

The Contribution of National Spontaneous Reporting Systems To Detect Signals of Torsadogenicity: Issues Emerging From the ARITMO Project

Drug Safety

Emanuel Raschi^{1*}, Elisabetta Poluzzi^{1*}, Francesco Salvo^{2,3,4}, Ariola Koci¹, Marc Suling⁵, Stefania Antoniazzi^{2‡}, Luisella Perina¹, Lorna Hazell⁶, Ugo Moretti⁷, Miriam Sturkenboom⁸, Edeltraut Garbe⁵, Antoine Pariente^{2,3,4}, Fabrizio De Ponti¹

* equally contributed to the present work

¹ Department of Medical and Surgical Sciences, University of Bologna, Italy

² Univ. Bordeaux, U657, F33000 Bordeaux, France

³ INSERM U657, F33000 Bordeaux, France

⁴ CIC Bordeaux CIC1401, F33000 Bordeaux, France

⁵ Leibniz Institute for Prevention Research and Epidemiology - BIPS, Bremen, Germany

⁶ Drug Safety Research Unit, Southampton, UK

⁷ Department of Public Health and Community Medicine, University of Verona, Italy

⁸ Erasmus Medical Center, Rotterdam, The Netherlands

[‡] Current affiliation: Unit of Clinical Pharmacology, Department of Biomedical and Clinical Sciences, University Hospital "Luigi Sacco", Università di Milano, I20157 Milan, Italy

Correspondence: fabrizio.deponti@unibo.it

Electronic Supplementary Material

Table S1. Free text search strategy (i.e., a list of terms and strings) used to extract cases from the narratives in the Italian and French databases.

Outcome definition *	Italian version	French version
Group 1	*torsade* OR (*torsione* And *punta*)	*torsade* OR *TdP*
Group 2A and 2B	*qt* OR (*onda* AND *u* And NOT *inversio*) OR (*fenomeno* AND *R su T*) OR *ripolarizzazione*	qt* OR (*onde* AND *u* AND NOT *inversio*) OR ((*phénomèn* or *phenomen*) AND *R sur T*) OR *repolarisation*.
Group 3A	(*ventricular* OR *cardiac*) And *fibrill* AND NOT *atri*	(*ventriculaire* OR *cardiaqu*) AND *fibrill* AND Not (*atri* OR *auriculo*)
Group 3B and 3C	(*tachicardi* OR *tachiaritm* Or *extrasistol*) AND NOT *sopraventri* AND NOT *atri* And Not *sovraventri*	(*tachycardi* OR *tachyarythm* OR *extrasystol*) AND NOT (*supraventri* OR *atri* OR *sus-ventric* or *auriculo*)
Group 4A	*morte improvvisa* OR *arresto cardi*	*mort inattendu* OR *arret cardi* OR *arrêt cardi*
Group 4B	*sincope* OR *incoscienza* OR *perdita di coscienza* OR *perdita di conoscenza* OR *Adams-Stokes*	*syncope* OR *perte de connaissance* OR *Adams-Stokes*.

* for details on the outcome definition see Poluzzi E, Raschi E, Koci A, Moretti U, Spina E, Behr ER, Sturkenboom M, De Ponti F. Antipsychotics and torsadogenic risk: signals emerging from the US FDA Adverse Event Reporting System database. Drug Saf. 2013 Jun;36(6):467-79. doi: 10.1007/s40264-013-0032-z.