
% of Females	64.74%	
Smoking	Never	64.52%
	Stopped	20.21%
	Less than 10 cigarettes a day	8.95%
	More than 10 cigarettes a day	6.32%
Type of asthma	Extrinsic	62.66%
Rhinitis co-morbidity	None	47.71%
	Allergic rhinitis	49.51%
	Chronic rhinitis	2.78%

As after the baseline visit the majority of the patients were switched to combination therapy consequently at the second/intermediate visit 92.7% of the patients received combination therapy; since it was the majority of the subjects included in the study only this group of patients on combination therapy was further analysed.

Our data shows significant improvement both in the clinical parameters and in terms in the patient reported outcomes (VAS) as well as the control stage of asthma.

The answers to all question shows a significant ($p<0.0001$) improvement in the control level of asthma; significantly more patients had no cough (2.58% vs. 73.44%) in the last week. The number of night time awakenings because of chest tightness decreased remarkably (74.63% vs. 4.43%). The use of SABA fall notably, as the number of patients who did not had to use their relievers grew from 6.06% to 70.19%. Patients who did not experienced the impairment of asthma on they daily activity rose from 20.83% to 89.1%. At the baseline visit 78% of the patients visited their doctor because they experienced a health status decline, while at the final visit of the study 98.82% had no problem with their asthma.

Results are summarised on figures from 2 to 4.

Figure 2. Asthma control at the baseline visit

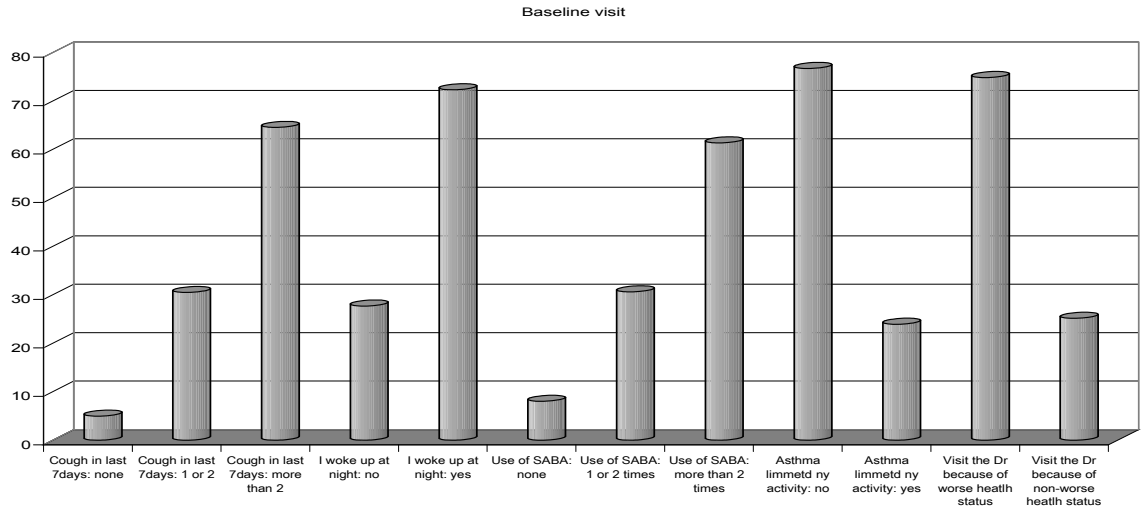


Figure 3. Asthma control at the second/intermediate visit

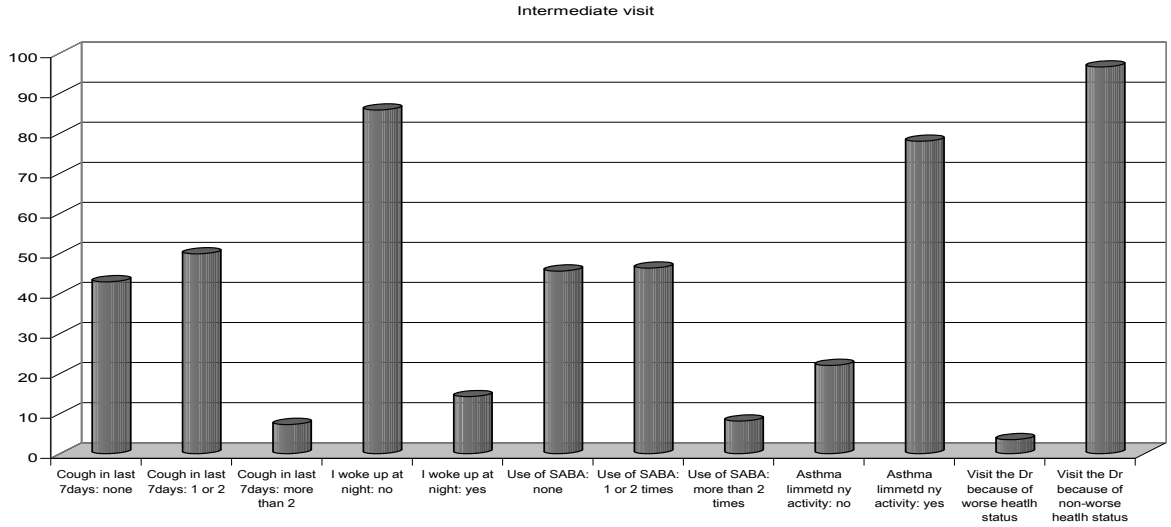
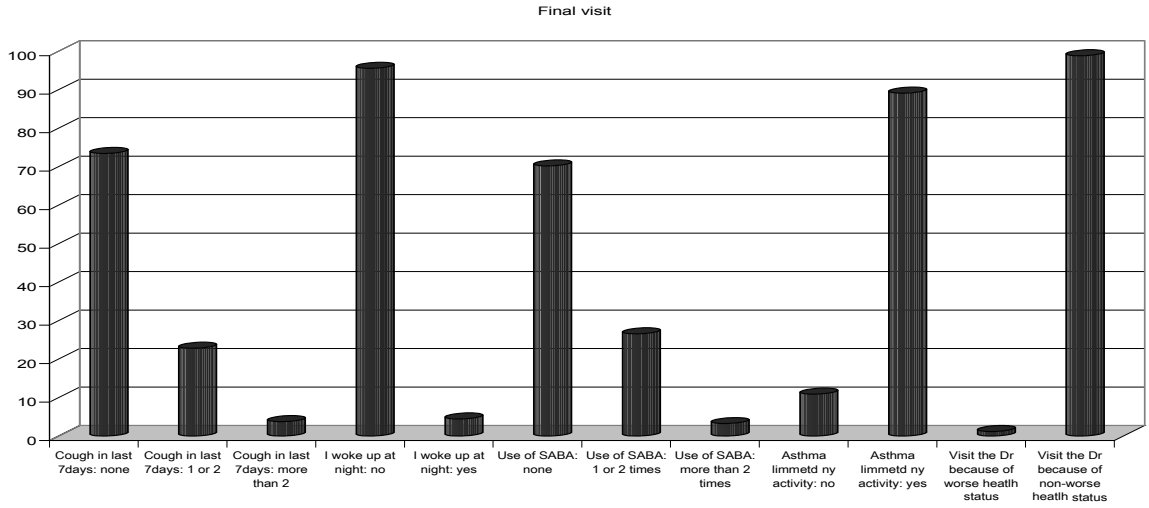


Figure 4. Asthma control at the final visit



The number of physical examination of the lungs resulting in positive clinical outcomes decreased significantly ($p<0.0001$), as well as there was a significant improvement in the FEV1 score and VAS scores ($p<0.0001$) if comparing the two visits to the baseline visit, as it is shown on figure 5, and similarly there was a major improvement in the number of patients becoming fully controlled by the end of the three month period, as it is summarised on figure 6.

Figure 5. The physical examination test, FEV1 and VAS score

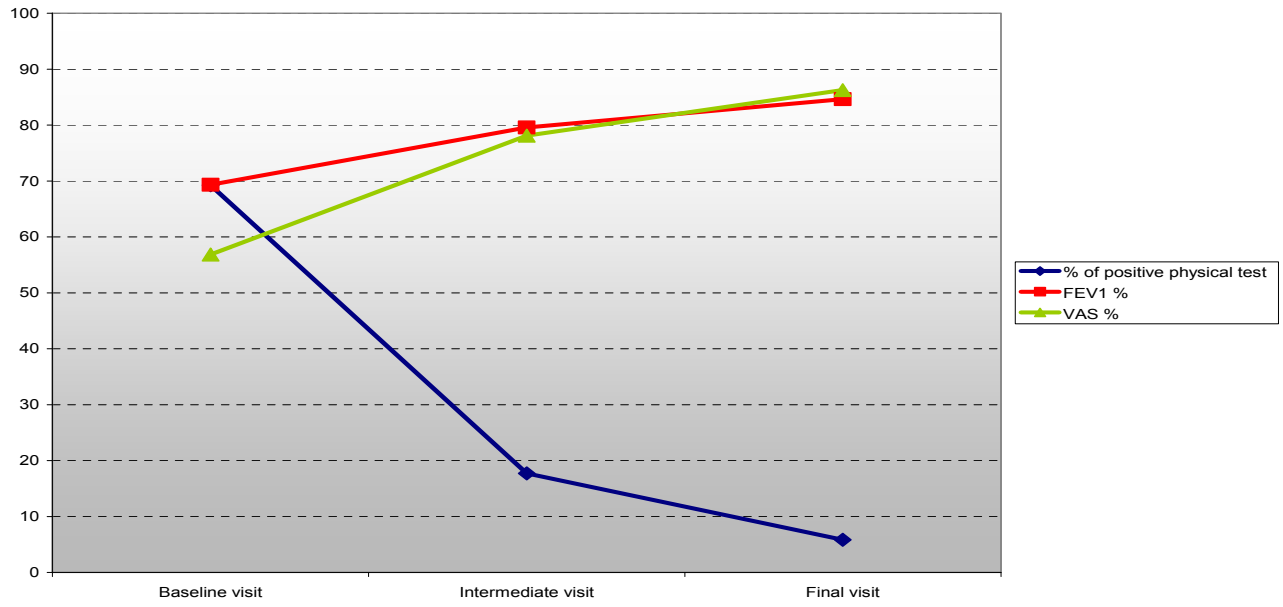
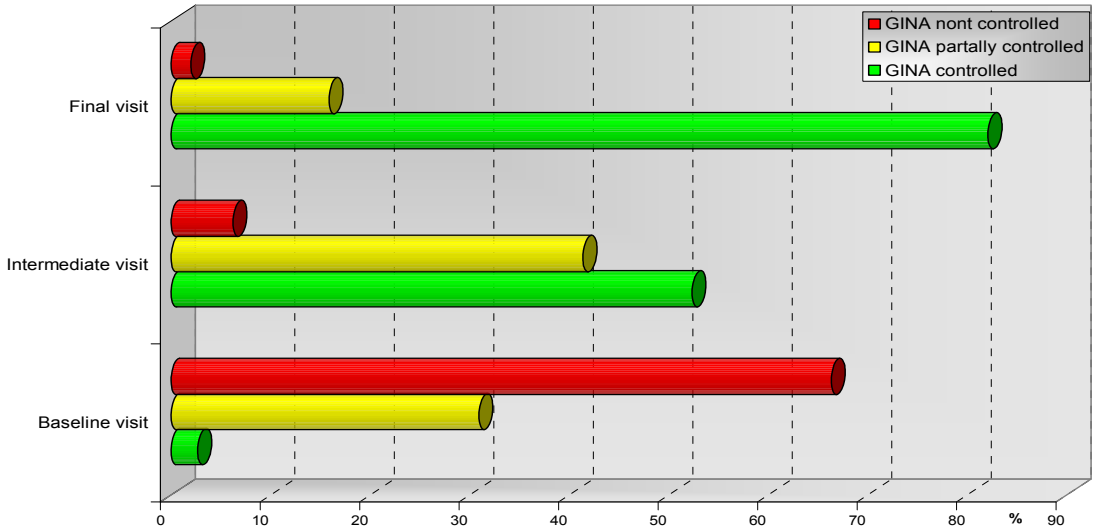


Figure 6. Asthma control according to the GINA guidelines



Asthma medication

In the study as it was mentioned before that 92.7% of patients after the first visit were swished to combination therapy of ICS+LABA. The medications that was prescribed is summarised on table 2.

Table 2. Medication used in the study with over a 1% share

Visit	Type of the drug	Proportion %
Baseline visit	ICS and SABA	36.82%
	SABA	18.01%
	ICS	13.33%
	ICS and LABA	5.92%
	ICS and LABA and SABA	4.36%
	ICS and SABA and xantines	3.93%
	SABA and xantines	3.24%
Intermediate visit	Combination	58.19%
	Combination and SABA	28.29%
	Conbination and SABA and xantines	4.55%
	Combination and leucotrienes	2.87%
	Combination and xanatines	1.74%
	Combination and leucotrienes and SABA	1.62%
Final visit	Combination	57.76%
	Combination and SABA	22.62%
	Combination and leucotrienes	5.92%
	Combination and leucutriens and SABA	3.74%
	Combination and SABA and xantines	3.18%
	Combination and xanatines	1.50%