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

Cárdenas Sierra M., Palacios Filardo M., Goikolea Ugarte FJ., Knetch A., Ibarra Barrueta O., Miron Elorriaga G., De Juan Arroyo AM., Cobas Belso M., Martin Torrente A., Menendez Liendo L., Gemio Zumalave PR.,
Pharmacy Service, Hospital Galdakao-Usansolo

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

Collected variables

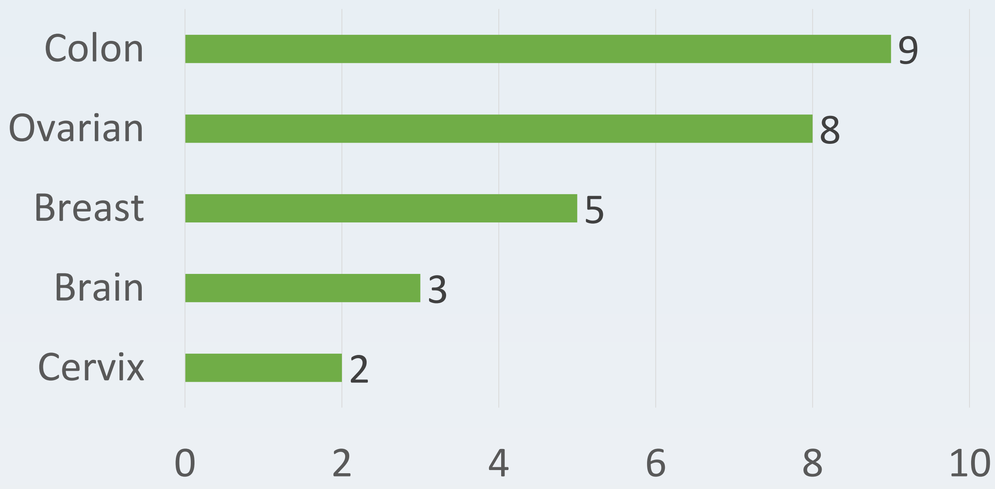
DEMOGRAPHIC
- Age
- Sex

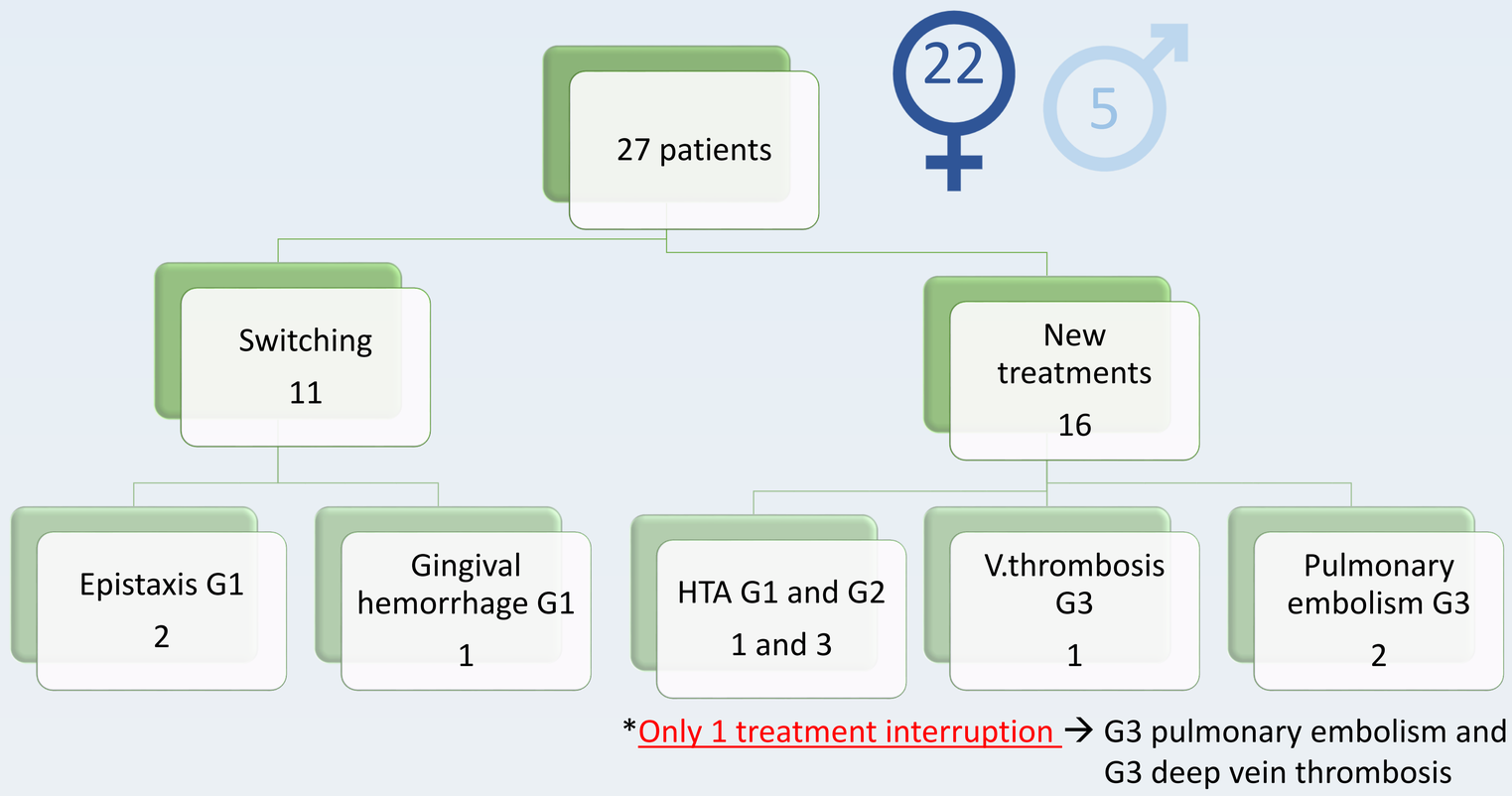
CLINICAL
- Type of cancer
- Baseline blood presure (BBP)
- Days with biosimilar
- Treatment
  - New
  - Switching
    - Restart
    - Change in line
    - Maintenance: ovarian, cervix and brain

TOXICITY/ADVERSE EVENTS (AE)
- Type of AE
- Grade of AE (CTCAE criteria)
- Treatment interruption

RESULTS

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





*Only 1 treatment interruption → G3 pulmonary embolism and G3 deep vein thrombosis

Most frecuent 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).