The ASTRO-LAB project:
Assessment of the safety of Long Acting β-agonists in asthma
by combining health care databases and direct patient follow-up:
Focus on detailed pattern of use of therapy

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ERS Annual Congress – Barcelona – September 7-11, 2013

RATIONALE

• The efficacy of long-acting β-agonists (LABAs) in asthma has been demonstrated, their safety remains an issue, particularly in children.
• Although co-therapy with inhaled corticosteroids (ICs) is recommended in persistent asthma, its inadequate use also may contribute to the occurrence of exacerbations.
• The main objective of the ASTROLAB project is to assess the safety profile of LABAs (alone or not) in children and adults, with a specific interest on detailed patterns of use, and their relationship with adverse outcomes.

STUDY POPULATION

Population: 3,000 patients (1,500 children -6 to 18 years- and 1,500 adults) will be selected in France and the United Kingdom based on prescribed anti-asthma therapy.

• In France, patients are identified among a register completed by about 500 general practitioners from the CNGE (College National des Généralistes Enseignants).
• In the United-Kingdom, patients are identified in the THIN database, a collection of pseudo-anonymised Electronic Medical Records.

Inclusion criteria
To be pre-selected in the study, patients from 6 to 40 years, with available medical history of at least 12 months, must have the same prescribed asthma therapy pattern for at least 6 months (consecutively or not) during the 12-month period prior to enrolment:
• ICs (no LABA),
• LABA (no ICs),
• LABA/ICs (fixed combination), or
• LABA+ICs (in 2 separate canisters)

RESULTS

• In France, at the present time, 2,160 patients from 6 to 40 years, with at least 2 prescriptions of LABA and/or ICs during the last 12 months have been recorded in the registry. Among them, 1,542 (71%) met inclusion criteria.
• In the United-Kingdom, 105,921 patients from 6 to 40 years with at least one prescription of LABA and/or ICs during the last 24 months or a recorded diagnosis of asthma were identified in the THIN database. Among them, 30,926 met the inclusion criteria.

DISCUSSION

• Major differences in controllers therapy prescribing behaviours are observed between France and the UK. In France, general practitioners prescribe essentially LABA/ICS fixed combinations, while UK patients mostly receive ICs without LABA.
• A limited percentage of the patients received LABA without ICs (1% in France and 0.08% in the UK), which is in line with the revised British guidelines on the management of asthma (January 2012).
• In Astro-Lab, recruiting patients under LABA alone or with ICs in a separate canister are essential to identify a potential contribution of differential adherence to ICs and to LABAs. Therefore all these patients will be invited to participate in the study.

CONCLUSION

Major differences in asthma therapy prescribing behaviors have been observed between France and the United-Kingdom. Astro-Lab purpose is to provide new evidence for regulators about the safety of LABAs in asthma.

Acknowledgments: The Research leading to these results has received funding from the European Community’s 7th Framework (FP7/2007-2013) under grant agreement n°282593.
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