

# A COMPARATIVE ANALYSIS OF THE EFFICACY OF ADJUVANT TREATMENT WITH PEMBROLIZUMAB OR NIVOLUMAB IN PATIENTS WITH STAGE IIB/IIC MELANOMA

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## BACKGROUND AND IMPORTANCE

Patients with stage IIB/IIC melanoma have a comparable or elevated risk of recurrence and metastatic disease in comparison to those with stage III melanoma. Two drugs have recently been approved for adjuvant treatment.



Pembrolizumab



Nivolumab

There are no direct or indirect comparisons between existing treatments.

## AIM AND OBJECTIVES

The objective is to ascertain whether pembrolizumab (PEMBRO) and nivolumab (NIVO) can be designated as equivalent therapeutic alternatives (ETA) for patients with stage IIB/IIC melanoma through an indirect treatment comparison (ITC) adjusted using a common comparator.

## MATERIAL AND METHODS

### Graphical Analysis

Positioning was determined following the ETA Guidance.



### Literature search

To identify phase III clinical trials (CTs)

### Relevant indicator ESMO CRITERIA

Hazard Ratio (HR)  
 $\Delta$ : < 0.65  
 (and inverse, 1.54)



### RFS at 12 Months

Recurrence-free survival (RFS) was primary endpoint for treatment efficacy

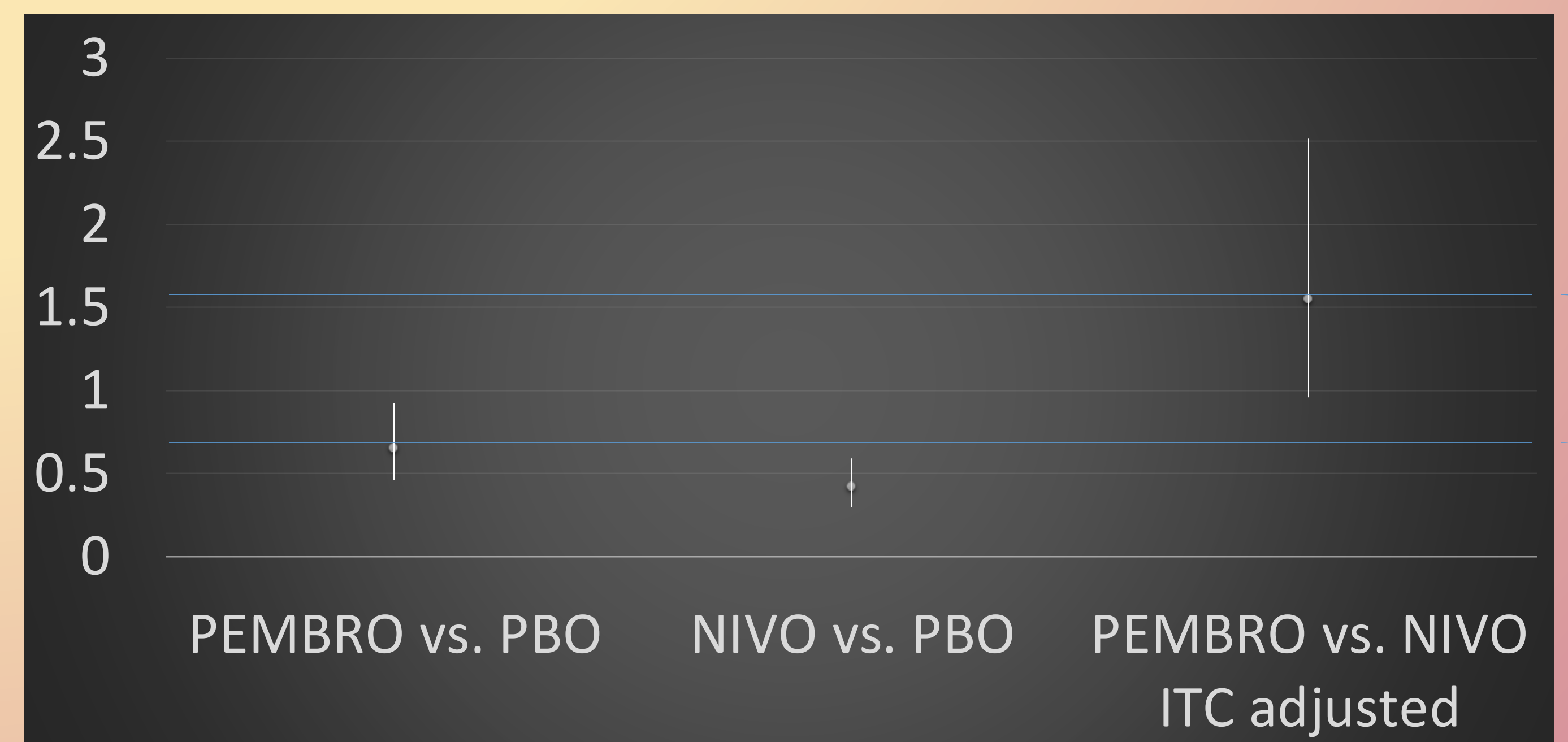
### ITC Methodology

Calculator: Canadian Health Technology Agency's Indirect Treatment Comparisons Methodology proposed by Bucher

## RESULTS

Two CTs were included. The CTs were: phase III, multicentre, randomised, double-blind, placebo-controlled and and the patients were >12 years with stage IIB/IIC melanoma.

Reference (CTs)	SLR [HR (95%CI)]	ITC [HR (95%CI)]
Pembrolizumab (Keynote-716)	0.65 (0.46 – 0.92)	1.548 (0.954 – 2.512)
Nivolumab (CheckMate-76K)	0.42 (0.30-0.59)	



The 95%CI exceeds the equivalence margin by more than 50%.

## CONCLUSION AND RELEVANCE

In accordance with the ETA guideline, PEMBRO and NIVO cannot be considered ETA for adjuvant treatment of patients with stage IIB/IIC melanoma, as there could be a probably relevant difference. The 95%CI obtained is wide, reflecting the imprecise result for pembrolizumab, which would be a limitation of our study.



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