A TWO-YEAR RETROSPECTIVE ANALYSIS OF ADVERSE DRUG REACTIONS WITH FLUOROQUINOLONE AND QUINOLONE ANTIBIOTICS

V. Borsi[1], M. Del Lungo[2], L. Giovannetti[1], M.G. Lai[1], M. Parrilli[1]

[1] Azienda USL Toscana Centro, Pharmacovigilance Centre, Florence, Italy
[2] Dept. of Neurosciences, Psychology, Drug Research and Child Health (NEUROFARBA), Section of Pharmacology and Toxicology , University of Florence, Italy

5PSQ-031

24th Congress of eahp european association of hospital pharmacists

27-29 March 2019

BACKGROUND

On 9 February 2017, the Pharmacovigilance Risk Assessment Committee (PRAC) initiated a review[1] of disabling and potentially long-lasting side effects reported with systemic and inhaled quinolone and fluoroquinolone antibiotics at the request of the German medicines authority (BfArM) following reports of long-lasting side effects in the national safety database and the published literature.

PURPOSE

To review the adverse drugs reactions (ADRs) of systemic and inhaled fluoroquinolone and quinolone antibiotics that involved peripheral and central nervous system, tendons, muscles and joints reported from our Pharmacovigilance Department (PVD).

MATERIAL AND METHODS

Retrospective analysis of ADRs reported in our APVD involving ciprofloxacin, flumequine, levofloxacin, lomefloxacin, moxifloxacin, norfloxacin, ofloxacin, pefloxacin, prulifloxacin, rufloxacin, cinoxacin, nalidixic acid, pipemidic given systemically (by mouth or injection). The period considered is September 2016 to September 2018.

RESULTS

22 ADRs were reported in our PVD involving fluoroquinolone and quinolone antibiotics in the period considered and that affected peripheral or central nervous system, tendons, muscles and joints. The mean patient age was 67,3 years (range: 17-92 years). 63,7% of the ADRs reported were serious, of which 22,7% caused hospitalization and 4,5% caused persistent/severe disability. 81,8% of the ADRs were reported by a healthcare professional (physician, pharmacist or other) and 18,2% by patient or a non-healthcare professional. Fluoroquinolone and quinolone antibiotics reported in these ADRs were mainly used for urinary tract infections (40,9%) and respiratory tract infections (31,8%).

Line listing of selected seriuos reports

PATIENT SEX	AGE (years)	GRAVITY	OUTCOME (at the day of the report)	PRIMARY SOURCE QUALIFICATION	SUSPECT DRUG LIST	REACTION LIST PT	CONCOMITANT DRUG LIST
F	92	Other relevant clinical condition	Improvement	Healthcare professional	Levofloxacin	Abdominal pain, Disorientated, Hyperactivity, Absent-minded	Allopurinol
M	73	Hospitalized	Not resolved	Healthcare professional	Ciprofloxacin	Confusional state	Diclofenac
M	90	Other relevant clinical condition	Improvement	Healthcare professional	Levofloxacin	Fatigue, Circadian rhythm sleep disorder, Confusional state, Psychomotor retardation, Tonic clonic movements	Pantoprazole, Levothyroxine, Nytroglicerin, Glycopyrronium bromide, Escitalopram, Hydrochlorothiazid, Canrenone, Dorzolamide, Timolol, Enoxaparin
M	45	Disabled	Not resolved	Patient	Levofloxacin	Fatigue, Blurred vision, Dry eye, Insomnia, Nightmare, Tendon Pain	Not reported
F	46	Hospitalized	Not known	Patient	Levofloxacin	Diarrhoea, Insomnia, Nausea, Decreased appetite	Not reported
F	77	Hospitalized	Not known	Healthcare professional	Ciprofloxacin	Confusional state, Seizure, Tremor	Not reported

CONCLUSION

On 5 October 2018, the European Medicines Agency (EMA) PRAC has recommended restricting the use of fluoroquinolone and quinolone antibiotics[2] (used by mouth, injection or inhalation), that will become applicable only after the decision of the Committee for Medicinal Products for Human Use (CHMP). In the meantime, this work could help in make the healthcare professionals aware of a range of possible side effects (apart from Achilles tendon disorders) attributable to fluoroquinolone and quinolone antibiotics and that could be life-changing and wide ranging.

http://www.eahp.eu/24-5PSQ-031

REFERENCES

1. EMA Quinolone and fluoroquinolone Article 31 referral – Notification. Available at https://www.ema.europa.eu/documents/referral/quinolone-fluoroquinolone-article-31-referral-notification_en.pdf (accessed: 15 october 2018).
2. EMA Quinolone and fluoroquinolone Article 31 referral – Recommendation provided by PRAC. Available at https://www.ema.europa.eu/documents/referral/quinolone-fluoroquinolone-article-31-referral-recommendation-provided-prac_en.pdf (accessed: 15 october 2018).

Contact: valentina.borsi@uslcentro.toscana.it