4. SPECIAL CONDITIONS

CURRENT STATUS OF REGISTRY OF MONOCLONAL GAMMOPATHIES - THE CZECH MYELOMA GROUP "REAL WORLD“ DATABASE

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Introduction. The collection of "real-world" clinical data in patients with hematological malignancies through dedicated registries is becoming increasingly important due to limited patient recruitment into clinical trials caused by strict inclusion criteria. Low-grade malignancies, in particular, require long-term follow-up and the availability of valid, high-quality data. These considerations led us to the establishment of the Registry of Monoclonal Gammopathies (RMG) in 2007, which has since become the main project of the Czech Myeloma Group (CMG). Currently, five registry modules are active: monoclonal gammopathy of undetermined significance (MGUS), smoldering multiple myeloma (SMM), multiple myeloma (MM), AL amyloidosis (ALA), and Waldenström’s macroglobulinemia (WM).

Aim To present the current status of the RMG with respect to the volume of collected data.

Methods. Prior to inclusion in the registry, all patients provide written informed consent. Data on diagnosis, demographics, treatment, and survival are prospectively collected and regularly updated via an online system. The registry undergoes regular monitoring, and entered data are verified by an external monitor, following standards comparable to those used in clinical trials. Collected data are continuously updated to reflect advances in diagnostic and therapeutic procedures. These activities are carried out by the RMG Working Group in close cooperation with the Institute for Biostatistics and Analysis, which administers the registry database. The database currently operates on the CLADE-IS platform. In 2018, a new data-visualization system was introduced, enabling participating centers to analyze their own data and perform pilot validations for joint analyses.

Results. By the end of 2025, 23 centers (19 from the Czech Republic and 4 from Slovakia) were contributing data to the RMG. The registry included data from 11,173 patients with MM, 5,265 with MGUS, 408 with SMM, 402 with WM, and 176 with ALA, totally 17,828 patients. The median follow-up time was 10 years for patients with MGUS and 7 years for patients with MM. The extensive dataset has enabled numerous analyses and publications focusing on diagnostic characteristics and, in particular, treatment outcomes of MM patients receiving novel therapies in the Czech Republic. Based on registry data, proprietary prognostic models for progression in MGUS and SMM have been developed. RMG data have also been repeatedly utilized in international collaborative projects involving the CMG, including Harmony and Honeur.

Conclusions. The RMG is one of the largest registries of its kind in Europe and likely worldwide. Its major strength lies in the collection of verified, up-to-date data that allow for rapid analyses in response to evolving trends in myeloma research and treatment. The registry supports the development of new clinical guidelines and serves as an effective research platform. Additionally, RMG data have been repeatedly used to prepare supporting materials for reimbursement negotiations with health insurance providers and governmental regulatory authorities, facilitating the introduction of new drugs into treatment standards in the Czech Republic.