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Safe Multidisciplinary Management of New Therapies: The Ritmo Project (Real Time Continuous Web Monitoring)

Author Block: Laura Lopi, Fulvio Glisenti, Elena Rocco, Emanuele Visco, Clara Villa, Savina Nodari, University of Brescia, Department of Clinical and Surgical Specialities, Cardiology Section, Brescia, Italy, Health Telematic Network, Brescia, Italy

Abstract:
Background: Fingolimod is an immunosuppressive drug that prevents the typical autoimmune responses of multiple sclerosis (MS). This drug can cause, even after the first dose, bradycardia and atrioventricular conduction block (AVB). According to a decree of the Committee for Medicinal Products for Human Use (CHMP), the first administration of a dose of fingolimod must meet the following conditions: a) 12-lead electrocardiogram (ECG) and blood pressure (BP) evaluations before first dose administration; b) continuous ECG and BP monitoring every hour during the first 6 hours of treatment. The aim of the study was to evaluate the efficacy of our virtual Intensive Care Unit connected to selected Departments of Neurology for cardiology monitoring via web, during the first dose administration of fingolimod in patients (pts) with MS.

Methods: Health Telematic Network (HTN), in collaboration with our Cardiology Department, has installed in several Neurology Departments in the country intensive care equipment with real time monitoring via the web of ECG, BP and oximetry. The telemonitoring system is composed of an IntelliVue MP2 monitor, for 12-lead ECG recording, and by an IntelliVue Philips M3150 Central, for continuous remote monitoring of ECG end the detection and storage of arrhythmias. The HTN Cardiologist thus can evaluate in real time ECG monitored and each alarm detected.

Results: From Jan 2014 to Jun 2016, 172 sites participated and 4003 pts were enrolled. The telemonitoring system recognized 3205 episodes of bradycardia, 187 first degree AVB, 138 second degree AVB Mobitz I, 38 second degree AVB Mobitz II, 409 pathological lengthening of the QTc interval, single monomorphic ventricular ectopic beats in 138 pts, bigeminy ventricular extrasystoles in 12 pts and polymorphic ventricular extrasystoles in 3 cases. 5 cases of non-sustained ventricular tachycardia occurred and were recognized.

Conclusions: This real time telemonitoring project was an optimal solution for the administration of the first dose of fingolimod, according to current indications of the CHMP. The RITMO project could lead the way for the use of a multidisciplinary approach for the management of new therapies.

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