

## PHARMACOVIGILANCE IN SPA MEDICINE

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**Introduction:** Pharmacovigilance is devoted to the study of the Adverse Drug reactions (ADR), hazards and adverse events (AE) associated to the use of pharmaceutical products. In Italy, for spa treatments the collection of reports on AE and/or ADR is very scarce or almost nonexistent. On the basis of these considerations and given the importance that pharmacovigilance assumed in recent years for the National Health Service sustainability, the main results, obtained in various studies carried out in different Italian spa's structures, have been systematized. The purpose of the present study is to perform a depth analysis in this field and to sensitize General Practitioners and Specialists in spa therapy to spontaneous report of AE and/or ADR related to spa treatments prescription in order to fill the gaps in this medical area.

**Patients and methods:** Prospective observational studies carried out in spa's Italian structures (e.g. Lurisia spa-CN, Teleso spa-BN, Terme Nitrodi spa-Ischia-NA, Terme Rosapepe spa-Contursi-SA, Stufe di Nerone spa-NA) in the period 1997-2016 were considered for a total of 1157 subjects (685 female gender and 472 male gender), aged between 3-89 years. These subjects had been sent by their General Practitioner or Pediatricians or other Specialists to carry out a spa cycle for treatment of their chronic diseases. We considered descriptive characteristics of the enrolled subjects and the following outcomes: the chronic pathologies that motivated the spa prescription; the frequency of use of the spa application methods and the effectiveness and safety of the used treatments, deduced from the remission rate of the symptomatology considered and by the occurrence of AE or ADR, respectively.

**Results:** The data analysis showed that: the majority of the subjects who have undergone spa treatments were retired. Moreover, the osteoarthritis, which is the most common chronic condition of the joints, was also the most frequent pathologies that had led physicians to prescribe spa treatments and consequently the spa mud-bath cycle was the most widely used spa application method. An improvement in the symptomatology with a good-excellent result was found in over 74% of the analyzed cases. In almost all the patients a good local and systemic tolerability was observed, even if there were cases of interruption of the treatment due to adverse events, including increase of painful symptomatology (0.25%), increase of inflammatory process (0.2%).

**Conclusions:** Based on these preliminary results, General Practitioners and spa Physicians started to become aware on the importance of pharmacovigilance also in spa medical area. This might be very useful for setting up a health-monitoring center (which could be called "crenovigilance center") that implements a rational planning and integration of the available therapeutic aids for treatment of chronic pathologies with a great social impact.