AstraZeneca

STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: No applicable
ACTIVE INGREDIENT: No applicable

Study No: NIS-CFR-DUM-2007/8
COMPAR : Comparison and Description of Coronary Patients Management With or Without Heart Failure in Cardiology Consulting

Developmental phase: No applicable
Study Completion Date: LSLV = 28 January 2009
Date of Report: 11 January 2010

OBJECTIVES:

The primary objective of this survey, conducted from June 2008 to January 2009, was to compare blood lipid control in coronary patients with or without heart failure (HF vs non-HF) managed in cardiology consulting. Predefined secondary objectives were the frequency of cardiovascular and predisposing risk factors, control of these factors, signs of subclinical lesions, therapeutic management and mode of follow-up of these patients.

METHODS and RESULTS:

More than 1,500 coronary patients analysed
A total of 416 cardiologists (85.4% male; mean age: 51.6 ± 8.0 years) participated in this study. One half (51.5%) were in private practice and the other half were in mixed practice. The geographical distribution of cardiologists complied with DRESS data, with a slight under-representation of the Parisian region.
These 416 cardiologists included a total of 1,645 patients. After exclusion of protocol violations, the files of 1,527 patients were analysed. One half (760) had heart failure. 81.4% of patients were male and the sex ratio was identical for patients with and without HF. The mean age of these patients was 68.7 years; on average, HF patients were older (72.1 years vs 65.4 for non-HF). Consequently, more than one half of patients were retired (55.1%) with, once again, a much greater share of HF patients (61.5% vs 48.7% for non-HF patients). Weight, height and waist circumference were comparable between groups. BMI was greater than 25 kg/m^2 for more than 60% of patients. A slightly higher percentage of HF patients were overweight (BMI: 25 to 30 kg/m^2; 46.8% vs 44.1%) or obese (BMI > 30 kg/m^2; 20.3% vs 16.6%).

Patients regularly followed

The very great majority (93%) of patients with or without HF were regularly followed, usually every six months. However, HF patients were more frequently reviewed quarterly than non-HF patients (34.8% vs 14.4%). They were also followed by their general practitioner, usually once a month for HF patients (62.1% vs 36.4% for non-HF patients). An electrocardiogram (ECG) had been performed during the previous year for 99.9% of patients. It was normal for one half of non-HF patients and for 6.8% of HF patients. ECG was performed an average of every 6.6 months and echocardiography was performed an average of every 13.9 months (11.4 ± 6.3 months for HF patients vs 16.5 ± 9.5 months for non-HF patients).

28.9% of HF patients presented left ventricular hypertrophy (LVH) (vs 12.0% of non-HF), 25.4% presented atrial fibrillation (AF) (vs 2.6% of non-HF), 68.8% presented sequelae of myocardial infarction (MI) (vs 42.2% of non-HF) and 26.8% presented left bundle branch block (vs 5.4% of non-HF).

HF patients had a longer history of coronary heart disease (92.6 vs 70.3 months). They more frequently had a history of acute coronary syndrome (ACS) (80.9% with a mean history of 83.6 months vs 74.7% with a mean history of 63.7 months for non-HF). Angioplasty had been performed less frequently in HF patients (60.0% vs 72.7%) in contrast with coronary artery bypass graft (31.2% vs 26.2%).

Mean blood pressure was slightly higher in non-HF patients (SBP: 133.0 ± 14.6 mmHg vs 127.8 ± 17.1 mmHg in HF patients; DBP: 77.3 ± 8.4 mmHg vs 75.0 ± 9.8 mmHg in HF patients). In contrast, heart rate was higher in HF patients (68.1 ± 11.8 bpm vs 64.7 ± 11.4 bpm) and, logically, left ventricular ejection fraction was markedly lower (38.8 ± 9.7% vs 61.7 ± 7.8%).

A blood glucose assessment was available for 77.3% of patients. HbA1c was greater than 7% in 19.1% of HF patients and 13.5% of non-HF patients. Similarly, fasting blood glucose was greater than 1.26 g/l in 21.5% of HF patients versus 14.8% of non-HF patients.

The main reason for the visit was a recent clinical or laboratory event in only 19.3% of patients, but much more frequently in HF patients that in non-HF patients (29.3% vs 9.4%).

Lipid assessment: 30% of patients with or without HF were still not controlled

More than 80% of patients, with or without HF, had hypercholesterolaemia. At the time of inclusion, fewer HF patients had a lipid assessment dating less than one year (84.5% of HF patients vs 90.3% of non-HF patients, $p = 0.001$).

Hypercholesterolaemia was not controlled in 30% of patients with or without HF. 25.3% of patients had an LDL-cholesterol (LDL-c) greater than 1 g/l, with no marked difference between HF patients (24.1%) and non-HF patients (26.5%).

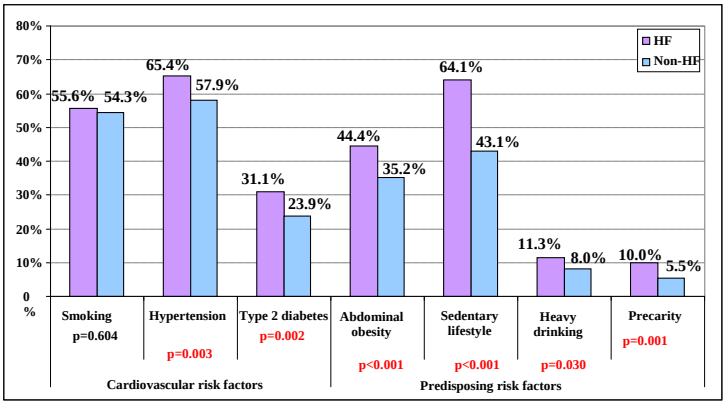
On average, HF patients presented considerably more cardiovascular risk factors (3.6 ± 1.5 vs 3.1 ± 1.5 in non-HF patients). More than one half of HF patients (51.2%) presented more than 3 risk factors versus one third of non-HF patients (37.2%).

Cardiovascular risk factors significantly more frequent in heart failure patients

As shown in Figure 1, regardless of the type of risk factor, HF patients more frequently presented hypertension or type 2 diabetes. Similar results were observed for predisposing risk factors. More HF patients presented abdominal obesity, sedentary lifestyle, heavy

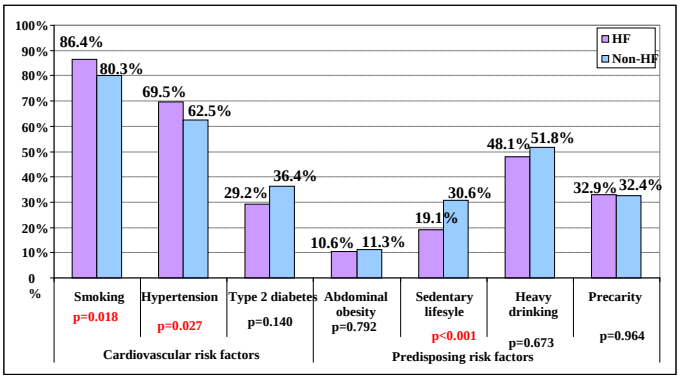
drinking and psychological or social precarity. Only the frequency of smoking was comparable between the two groups.

Figure 1 - Current or previous risk factors



Smoking and hypertension were significantly more effectively controlled in HF patients that in non-HF patients. Inversely, type 2 diabetes, abdominal obesity, sedentary lifestyle and heavy drinking were more effectively controlled in non-HF patients (Figure 2).

Figure 2 – Control of risk factors



In terms of target organs lesions, similar numbers of patients with and without HF had a history of stroke. In contrast, HF patients more frequently presented peripheral artery disease (22.8% vs 14.7% of non-HF patients) or renal failure (23.4% vs 6.6 of non-HF patients).

Comparable modalities of follow-up

The frequency of complementary investigations (ECG, echocardiography, glucose and lipid assessment) was essentially the same in the two patient groups, apart from echocardiography (every 11.4 ± 6.3 months for HF patients versus every 16.5 ± 9.5 months for non-HF patients).

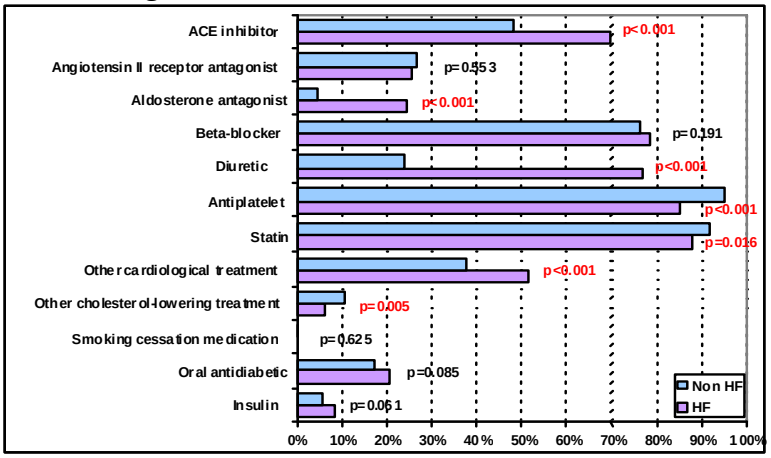
In HF patients, the presence of a particular risk factor did not influence the frequency of complementary investigations apart from that of lipid assessment in the case of hypercholesterolaemia (every 9.9 months in non-controlled patients vs every 10.7 months in controlled patients, p = 0.004).

More intensive management for heart failure patients

Management was more intensive for HF patients. They were more frequently on a special diet (84.0% versus 74.1% in non-HF patients, p<0.001): antidiabetic diet (31.9% versus 25.7% in non-HF patients, p = 0.024) and low-salt diet (79.6% versus 20.8% in non-HF patients, p<0.001). In contrast, non-HF patients were more frequently on a low cholesterol diet (92.2% versus 81.3% of HF patients, p<0.001). The frequency of low-calorie diet was comparable between the two groups.

HF patients were more often treated with at least an angiotensin-converting enzyme inhibitor (ACE inhibitor) (and at significantly higher doses), aldosterone antagonist, diuretic (and at significantly higher doses) or other cardiological treatment. Inversely, they were significantly less often treated with antiplatelet drugs, statins or other cholesterol-lowering drugs (Figure 3). Beta-blockers, antiplatelet drugs or other cardiological treatments were administered at significantly lower doses in HF patients than in non-HF patients.

Figure 3 - Treatment on arrival at the visit



Treatment with ACE inhibitor (increased dosage and initiation), aldosterone antagonist, beta-blocker and diuretic (increased dosage and initiation) was modified at the time of the visit significantly more often in HF patients than in non-HF patients. Only statin therapy was modified significantly more often in non-HF patients than in HF patients.