

STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: -

ACTIVE INGREDIENT: -

Study No: NIS-PFR-DUM-2010/1

Gastroprotective Agent Utilization and Compliance in Elderly Patients Taking Non-steroidal Anti-inflammatory Drug (NSAID) in France

Developmental Phase:

Study Completion Date: November 2010

Date of Report: 14 March 2011

OBJECTIVES:

The objective of the study was to assess in general population NSAID and gastroprotective agent utilization and compliance in elderly people.

METHODS:

From October 2010 to November 2010, 10,000 self administered questionnaires were sent to French people older than 65 to a panel of French people (Access Santé). For each patient, demographic characteristics, NSAID and gastroprotective agent (including PPI, misoprostol, H2-blockers, antiacids/alginates) intakes were recorded. Treatment compliance was also evaluated through a specific questionnaire (Girerd) for both types of drugs.

RESULTS:

7,976 people sent back their questionnaire (79.8%). Among them, 1,410 (18%) were taking NSAID, currently (n=815, 10%) or within the last month (n=595, 8%).

NSAID intake was more frequent among female (21%) than male (13%, p<0.01), and decreased with the age from 20% among patients 66-69 years old to 11% among those older than 85. The NSAID was prescribed for 89% of the patients by a general practitioner (78%). The mean duration for the prescription was 29 days (less of 15 days in 40%). The main reason for NSAID intake was osteoarthritis (79%), followed by low back pain (56%), muscle pain (34%) and headache (17%). Diclofenac was the most frequent NSAID taken (22%). Patients did not take their NSAID for lack of pain (51%) or NSAID related adverse events

(12%). The most frequent NSAID adverse events were gastric pain/burning (28%), diarrhea/constipation (15%) and abdominal pain (9%).

In addition to the age, 26% of patients had other gastrointestinal risk factors (RF): respectively 12%, 3%, 2% and 2% were taking concomitant low dose aspirin, anti-platelet drug, anticoagulant or corticosteroid; respectively 8% and 3% had a history of gastroduodenal ulcer or of digestive bleeding respectively.

Among the 1,410 patients taking NSAID, only 767 (55%) received a gastroprotective therapy (PPI in 42%). Gastroprotection increased with the age of the patients, from 51% (PPI 37%) among patients 75-79 years old to 62% (PPI 53%) for patients older than 85. On top of the age, if one more RF was identified, the gastroprotection rate was 65% (PPI : 54%), two more, 87% (PPI : 82%), $p < 0.01$ for 3RF vs 1RF, 2RF vs 1RF, 2RF vs 3RF. History of gastroduodenal ulcer was the most important trigger for the presence of gastroprotection : 85% (PPI : 69%).

Compliance questionnaire¹ was available for 1,253 patients taking NSAID. 64% had no compliance trouble, 32% had minor compliance problems and 4% were considered with bad compliance. The main reasons were the NSAID adverse events for 15% (abdominal pain 10%, diarrhea/constipation for 8%, gastric pain/burning 7%) and the oversight for 15%. There is no difference according to the numbers of drugs taken by the patient

Compliance questionnaire was available for 508 patients taking PPI. 68% had no compliance trouble, 31% had minor compliance problems and 1% were considered with bad compliance. There was no difference in terms of compliance between patients taking NSAID with and without gastroprotection.

AZ Synopsis Template 2010 June 4

¹ Mulazzi I, Cambou JP, Girerd X, Nicodeme R, Chamontin B and Amar J. Six-item self-administered questionnaires in the waiting room: an aid to explain uncontrolled hypertension in high-risk patients seen in general practice. J Am Soc Hypertens 2009, 3 : 221-7.