

## STUDY REPORT SUMMARY

### ASTRAZENECA PHARMACEUTICALS

**FINISHED PRODUCT:** None  
**ACTIVE INGREDIENT:** Not Applicable

<b>Study No:</b> NIS-CCH-DUM-2008/1
-------------------------------------

Management of DM Patients with retinopathy
--

**Developmental Phase:** NIS

**Study Completion Date:** December 2009

**Date of Report:** 08.06.2010

### OBJECTIVES:

Practising physicians from all Swiss language regions participated in this Non Interventional Study (NIS) between September 2008 and December 2009 that was originally planned to include 2500 patients.

Aim to this NIS is to retrospectively document the management of diabetic patients with retinopathy in a naturalistic setting in Switzerland. Following elements are going to be analyzed:

- which medication are used to keep blood pressure under control?
- which medication are used for metabolic control?
- the average control level of metabolism and blood pressure is compliant with the international guidelines?
- laser photocoagulation plays a role in the control of metabolism and blood pressure?
- there are differences in the control of metabolism and blood pressure between patients with DM I or DM II?
- There is an influence of renal failure on the choose of medication?

## **METHODS:**

Non interventional study with a retrospective evaluation of patients in a naturalistic setting. Descriptive statistic analysis were applied

## **RESULTS:**

Some 32 physicians contributed data from 170 diabetic patients with retinopathy. The number of patients per physician ranged between 1 and 35.

The data of 170 patients were available, among them 67 women (39.4%), 102 men (60.0%) and one person of unknown gender (0.6%). The age ranged between 27 and 89 years. Some 68 patients (40.0%; 43.3% of females/37.3% of males) were suffering from type I diabetes, 102 patients (60.0%; 56.7% of females/62.7% of males) from type II.

As would be expected, type I diabetics were, on average, younger than type II patients (mean 47.3 years vs. 65.9 years) and less obese.

It was unfortunate that the planned case numbers (2500) could not be reached. Larger case numbers would doubtlessly have revealed more connections between clinical conditions and the choice of medications and dosages.

Nevertheless, extensive and careful data checking and processing helped achieve evidence to answer the questions posed in the project plan:

1. Which medications are used for blood pressure control?

Some 98.3% of patients considered hypertensive were receiving antihypertensive treatment, as did 25% of the non-hypertensive patients, possibly for prophylaxis.

37.3% of type I and 89.3% of type II patients were considered hypertensive (Table 1).

The choice of drug class was mainly determined by the hypertensive assessment and, in the case of diuretics and beta blockers, renal status. Diabetic type and previous laser coagulation did not have effects other than through mediating hypertension.

Alpha blockers were only marginally used, clonidine not at all.

2. Which medications - and which dosages - are used for metabolic control?

Some 91.7% of patients considered dyslipidemic were receiving treatment for metabolic control, as were 8.5% of the non-dyslipidemic patients, possibly for prophylaxis.

In Table 28, the proportions of diabetic patients receiving statins thus reflects the prevalence of the diabetic conditions cited in Table 1.

The choice of drug class was mainly determined by the hypertensive assessment and, in the case of diuretics, alpha and beta blockers, renal status. Diabetic type and previous laser coagulation did not have effects other than through hypertension.

Only statins were used in numbers allowing statistical conclusions.

3. Do metabolic and blood pressure control conform with internationally accepted recommendations?

Glycemic control seems inadequate to prevent future damage. Blood pressure control could (should) still be improved. Metabolic control could likewise be improved.

4. Are there differences with respect to blood pressure and metabolic control between diabetic patients with and without retinal laser coagulation?

Systolic blood pressure is significantly lower by about 5 mm Hg and diastolic pressure by about 1.5 mm Hg in hypertensive patients where laser coagulation has been

performed. LDL and triglycerides are insignificantly lower (better) in patients where laser coagulation has been performed, the HDL does not differ.

5. Are there differences in blood pressure and metabolic control between type I and type II diabetic patients?

Type II diabetics are at a significantly higher risk for hypertension, but they are also older and more obese.

With treatment, type II systolic blood pressure is still higher than in type I, while diastolic blood pressure does not differ.

With treatment, LDL is insignificantly lower and HDL higher (both better) in type I, while triglycerides are significantly lower (better).

6. What impact does renal insufficiency exert on the choice of medication?

Renal insufficiency does not exert a significant impact on the choice of insulin or oral diabetics.

With renal insufficiency, diuretics and beta blockers are chosen significantly more frequently than with intact kidneys, and there is a strong trend for the use of more calcium channel blockers.