REAL WORLD DATA ON BIOLOGICAL DRUGS USED IN ONCOLOGY: A 5 YEARS PICTURE' IN SOUTHERN ITALY

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In recent years, the use of biological drugs in onco-hematology rapidly increased. Most of the recently marketed biological drugs in this therapeutic area are monoclonal antibodies and tyrosine-kinase inhibitors, which improved quality of life and progression-free and overall survival. The high costs of these drugs may have important implications for the National Health Systems. It is therefore necessary to explore the pattern of use and the economic impact of these drugs in routine care.

To investigate the use and the costs of biological drugs in onco-hematology in a general population of Southern Italy in the years 2010-2014.

This was a retrospective, drug-utilization study, using data from the administrative healthcare databases of the Local Health Unit (LHU) and the two main hospitals of Messina Province, during the years 2010-2014. The biological study drugs were classified into monoclonal antibodies (mAb), fusion proteins, immunomodulatory agents and small molecules, the latter including tyrosine kinase inhibitors (TKi), mammalian target of rapamycin inhibitors (mTOR-i) and proteasome inhibitors. The prevalence of the study drugs use as well as the corresponding costs were calculated over time and stratified by type of biological drug received at the ID.

Biological drug users (i.e., patients receiving at least one study drug during the years 2010-2014) were characterized, in term of demography (age and sex) and type of cancer, stratifying by type of biological drug received at the ID.

On a total population of 653,810 residents in the catchment area of Messina in the years 2010-2014, 2,627 (0.4%) patients received at least one study drug. During the study years, the prevalence of use doubled from 6.3 to 12.6 per 1,000 inhabitants, to a larger extent for small molecules (+126%) than for Mab (+85.2%).

The costs of the biological study drugs rapidly grew during the study years from 6.6 million Euros in 2010 (N. users = 591) to 13.6 Euros in 2014 (N. users = 1,150), for a total expenditure of 50,005,656.50 Euros.

Based on the study drug dispensed at ID, 1,714 patients (65.2%) received a mAb, while 913 (34.8%) were dispensed a small molecule; of the latter ones, TKi were more frequently prescribed (N= 637, 69.8%).

Mab users were more frequently females (60.0% of all Mab users) and mostly 45-64 years old (47.6%). The main indications of use were lymphomas, breast cancer and colorectal cancer (18.7%, 17.6% and 10.7%, respectively). On the other hand, small molecules users were more likely to be

males (57.2%) and to be older (65-79 years old: 46.4%) than mAB users. The main indications of use were lung cancer, multiple myeloma and leukemia (14.6%, 14.2% and 11%, respectively).

The use and corresponding expenditure of biological drugs in oncology rapidly increased in recent years in Messina province. Real world data are essential to monitor the benefit-risk profile as well as economic impact of these drugs in routine care, with the final goal to optimize the use of high cost biological drugs also in cancer patients. Networks of claims databases can be valid tools to timely monitor at loco-regional level the uptake of newly marketed high cost drugs.