SAFETY OF BEVACIZUMAB BIOSIMILAR IN CLINICAL PRACTICE IN NEW AND SWITCHED TREATMENTS

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INTRODUCTION

Efficacy and safety of emerging biosimilars is ensured by the comparative studies required for their centralized approval by the European Medicines Agency. However, there is a lack of studies of biosimilars safety in clinical practice. Recently a new biosimilar bevacizumab, Zirabev®, has been commercialized.

OBJECTIVE

To assess safety of bevacizumab biosimilar Zirabev® in clinical practice

MATERIALS AND METHODS

Prospective observational study from February to July 2021

RESULTS

Age -> 57,5 ± 13,7 years
BBP -> 124,3 ± 18,2/ 78,0 ±7,2 mmHg
Days with biosimilar-> 112,7 ± 46,9 days

- Type of cancer
- Baseline blood pressure (BBP)
- Days with biosimilar
- Treatment
  - New
  - Switching
- Restart
- Grade of AE (CTCAE criteria)
- Change in line
- Maintenance: ovarian, cervix and brain
- Treatment interruption

TOXICITY/ADVERSE EVENTS (AE)

CLINICAL

Most frencuent AE hypertension (G1-G2)

Most serious AE thrombotic-like events (G3)

CONCLUSIONS

Initiation of use of bevacizumab biosimilar in our center has shown a positive safety profile. Thrombotic-like reactions were more severe comparing to bibliography. Nevertheless, there were no serious adverse events (G4-5).