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AUC-SURVIVAL REANALYSIS OF TROPICS-02 TRIAL WITH SACITUZUMAB GOTIVECAN FOR METASTATIC LUMINAL BREAST CANCER

Authors: Bretones-Pedrinaci JI[1], Dominguez-Santana CM[2], Jimenez-Carbelo N[1], Castro-Vida MA [1], Alegre del Rey EJ[2].
1-HOSPITAL DE PONIENTE, PHARMACY, ALMERIA, SPAIN. 2-HOSPITAL UNIVERSITARIO PUERTO REAL, PHARMACY, CADIZ, SPAIN.

For further information contact:
ignabreci@hotmail.com

BACKGROUND AND IMPORTANCE

Sacituzumab govitecan (SG) was recently approved by European Medicines Agency for heavily treated metastatic breast cancer (mBC) patients positive hormone receptor (HR+) and human epidermal growth factor receptor-2(HER2) negative supported by TROPiCS-02 trial which compare standard chemotherapy (ChT). Pivotal study results in overall survival (OS) was **HR=0,78** IC95% (0,65-0,95). OS difference in median survival times was: **3,3 months**. Although medians are commonly used in oncology to measure the magnitude of the benefit between different drugs, this is not accurate because only measures the difference in one point of the curves. A visual inspection of Kaplan-Meier's survival functions of TROPiCS-02 suggested that the difference of medians could overestimate the OS benefit, as the curves separate in the central area.
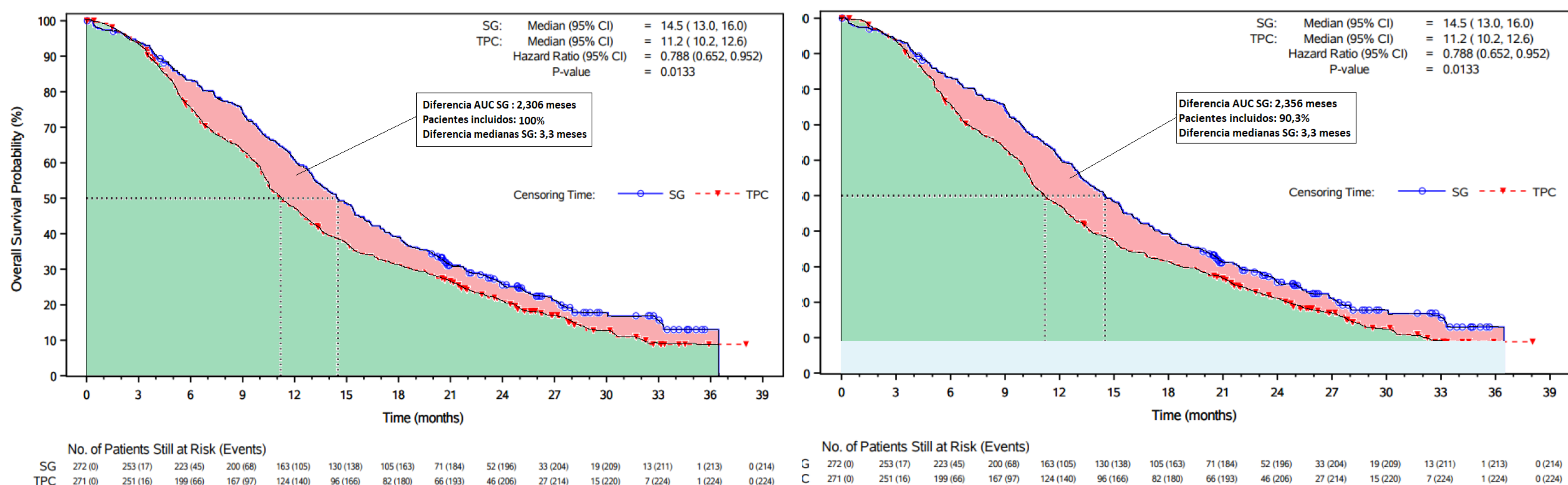
AIM AND OBJECTIVES

The aim of study was to reanalyse the OS benefit of SG from pivotal clinical trial by calculating the difference in mean survival time by area-under curves (AUC)-based methods.

MATERIAL AND METHODS

We use WebPoltDigitizer 4.6 to extract survival data at 100 points in each Kaplan-Meier's OS curves.
Mean survival times were estimated by AUC with Seruga's method (Ann Oncol 2012). with or without a correction from Fenix's method (1) (Eur J Clin Pharm 2015). The later prevents underestimation by subtracting the areas corresponding to the proportion of the population whose survival is greater than the maximum observation time.

RESULTS

The AUC-estimated difference for SG vs. standard ChT were **2,30 by Seruga's AUC method and 2,35 months** with the correction from Fenix et al. It was 1 month less than the difference of medians showed the pivotal study.

CONCLUSION AND RELEVANCE

European Society Medical Oncology rated this drug-indication with a score of 3 (not substantial benefit) in their Magnitude of Clinical Benefit Scale (0 to 5). Moreover, the difference of medians overestimated the benefit in the pivotal trial, as it was just shown by AUC-methods. These results suggest a modest benefit for SG in mBC HR+/HER2-. Indeed AUC-methods could be a good option when difference of medians are doubtful to estimate the benefit; its use should be extended.

REFERENCES

1-Fenix-Caballero S, Diaz-Navarro J, Prieto-Callejero B, Rios-Sanchez E, Alegre-del Rey EJ, Borrero-Rubio JM. New graphic AUC-based method to estimate overall survival benefit: pomalidomide reanalysis. J Clin Pharm Ther 2016; 41(1):1–3.