ADJUSTED INDIRECT COMPARISON OF CEMIPLIMAB IN COMBINATION WITH CHEMOTHERAPY VS. IMMUNOTHERAPY ALONE IN THE FIRST-LINE TREATMENT OF METASTATIC NON-SMALL-CELL LUNG CANCER IN PATIENTS WITH PD-L1≥50%

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BACKGROUND AND IMPORTANCE

Cemiplimab with chemotherapy is licensed for the treatment of **first line** adult patients with locally advanced **Non-Small Cell Lung Cancer** who are not candidates for chemoradiation, or metastatic, expressing PD-L1≥1%. Cemiplimab alone has the same indication in patients expressing PD-L1≥50%. Pembrolizumab and atezolizumab are also indicated in metastatic stage in patients with PD-L1≥50%.

AIM AND OBJECTIVES

To know whether **cemiplimab in combination with chemotherapy** (ct) and **mono-immunotherapy** can be declared **equivalent therapeutic alternatives** (ETA).

MATERIALS AND METHODS

✓ Phase III randomized clinical trials (CT) with similar characteristics were searched in **MEDLINE-Pubmed**.

✓ **Adjusted indirect comparison** (IC) was performed using **Bucher's method** (ITC calculator).

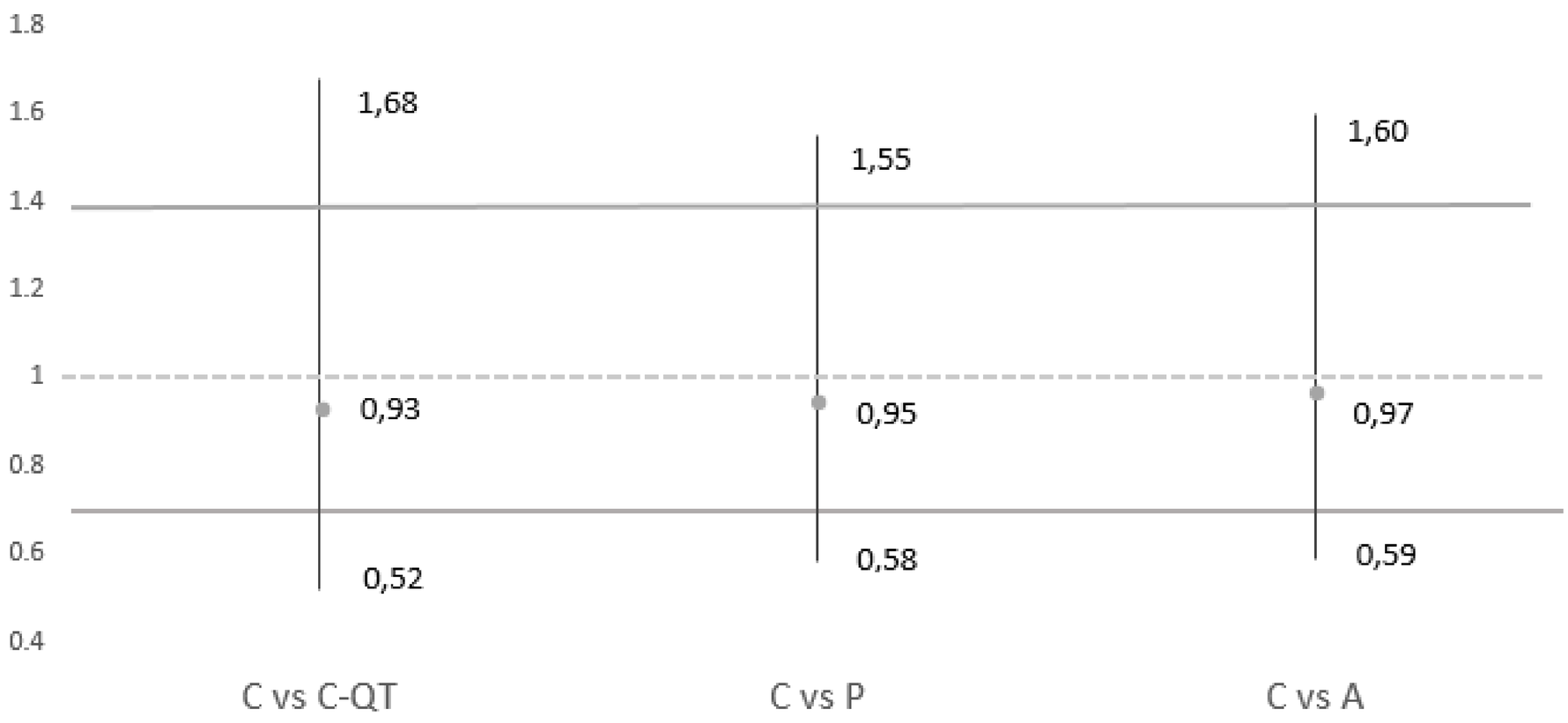
✓ Primary endpoint: **overall survival** outcomes in patients with **PD-L1≥50%**.

✓ All the combinations were compared with cemiplimab monotherapy.

✓ **Delta value (Δ),** maximum clinically irrelevant difference, was taken as the value from the ESMO-MCBS Guidelines to consider substantial benefit, **HR=0.70 and its inverse 1.43**.

✓ The **GENESIS-GHEMA guidelines** were applied to declare them as **ETA**

RESULTS



CT of cemiplimab excluded never-smokers (less than 100 cigarettes through life), and the small amount of never-smokers included on other monotherapy trials showed uncertain benefits.

According to the ETA guidelines, **cemiplimab+ct, atezolizumab, pembrolizumab and cemiplimab** showed "**probable clinical equivalence**". Clinically relevant differences between them cannot be discarded, since the confidence intervals exceed the equivalence margins, but this occurs at both extremes, and they can be considered as alternatives with similar effectiveness. **Cemiplimab+ct** presents a comparative **handicap** on **safety** because of the **toxicity of chemotherapy.**

CONCLUSION AND RELEVANCE

In this setting, **atezolizumab, cemiplimab and pembrolizumab monotherapies** can be positioned as **ETA**; their selection should be based on economic comparisons. Among the never-smoker subpopulation, the comparative effectiveness between immune-chemotherapy and mono-immunotherapy should be assessed.