

recommendations, magnification in the perception of adverse effects of classic treatments and therapeutic inertia. Review of the prescriptions by the specialist pharmacist was an added value in optimising the treatment of these patients by means of a multidisciplinary team. It will be interesting to analyse the results at the 1 year follow-up when all patients should have received a visit: the changes implemented, control of the lipid profile after the intervention as well as the savings in drug costs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-136 DISPROPORTIONALITY ANALYSIS OF THE SKIN TOXICITY OF INGENOL MEBUTATE USING THE FDA ADVERSE EVENT REPORTING SYSTEM DATABASE

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10.1136/ejpharm-2021-eahpconf.255

Background and importance Ingenol mebutate was granted a marketing authorisation from European Medicines Agency (EMA) to treat actinic keratosis. On 30 April 2020, due to an increased risk in provoking skin cancer in treated patients compared with imiquimod, the EMA withdrawn it after a safety data review. The final results of the 3 year safety study (NCT01926496) in 484 patients showed that, among skin malignancies, squamous cell carcinoma (SCC) had a higher incidence with ingenol mebutate gel compared with imiquimod (3.3% versus 0.4% of patients).

Aim and objectives This study aimed to evaluate the safety issue (signal) of increased occurrence of skin malignancy (eg, SCC of the skin) during therapy with ingenol mebutate by mining of the FDA Adverse Event Reporting System (FAERS) database.

Material and methods By querying the FAERS database, we searched for cases of SCC associated with ingenol mebutate using the following MedDRA preferred terms (PTs) 'squamous cell carcinoma of skin', 'skin squamous cell carcinoma metastatic' and 'skin squamous cell carcinoma recurrent'. With a contingency table, we computed the PRR to evaluate the strength of association between SCC and ingenol mebutate.

Results We found the following co-occurrence data: ingenol mebutate/SCC (DE)=90 reports, ingenol mebutate/other ADR (De)=5128, other drugs/SCC (dE)=2882 and other drugs/other ADR (de)=13 899 084 from 2012 to 2020. The two by two contingency table showed a value for PRR of 44.4105 (95% CI 33.332 to 59.1711, $p < 0.001$). Assessment of SCC reports revealed that all ADR were serious and resulted in different outcomes: 80% other outcomes, 11.11% life threatening, 6.6% hospitalised and 2.2% disabled. Patients affected were aged 65–85 years (56.6%), 18–64 years (23.3%), >85 years (7.7%) and not specified (12.2%); 75.6% were men and 23.3% women.

Conclusion and relevance Disproportionality analysis showed that the ingenol mebutate–SCC pair was reported more often than expected. Based on this statistical association, our data confirmed the safety signal evaluated by the EMA that led to the withdrawal of ingenol mebutate from the

EU market. In addition, it raises the question of why the FDA has not revoked the marketing authorisation of the drug in the USA.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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Conflict of interest No conflict of interest

5PSQ-137 ADEQUACY OF DIAGNOSIS AND TREATMENT OF PHARYNGOTONSILLITIS

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10.1136/ejpharm-2021-eahpconf.256

Background and importance Acute pharyngotonsillitis is the most prevalent infectious disease in primary healthcare, with inadequate prescription of antibiotics without diagnostic evidence through the application of the Centor criteria and the rapid antigen detection test for group A β -haemolytic *Streptococcus*.

Aim and objectives To evaluate in our territory the degree of adequacy of: (1) the diagnostic procedures for pharyngotonsillitis and (2) antibiotic treatment.

Material and methods A retrospective observational study was conducted in patients diagnosed with pharyngotonsillitis during 2019 in 20 primary healthcare centres. Demographic variables (age and sex), Centor criteria, rapid antigen test and antibiotic prescriptions were collected.

Results 5283 patients were included, aged 9 (6–13) years, and 2759 (52.2%) were women. Of 1062 (20.1%) adult patients, 234 (22%) did not have a record of the Centor score, and 420 (39.5%) with a Centor score ≥ 2 did not undergo an antigen test. Antibiotic treatment was given to 76 (7.2%) patients without registration of the Centor score or test, to 53 (5%) with a Centor score < 2 and no test, and to 49 (4.6%) with a negative test. In contrast, 4 (0.4%) patients with a Centor score of ≥ 2 and a positive test did not receive an antibiotic. Of 4221 (79.9%) paediatric patients, 295 (7%) did not have a record of the Centor score, and 1492 (28.2%) with a Centor score ≥ 2 did not undergo a test. Antibiotic treatment was given to 97 (2.3%) patients without registration of the Centor score or test, to 53 (1.3%) with a Centor score of < 2 and no test, and to 213 (5.1%) with a negative test. In contrast, 84 (2%) patients with a Centor score of ≥ 2 and a positive test did not receive an antibiotic.

Conclusion and relevance The pharyngotonsillitis diagnostic workup (application of the Centor criteria and rapid antigen test) was far from optimal, especially in the adult population. Accordingly, there was a moderately inappropriate prescription of antibiotics, although less in the paediatric population. Optimising the use of antibiotics in pharyngotonsillitis treatment requires maintenance of the dissemination of recommendations and advice.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest