

IVABRADINE PRESCRIPTION ACCORDING TO PHARMACOVIGILANCE RISK ASSESSMENT COMMITTEE RESTRICTIONS

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OBJECTIVES

To review ivabradine prescriptions in our patients and compliance with the Pharmacovigilance Risk Assessment Committee (PRAC) restrictions for the use of ivabradine in patients diagnosed with Chronic Stable Angina Pectoris (CSAP), which were published in 2014 and are the following:

- Begin treatment only if resting Heart Rate (HR) is above 70 beats per minute (bpm), initial dose not exceeding 5 mg bid (2.5 mg bid for patients older than 75 years).
- Maximum maintenance dose: 7.5 mg bid.
- Monitor HR before starting treatment and after changing dose.
- Withdraw treatment in case of Atrial Fibrillation (AF).
- Do not use ivabradine combined with diltiazem or verapamil.

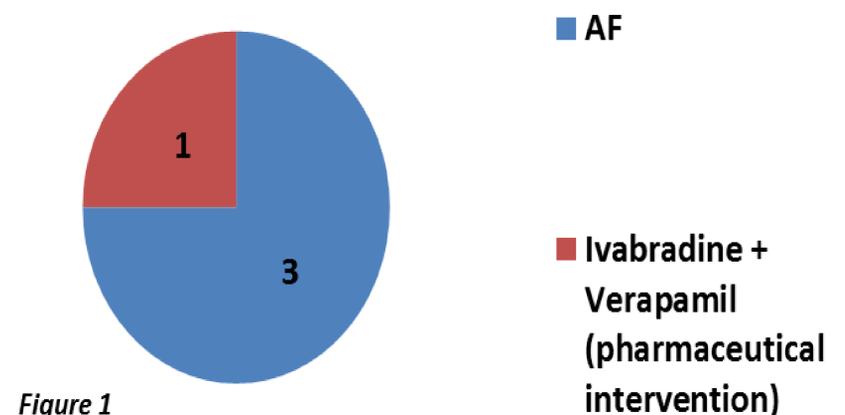
METHODS

Observational, prospective study including all patients prescribed ivabradine and diagnosed with CSAP from february to may 2015. Data collected: gender, age, HR, dates in which treatment was started and discontinued, diagnosis, initial and maintenance dose, diltiazem or verapamil treatment and occurrence of AF. The prescription was considered adequate if it followed every PRAC recommendation.

RESULTS

34 patients were prescribed ivabradine and 17 of them were included in our study based on a CSAP diagnosis. At the beginning, resting HR was above 70 bpm and initial dose was 5 mg bid for all the patients. Maintenance dose was never above 7.5 mg bid. In 4 patients, ivabradine was withdrawn (see Fig 1) Compliance with PRAC guidelines was found in 16 out of 17 patients, which results in a percentage of 94%.

REASONS FOR IVABRADINE WITHDRAWAL



DISCUSSION

3 out of 17 patients (17.6%) developed AF during treatment, a higher percentage than that showed by the SIGNIFY¹ study (4.6%).

CONCLUSIONS

We strongly believe that treatment with ivabradine should be closely monitored by hospital pharmacists, regarding its pharmacological and safety profiles.

ACKNOWLEDGEMENTS/REFERENCES

1. Fox K, Ford I, Steg PG, Tardif JC, Tendera M, Ferrari R. Bradycardia and atrial fibrillation in patients with stable coronary artery disease treated with ivabradine: an analysis from the SIGNIFY study. *Eur Heart J.* 2015 Sep 17; ehv451.

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