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REAL WORLD DATA OF MONOCLONAL ANTIBODIES FOR THE TREATMENT OF HYPERLIPIDEMIA: ANALYSIS THREE YEARS AFTER INTRODUCTION IN CLINICAL PRACTICE

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BACKGROUND AND IMPORTANCE

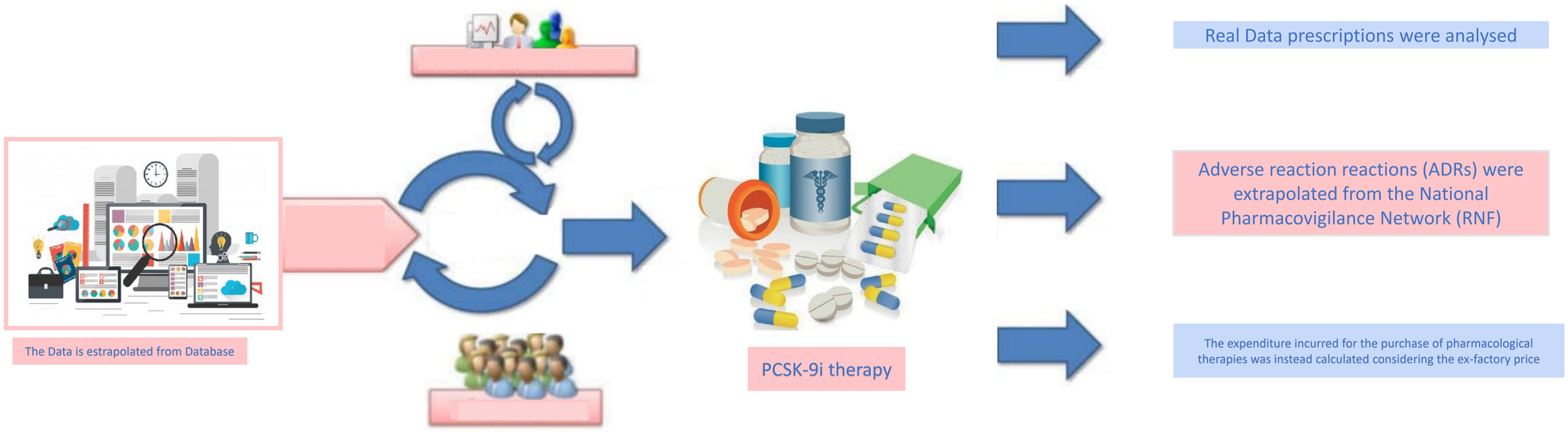
Hyperlipidemias are the main risk factor for the early manifestations of atherosclerosis and related complications. In recent years, new monoclonal antibodies are available in clinical practice (evolocumab and alirocumab), called PCSK9-inhibitors (PCSK9i). Web-based monitoring register in use monitor the access to therapy.

AIM AND OBJECTIVES

The objectives of the study were to determine the direct healthcare costs in the three-year period 2017-2019, as well as the incidence of adverse events reported by clinicians related to PCSK-9i therapy at the regional level.

MATERIAL AND METHODS

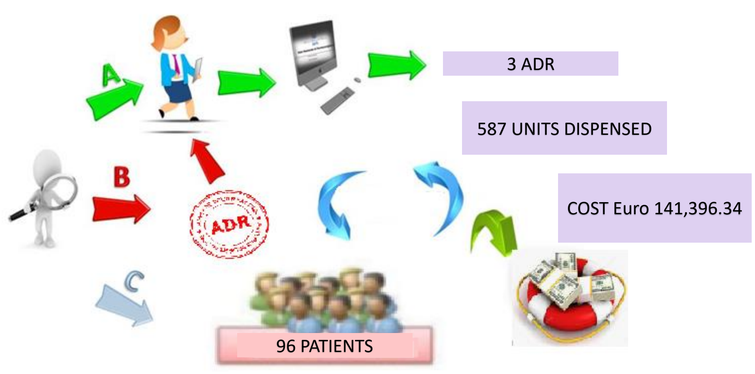
A retrospective study was conducted. The real data (prescription, dispensed units) have been derived from informatics administrative databases. The expenditure incurred for the purchase of pharmacological therapies was instead calculated considering the ex-factory price net of the SSN discounts. Adverse reaction reactions(ADRs) were extrapolated from the National Pharmacovigilance Network (RNF) and evaluated using the Naranjo's algorithm.



RESULTS

In 2017, first year PCSK9i became available, a total of 96 patients were treated (78.5% evolocumab; 21.5% alirocumab), for a total of 587 units dispensed and expenses incurred equal to Euro 141,396.34. In the period under study, there is a growing trend in units dispensed. 2018 shows an increase of +429% vs 2017, probably due to the conclusion of some clinical trials. Evolocumab was preferred to alirocumab (delta 2018-2019=+163.70%). In particular, one of the five Local Health Authorities appears to have dispensed 46.81% of the total units.

Only 3 ADRs occurred in regional patients. Patients (M: F = 2: 1), with mean age 64.33 ± 15.27 years, had been in treatment for 45 days. 75% of ADRs are attributable to evolocumab.



Naranjo's algorithm revealed that 25% of ADRs related to evolocumab are classified as possible, 75% as likely (distributed equally between the two active ingredients).

CONCLUSIONS

Although the analysis shows an increase in the use of evolocumab, the incidence of use still remains too low compared to potential patients eligible for treatment (n = 637) [1]. The clinical pharmacist, thanks to his knowledge and skills, is able to take up the challenge that the new paradigm of real world data is posing to us and generating "real data for real tests".