Supplementary Information

Sirolimus Therapy and Dyslipidemia in Neonates and Infants: A Retrospective Cohort and Pharmacovigilance Analysis

Akinobu Taniguchi, Basile Chrétien, Takashi Maeda, Kazuto Ueda, Ryosuke Miura, Ryuichi Tanaka, Toshihiko Suzuki, Yukako Muramatsu, Yoshiaki Sato, Kazuki Nishida

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The READUS-PV checklist for abstracts

Section and topic	Item #	Checklist item	Location where item is reported
Background	*1a*	*State the aim/rationale for performing the study.*	*L2 to 4*
	1b	*Specify the adverse event(s) and/or the drug(s) under study, when applicable.*	*L2 to 4*
	1c	*Specify the specific population or setting, when applicable.*	*L2 to 4*
Methods	*2a*	*Identify the study as a "disproportionality analysis" and specify the type of data used.*	*L 10 and 11*
	2b	*Specify the name of the database(s) used and the type of access.*	*L10*
	2c	*Specify the timeframe and geographical region, when applicable.*	*L10-11*
	2d	*Specify the disproportionality measure(s) used and their statistical significance threshold(s).*	*L14*
	2e	*Specify if a case-by-case analysis is performed.*	*NA*
Results	*3*	*Report main findings including their precision (e.g., 95% confidence intervals), together with a short summary of the case-by-case analysis.*	*L16 to 21*
Conclusion	*4a*	*Clearly report key conclusions.*	*L22 to 25*
	4b	*Acknowledge that the disproportionality analysis is a hypothesis generating or refinement approach.*	*L23 to 25*
	4c	*State the implications and clinical relevance of the findings.*	*L23 to 25*

The READUS-PV checklist

Section and topic	Item #	Checklist item	Location where item is reported
Title			
	1a	*If disproportionality analyses are a prominent component of the published study, the study should be identified as a "disproportionality analysis". The type of data and name of the database(s) should be specified.*	*Not in title; Abstract L9–10 and Methods L77–79*
	1b	*Report the name of adverse event(s) and/or drug(s) under study, when applicable.*	*Title*
Introduction			
Background	*2a*	*Describe the drug(s) and its utilization, the nature of the adverse event(s) under study and its frequency, and the existing knowledge on the drug-event combination.*	*L2 to 39*
	2b	*Specify the rationale for performing the analysis, e.g., as part of routine pharmacovigilance, to investigate an overall safety profile, or to assess a pre-specified hypothesis.*	*L44 to 49*
	2c	*Explain why ICSR databases and disproportionality analysis are suitable to fill the knowledge gap.*	*L40 to 43*
Objectives	*3*	*State specific objectives, identifying the adverse event(s), the drug(s), and the reference group, including any pre-specified hypothesis, if applicable.*	*L46 to 49*
Methods			
Study design	*4a*	*Identify the study (i.e., "disproportionality analysis") and the type of data used (e.g., "individual case safety reports").*	*L77–79 and L100–102*
	4b	*Provide an outline of the entire study design, including primary and sensitivity analyses performed, and other designs such as case-by-case analysis or literature review.*	*L50 to 109*
Data description, access, and pre-processing	*5a*	*Specify the name of the database(s), the database(s) custodian, and the coverage. Specify the type/number of drugs included within the database and the thesaurus, taxonomies, or ontologies used for coding drugs and events.*	*L77 to 85*
	5b	*Specify the extraction dates and describe and justify all choices used for data pre-processing, including any data transformation or exclusion, if appropriate.*	*L77 to 85*
Variables definition	*6a*	*Describe the study population, including any restriction.*	*L77 to 90*
	6b	*Describe the nature and the meaning of key variables assessed in the work.*	*L80 to 99*
	6c	*Specify and justify any grouping of drugs or events. For drugs, specify and justify whether active ingredients/trade names/salts were considered and/or the selected role.*	*L80 to 99*
	6d	*Describe any additional data source used, the type of data, and how they interact with ICSRs.*	*L50 to 109*

Statistical methods	*7a*	*Present any descriptive analysis performed, specifying variables investigated, statistical tests, and significance thresholds.*	*L100 to 109*
	7b	*Describe the measure(s) selected for the disproportionality analysis including any threshold used to identify signals of disproportionate reporting. Explain the reason for this choice if applicable.*	*L100 to 109*
	7c	*Clearly describe any sensitivity analysis and any tool to control confounding, including any restriction, subgroup, stratification, adjustment, or interaction.*	*L100 to 109*
	7d	*Specify the variables and methods used for the case-by-case analysis, including any algorithm or criteria used to assess causality, if performed.*	*NA*
	7e	*Specify any statistical methods used for other data sources.*	*L52 to 74*
Results			
Participants	*8a*	*Specify the number of individual case safety reports included at each stage, including reasons for exclusion.*	*L84–85 and L146–147*
	8b	*Provide key demographic and clinical characteristics of cases, if possible comparing cases with any appropriate reference group.*	*L147-151*
Disproportionality analysis	*9*	*Present all results including confidence intervals. Present also results of sensitivity analyses, if performed.*	*L153-160 and Tables 2–4*
Case-by-case analysis	*10*	*Present the case-by-case analysis of key variables. Present the causality assessment, if applicable.*	*NA*
Discussion			
Key results	*11*	*Discuss key results with reference to study objectives and contextualize them within the current literature and other consulted sources. Clearly discriminate between expected reactions and emerging safety signals.*	*L180-218*
External validity	*12a*	*Discuss the external validity of the results to the general population.*	*L231-255*
	12b	*Discuss the potential relevance of results in clinical practice*	*L219–230 and L256–261*
	12c	*Propose further study designs if applicable*	*L253–255*
Limitations	*13*	*Present general limitations, making clear that disproportionality analysis alone cannot prove causation or measure incidence, and specific limitations, including confounding and reporting bias and efforts to mitigate them.*	*L231-255*
Declarations			
	14a	*Provide the source of funding/sponsorship and the role of the funders/sponsors for the present study and for any original study on which the present article is based.*	*L418–427*
	14b	*Clearly identify potential commercial and intellectual conflicts of interest (e.g., link to any drug/event investigated, whether financial, legal action, or software used).*	*L428–432*

	14c	*Declare any institutional approval needed or granted in the investigation.*	*L74–76 and L447–448*
	14d	*Include a statement on data availability, code availability (including the version of the statistical software used), and protocol registration.*	*L108–109 and L444–451; protocol registration: NA*

Fusaroli, M., Salvo, F., Begaud, B. *et al.* The Reporting of a Disproportionality Analysis for Drug Safety Signal Detection Using Individual Case Safety Reports in PharmacoVigilance (READUS-PV): Development and Statement. *Drug Saf* **47**, 575–584 (2024).