RISK OF HYPERTENSION IN PATIENTS TREATED WITH MIRABEGRON.
STRATEGY FOR PRIORITIZATION OF A DRUG SAFETY WARNING.

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BACKGROUND
On September 7th 2015, the European Medicines Agency (EMA) and the Spanish Agency for Medicines and Health Products (AEMPS) notified a drug safety warning (DSW) through a communication to healthcare professionals on the use of mirabegron. It showed new recommendations for its use in relation to the risk of increased blood pressure.

PURPOSE
To detect patients under mirabegron treatment with an increased risk of hypertension. To make a notification to physicians.

MATERIAL AND METHODS

Patients under main therapeutic groups of antihypertensive drugs treatment (angiotensin converting enzyme inhibitors, angiotensin II-receptor antagonists and calcium antagonists)

Patients under mirabegron treatment (February-July 2015)

Patients with increased risk of hypertension during treatment with mirabegron

•Summary of the DSW
•Analysis of the prescribing physicians and patients with increased risk of adverse reaction
•Information about other treatment options

RESULTS

810 patients under MIRABEGRON treatment

41,5% from UROLOGY service

45% treated with any AD

HIGHER RISK FOR THE ADVERSE REACTION OR POSSIBILITY OF HAVING ALREADY HAD IT

CONCLUSIONS

Five out of ten patients under mirabegron treatment can be considered as risk population for hypertension. The analysis allows prioritization on the diffusion of information identifying patients at risk and main prescribers. Further studies would be necessary to confirm the impact of this intervention.