

INDIRECT COMPARISON BETWEEN PEMBROLIZUMAB MONOTHERAPY AND PEMBROLIZUMAB CHEMOTHERAPY REGIMENS IN SQUAMOUS LUNG CANCER

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BACKGROUND AND IMPORTANCE

- **Pembrolizumab monotherapy (Pb)** showed benefit in overall survival (OS) and progression-free survival (PFS) versus chemotherapy alone (CT) in untreated metastatic non-small-cell lung cancer (mNSCLC) and PD-L1 \geq 50% expression.
- **Pembrolizumab-chemotherapy combination (Pb-CT)** presented benefit in OS and PFS untreated metastatic squamous NSCLC (mSNSCLC), regardless of PD-L1 expression.
- No randomized clinical trials (RCTs) of Pb-CT vs. Pb alone have been developed.

AIM AND OBJECTIVES

To assess the comparative efficacy between Pb and Pb-CT in untreated mSNSCLC patients with PD-L1 \geq 50% using an adjusted indirect treatment comparison (ITC).

MATERIAL AND METHODS

Bibliographic search at Pubmed database (02/10/2019).

- **Inclusion criteria:** phase III RCTs, Pb and Pb-CT treatments, similar mSNSCLC population (with PD-L1 \geq 50%), follow-up period and endpoints (OS or PFS).
- **Exclusion criteria:** mSNSCLC population with EGFR- or ALK-mutations.

ITC → developed using Bucher's method.

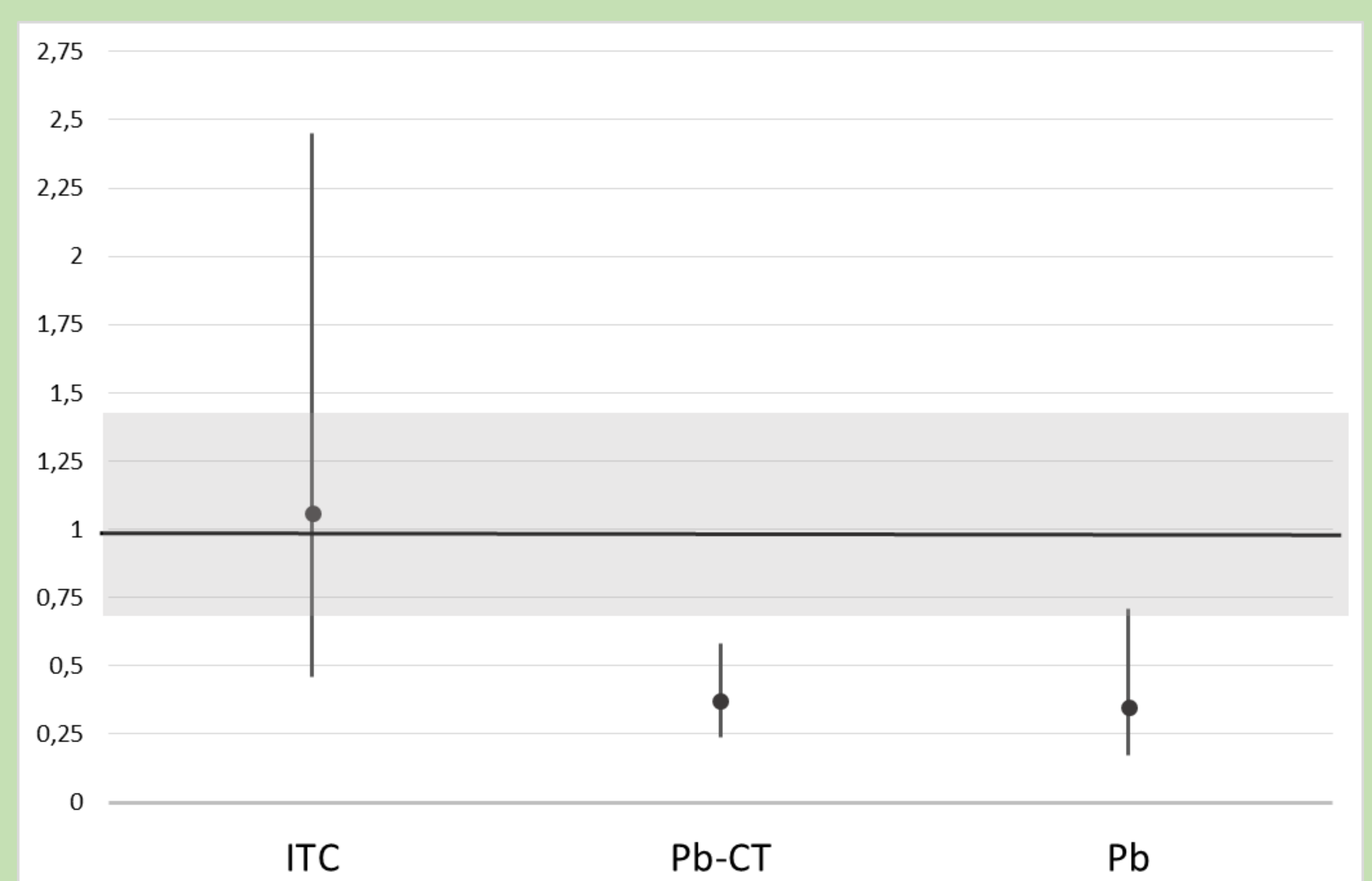
Δ → maximum acceptable difference as a clinical criterion of no-inferiority. Set at 0.70 (and its inverse, 1.43), value used to calculate the sample size in Pb-CT trial.

Shakespeare method → to estimate probability of results out of Δ margins.

RESULTS

- 2 studies found: one of each regimen.
- **Limitations** between Pb-CT and Pb trials:
 - Included populations: all patients vs. only patients with PD-L1 \geq 50% respectively, subgroup data used for ITC.
 - Small size of squamous subgroup.
- No OS data was available for squamous subgroup in Pb trial → then PFS was taken as primary endpoint for ITC.
- Results of RCTs and ITC:

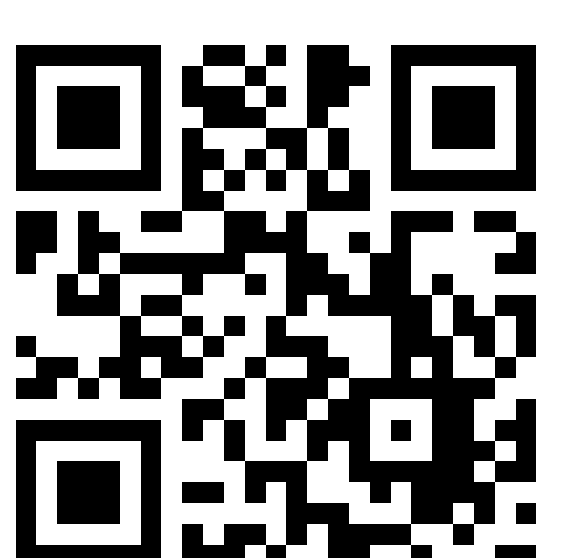
REFERENCE	PFS
Pb-CT vs. CT	HR=0.37 (95%CI, 0.24-0.58, PD-L1 \geq 50% subgroup)
Pb vs. CT	HR=0.35 (95%CI, 0.17-0.71, squamous subgroup)
Pb-CT vs. Pb (ITC)	HR=1.06 (95%CI, 0.46-2.45)



- No significant differences in PFS between Pb-CT and Pb were found. The 95%CI exceeded Δ on both sides (high level of uncertainty). Probability of a result out of Δ were 24.14% below and 16.54% above.

CONCLUSION AND RELEVANCE

ITC did not show significant differences in PFS between Pb-CT and Pb. No evidence of clinically relevant benefit from one or other regimen was found. Considering the toxicity related to addition of CT, Pb monotherapy would be preferable in untreated mSNSCLC with PD-L1 \geq 50%.



<https://www.eahp.eu/25-4CPS-076>