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Sintilimab Plus Chemotherapy for First-Line Treatment of Advanced or Metastatic Nonsquamous Non-Small-Cell Lung Cancer: A Systematic Literature Review and Network Meta-Analysis

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BACKGROUND

- For advanced or metastatic nonsquamous non-small-cell lung cancer (AMnsqNSCLC), immune checkpoint inhibitor (ICI) combinations are recommended as frontline standard-of-care treatment in patients with good performance status regardless of PD-L1 status[1]
- Sintilimab is an emerging and viable selective anti-PD-1 antibody that inhibits interactions between PD-1 and its ligands, PD-L1/PD-L2[2]
- The phase 3 ORIENT-11 trial demonstrated superior efficacy and manageable safety with the addition of sintilimab to pemetrexed and platinum chemotherapy in AMnsqNSCLC in an Asian population[3]
- Sintilimab plus chemotherapy was submitted for regulatory approval in the US based on the ORIENT-11 study. However, the FDA was unable to approve the application in its current form, with FDA recommending an additional multiregional clinical trial comparing sintilimab against the standard of care for first line metastatic nonsquamous NSCLC
- The development of new ICIs continues to be an emerging topic
- In the absence of head-to-head evidence from trials comparing sintilimab to other recommended therapies, a network meta-analysis (NMA) may help support future ICI combination treatment decisions

OBJECTIVES

- This SLR and NMA compared the efficacy and safety of sintilimab+pemetrexed+platinum (SPP) vs FDA-approved and NCCN recommended immune checkpoint inhibitor-based regimens (ICIs) for 1L treatment of AMnsqNSCLC

METHODS

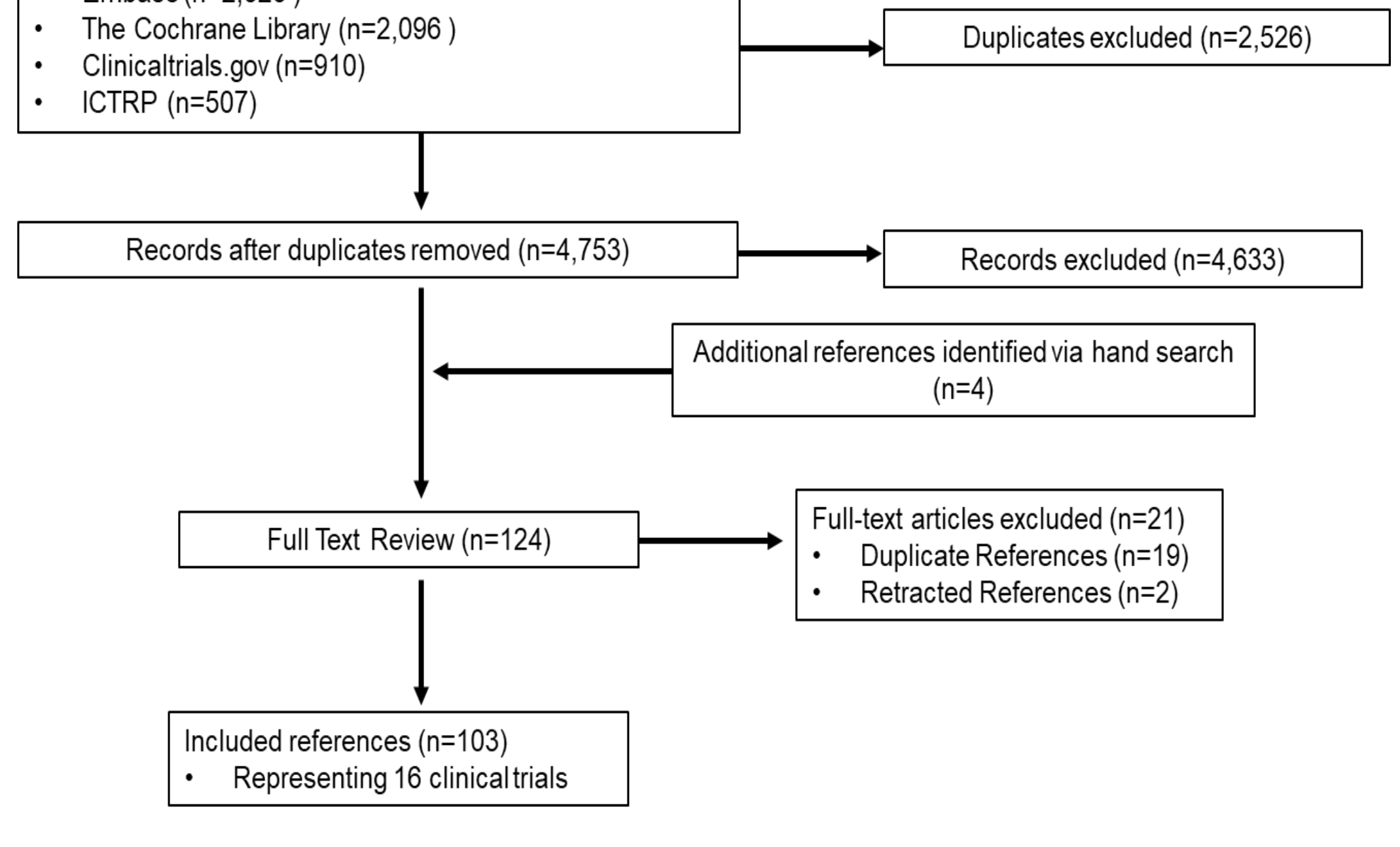
- Search strategy of PubMed, Embase CENTRAL, WHO ICTRP, and clinicaltrials.gov in accordance with PRISMA[4,5] and NICE[6,7] guidelines of relevant studies published between 1991 and September 2021
- NMA was conducted in accordance with the International Society for Pharmacoeconomics and Outcomes Research (ISPOR)[8] Taskforce and the NICE Decision Support Unit (DSU)[6,7] guidelines
- Bayesian fixed and random effects NMA with independent or simultaneous baseline models were assessed for the analysis,
- Time-to-event data were digitized from available publications of eligible trials using WebPlotDigitizer to assess and test the proportional hazards assumption[9,10]
- As proportional hazards assumption was met, the Woods method[11] was used for the NMA utilizing the reported hazard ratios and medians for OS and PFS
- A generalized linear NMA model with a logit link was used for high-grade AE (Grade ≥3) count data and objective response rate (ORR)
- Meta-Regression models were fitted for covariates (including Asian, former smoker, brain metastases, and year of study commencement)
- Sensitivity analysis excluded studies with >50% cross-over, studies with a mixed histology population (squamous and nonsquamous), studies with small sample sizes, or studies with unclear *EGFR* and *ALK* mutation status
- Convergence for all models were assessed using trace plots as modified by Brooks et. al., 1998.[12] Model fit was assessed using the deviance information criterion (DIC), with lower DIC indicating better fit
- Bayesian NMA was performed in JAGS via R using the R2JAGS package[13]

PICOS

Category	PICOS Inclusion Criteria	PICOS Exclusion Criteria
Participants	• Patients with AMnsqNSCLC w/o prior systemic therapy for metastatic disease w/o actionable genetic mutations that would make them eligible for targeted therapy*	
Intervention - Treatment	• Sintilimab/[cisplatin OR carboplatin]/pemetrexed (SINT+PEM+PLAT) • Pembrolizumab/[cisplatin OR carboplatin]/pemetrexed (PEMBRO+PEM+PLAT)) • Atezolizumab/carboplatin/paclitaxel/bevacizumab (ATEZO+BEV+PLAT+NAB/PAC) • Atezolizumab/carboplatin/nab-paclitaxel (ATEZO+PLAT+NAB/PAC) • Nivolumab/ipilimumab/[cisplatin OR carboplatin]/pemetrexed (NIVO+IPI+PEM+PLAT) • Nivolumab/ipilimumab (NIVO+IPI) • Pembrolizumab monotherapy • Atezolizumab monotherapy • Cemiplimab monotherapy • [Cisplatin OR Carboplatin]/pemetrexed	
Intervention - Comparison	• Any intervention listed above compared to: ○ placebo/pemetrexed/[cisplatin OR carboplatin] ○ Bevacizumab/paclitaxel/[cisplatin OR carboplatin] ○ Nab-paclitaxel/[cisplatin OR carboplatin] • Any comparison between interventions listed above	
Outcomes*	**Efficacy** (OS; PFS; ORR); **Safety** (Any AEs [grade ≥3])	• Relevant outcomes unreported
Study Designs	• Phase 2, 2b/3, 3, or 4 randomized controlled trials	• Phase 1 RCTs; Case studies; Single group designs; Observational trials; Cohort studies; Case control studies; Cross sectional designs; Letters; Commentaries; Reviews
Timeframe	• 1991-present	• Publications prior to 1991
Language	• English	• Non-English

Additional outcomes were included in the NMA analysis and are not shown here. * For studies reporting a mixed squamous and non-squamous NSCLC population, data will be extracted for the overall population. If additional information specific to the non-squamous NSCLC portion of the population is available, that information will also be extracted.

PRISMA DIAGRAM



Records identified through database search* (N=7,279)
- Pubmed (n=1,140)
- Embase (n=2,626)
- The Cochrane Library (n=2,096)
- Clinicaltrials.gov (n=910)
- ICTRP (n=507)

Duplicates excluded (n=2,526)

Records after duplicates removed (n=4,753)

Records excluded (n=4,633)

Additional references identified via hand search (n=4)

Full Text Review (n=124)

Full-text articles excluded (n=21)
- Duplicate References (n=19)
- Retracted References (n=2)

Included references (n=103)
- Representing 16 clinical trials

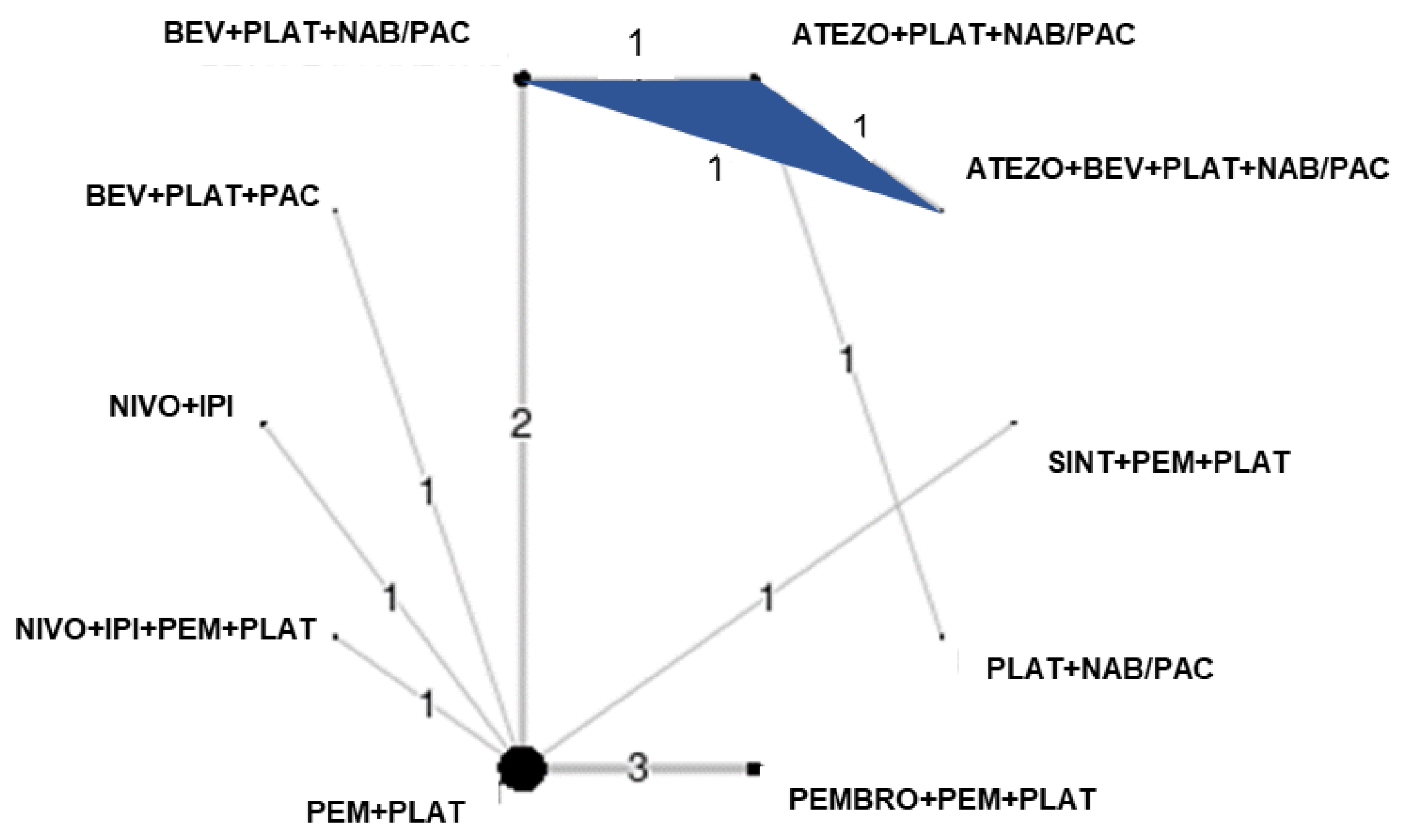
*Database search run July to September 2021

Study Baseline Characteristics

Study	Network Comparator Treatment	Randomized Patients N	Median Age, in years	Female, N (%)	Asian, N (%)	PD-L1 positive (≥1%), N (%)	PD-L1 negative (<1%), N (%)	ECOG 0, N (%)	ECOG 1, N (%)	ECOG 2, N (%)
ORIENT-11[1,2]	SINT+PEM+PLAT	266	61	62 (23)	266 (100)	181 (68)	85 (32)	76 (29)	190 (71)	0 (0)
	PEM+PLAT	131	61	32 (24)	131 (100)	87 (66)	44 (34)	34 (26)	97 (74)	0 (0)
KEYNOTE-021G[3]	PEMBRO+PEM+PLAT	60	63	38 (63)	5 (8)	39 (65)	21 (35)	24 (40)	35 (58)	1 (2)
	PEM+PLAT	63	66	37 (59)	5 (8)	40 (63)	23 (37)	29 (46)	34 (54)	0 (0)
KEYNOTE-189[4,5]	PEMBRO+PEM+PLAT	410	65	156 (38)	NR	260 (63)	127 (31)	185 (45)	221 (54)	1 (0.2)
	PEM+PLAT	206	64	97 (47)	NR	128 (62)	63 (31)	80 (39)	125 (61)	0 (0)
KEYNOTE-189 Japan extension study[6]	PEMBRO+PEM+PLAT	25	64	6 (24)	25 (100)	10 (40)	14 (56)	15 (60)	10 (40)	0 (0)*
	PEM+PLAT	15	66	3 (20)	15 (100)	6 (40)	6 (40)	9 (60)	6 (40)	0 (0)*
IMpower130[7]	ATEZO+PLAT+NAB/PAC	451	64	185 (41)	12 (3)	216 (48)	235 (52)	189 (42)	261 (58)	0 (0)
	PLAT+NAB/PAC	228	65	94 (41)	3 (1)	107 (47)	121 (53)	91 (40)	136 (60)	1 (0.4)
IMpower150[8,9]	ATEZO+BEV+PLAT+NAB/PAC	400	63	161 (40)	46 (12)	209 (52)	190 (48)	179 (45)	218 (55)	NR
	BEV+PLAT+NAB/PAC	400	63	160 (40)	56 (14)	195 (49)	200 (50)	159 (40)	238 (60)	NR
CHECKMATE-9LA[10]	NIVO+IPI+PEM+PLAT	361	65	109 (30)	NR	203 (56)	135 (37)	113 (31)	247 (68)	0 (0)*
	PEM+PLAT	358	65	106 (30)	NR	204 (57)	129 (36)	112 (31)	245 (68)	0 (0)*
CheckMate 227[11]	NIVO+IPI	583	64	190 (33)	NR	396 (68)	187 (32)	204 (35)	377 (65)	NR
	PEM+PLAT	583	64	198 (34)	NR	397 (68)	186 (32)	191 (33)	386 (66)	NR
PRONOUNCE[12]	PEM+PLAT	182	66	77 (42)	4 (2)	NR	NR	85 (47)	96 (53)	0 (0)*
	BEV+PLAT+PAC	179	65	75 (42)	0 (0)	NR	NR	84 (47)	95 (53)	0 (0)*
ERACLE[13]	PEM+PLAT	60	60	18 (30)	NR	NR	NR	47 (78)	13 (22)	0 (0)*
	BEV+PLAT+PAC	58	62	13 (22)	NR	NR	NR	46 (79)	12 (21)	0 (0)*
Kader et al.[14]	BEV+PLAT+PAC	20	53	5 (25)	NR	NR	NR	NR	NR	4 (20)
	PEM+PLAT	21	52	6 (29)	NR	NR	NR	NR	NR	7 (33)

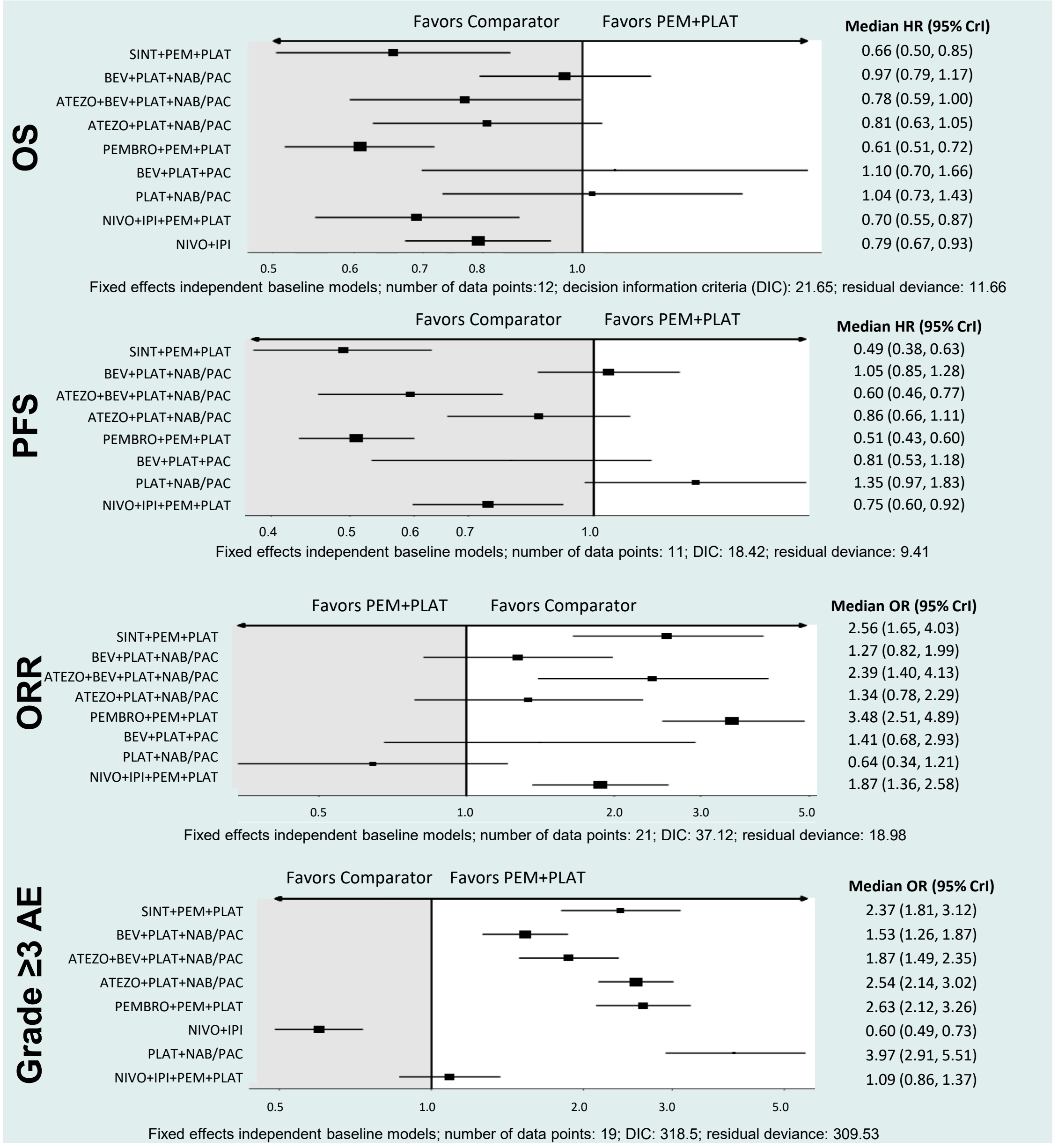
All studies included stage IV disease; some studies included stage IIIB to stage IV disease (ORIENT-11, ERACLE, Kader, and KEYNOTE-021G). Five of the 16 studies restricted eligibility to PD-L1-expressing patients and were therefore not eligible for inclusion in the evidence networks for the primary analysis. Sources for included studies: [1]Yang et al 2020; [2]Yang et al 2021; [3]Awad et. al., 2021; [4]Rodriguez-Abreu et. al., 2021; [5]Gandhi et. al., 2021; [6]Horinouchi et. al., 2021; [7]West et. al., 2019; [8]Socinski et. al., 2021; [9]Socinski et. al., 2020; [10]Paz-Ares et. al., 2021; [11]Hellman et. al., 2021; [12]Zinner et. al., 2015; [13]Galetta et. al., 2015; [14]Kader et. al., 2013. Full references available upon request. *Value defined by inclusion/exclusion criteria. Abbreviations: ATEZO, atezolizumab; BEV, bevacizumab; IPI, ipilimumab; NAB/PAC, nab-paclitaxel; NIVO, nivolumab; PEM, pemetrexed; PEMBRO, pembrolizumab; PLAT, platinum-based chemotherapy; SINT, sintilimab.

Evidence Network for OS Outcome



Shaded areas represent closed loops, node size are proportional to the number of patients, numbers represent the number of studies. Evidence networks were similar for the other outcomes.

Forest Plots of Outcomes



Fixed effects independent baseline models; number of data points:12; decision information criteria (DIC): 21.65; residual deviance: 11.66

Fixed effects independent baseline models; number of data points: 11; DIC: 18.42; residual deviance: 9.41

Fixed effects independent baseline models; number of data points: 21; DIC: 37.12; residual deviance: 18.98

Fixed effects independent baseline models; number of data points: 19; DIC: 318.5; residual deviance: 309.53

Efficacy and Safety Profiles

Overall Survival / Progression-free Survival

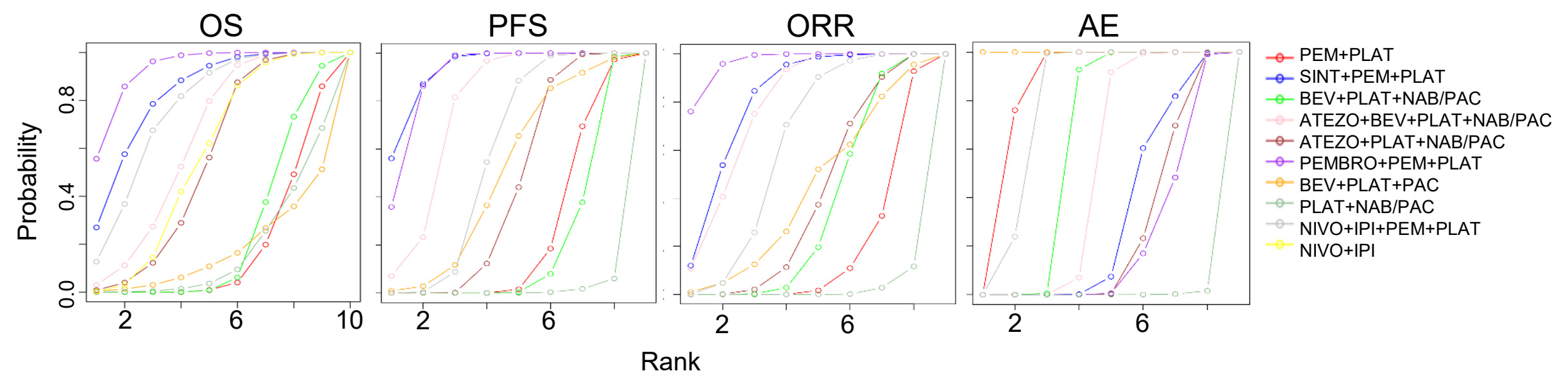
BEV+PLAT+PAC	0.95 (0.55, 1.64)	0.93 (0.60, 1.43)	0.90 (0.56, 1.43)	0.75 (0.46,1.24)	0.74 (0.47,1.17)	0.72 (0.43,1.18)	0.64 (0.40,1.05)	0.61 (0.37,1.01)	0.57 (0.36,0.90)
Rank 10	**PLAT+NAB/PAC**	0.98 (0.70, 1.37)	0.94 (0.72, 1.24)	0.79 (0.64,0.98)	0.77 (0.53,1.12)	0.75 (0.57,0.99)	0.68 (0.45,1.01)	0.64 (0.42,0.98)	0.60 (0.41,0.86)
Rank 1	Rank 9	**PEM+PLAT**	0.96 (0.79, 1.17)	0.81 (0.63,1.05)	0.79 (0.67,0.93)	0.77 (0.59,1.00)	0.69 (0.55,0.87)	0.65 (0.50,0.85)	0.61 (0.51,0.72)
SINT+PEM+PLAT	Rank 2	Rank 8	**BEV+PLAT+NAB/PAC**	0.84 (0.71, 1.00)	0.82 (0.64,1.06)	0.80 (0.67,0.95)	0.72 (0.53,0.97)	0.68 (0.49,0.94)	0.63 (0.49,0.82)
0.96 (0.71,1.30)	**PEMBRO+PEM+PLAT**	Rank 3	Rank 7	**ATEZO+PLAT+NAB/PAC**	1.02 (0.76,1.39)	0.95 (0.80,1.13)	0.86 (0.60,1.20)	0.81 (0.56,1.17)	0.75 (0.55,1.02)
0.83 (0.57,1.19)	0.86 (0.63,1.17)	**ATEZO+BEV+PLAT+NAB/PAC**	Rank 4	Rank 6	**NIVO+IPI**	0.97 (0.72,1.32)	0.87 (0.66,1.16)	0.83 (0.61,1.13)	0.77 (0.61, 0.97)
0.66 (0.48,0.92)	0.69 (0.53,0.90)	0.80 (0.57,1.13)	**NIVO+IPI+PEM+PLAT**	Rank 5	Rank 5	**ATEZO+BEV+PLAT+NAB/PAC**	0.90 (0.63,1.27)	0.85 (0.59,1.23)	0.79 (0.58,1.08)
0.62 (0.39,0.99)	0.65 (0.42,0.99)	0.75(0.47,1.21)	0.94 (0.60,1.47)	**BEV+PLAT+PAC**	Rank 6	Rank 4	**NIVO+IPI+PEM+PLAT**	0.95 (0.67,1.34)	0.88 (0.66,1.17)
0.57 (0.40,0.82)	0.60 (0.44,0.81)	0.70 (0.58,0.84)	0.87 (0.62,1.21)	0.92 (0.58,1.48)	**ATEZO+PLAT+NAB/PAC**	Rank 7	Rank 3	**SINT+PEM+PLAT**	0.93 (0.68,1.27)
0.49 (0.38,0.63)	0.51 (0.43,0.60)	0.59 (0.46,0.77)	0.74 (0.60,0.92)	0.79 (0.53,1.18)	0.86 (0.66,1.11)	**PEM+PLAT**	Rank 8	Rank 2	**PEMBRO+PEM+PLAT**
0.47 (0.34,0.65)	0.49 (0.38,0.63)	0.57 (0.48,0.67)	0.71 (0.53,0.95)	0.76 (0.49,1.18)	0.82 (0.70,0.97)	0.96 (0.78,1.17)	**BEV+PLAT+NAB/PAC**	Rank 9	Rank 1
0.37 (0.24,0.55)	0.38 (0.27,0.55)	0.45 (0.34,0.58)	0.55 (0.38,0.81)	0.59 (0.36,0.98)	0.64 (0.54,0.77)	0.75 (0.55,1.03)	0.79 (0.61, 1.00)	**PLAT+NAB/PAC**	

Objective Response Rate / Grade ≥3 Adverse Events

PLAT+NAB/PAC	0.64 (0.34, 1.21)	0.51 (0.32, 0.79)	0.48 (0.34, 0.67)	0.46 (0.17, 1.20)	0.34 (0.17, 0.70)	0.27 (0.17, 0.42)	0.25 (0.12, 0.55)	0.18 (0.09, 0.38)
Rank 9	**PEM+PLAT**	0.79 (0.50, 1.22)	0.75 (0.44, 1.28)	0.71 (0.34, 1.47)	0.53 (0.39, 0.73)	0.42 (0.24, 0.72)	0.39 (0.25, 0.61)	0.29 (0.20, 0.40)
Rank 1	Rank 8	**BEV+PLAT+NAB/PAC**	0.95 (0.70, 1.29)	0.90 (0.38, 2.12)	0.68 (0.39, 1.18)	0.53 (0.39, 0.72)	0.50 (0.26, 0.94)	0.37 (0.21, 0.64)
NIVO+IPI	Rank 2	Rank 7	**ATEZO+PLAT+NAB/PAC**	0.95 (0.38, 2.35)	0.71 (0.38, 1.34)	0.56 (0.41, 0.76)	0.52 (0.26, 1.05)	0.38 (0.20, 0.72)
0.60 (0.49, 0.73)	**PEM+PLAT**	Rank 3	Rank 6	**BEV+PLAT+PAC**	0.75 (0.34, 1.68)	0.59 (0.24, 1.47)	0.55 (0.23, 1.29)	0.40 (0.18, 0.90)
0.55 (0.42, 0.72)	0.92 (0.73, 1.16)	**NIVO+IPI+PEM+PLAT**	Rank 4	Rank 5	**NIVO+IPI+PEM+PLAT**	0.78 (0.42, 1.46)	0.73 (0.42, 1.26)	0.54 (0.34, 0.85)
0.39 (0.31, 0.50)	0.65 (0.54, 0.79)	0.71 (0.54, 0.92)	**BEV+PLAT+NAB/PAC**	Rank 5	Rank 4	**ATEZO+BEV+PLAT+NAB/PAC**	0.94 (0.46, 1.89)	0.69 (0.36, 1.30)
0.32 (0.25, 0.42)	0.54 (0.43, 0.67)	0.58 (0.43, 0.78)	0.82 (0.63, 1.07)	**ATEZO+BEV+PLAT+NAB/PAC**	Rank 6	Rank 3	**SINT+PEM+PLAT**	0.73 (0.42, 1.29)
0.25 (0.19, 0.34)	0.42 (0.32, 0.55)	0.46 (0.33, 0.64)	0.65 (0.48, 0.88)	0.79 (0.57, 1.09)	**SINT+PEM+PLAT**	Rank 7	Rank 2	**PEMBRO+PEM+PLAT**
0.24 (0.19, 0.29)	0.39 (0.33, 0.47)	0.43 (0.33, 0.55)	0.60 (0.49, 0.75)	0.74 (0.58, 0.94)	0.93 (0.70, 1.25)	**ATEZO+PLAT+NAB/PAC**	Rank 8	Rank 1
0.23 (0.18, 0.29)	0.38 (0.31, 0.47)	0.41 (0.31, 0.55)	0.58 (0.45, 0.75)	0.71 (0.54, 0.94)	0.90 (0.66, 1.24)	0.97 (0.76, 1.22)	**PEMBRO+PEM+PLAT**	Rank 9
0.15 (0.11, 0.21)	0.25 (0.18, 0.34)	0.27 (0.19, 0.39)	0.39 (0.27, 0.54)	0.47 (0.32, 0.67)	0.60 (0.40, 0.88)	0.64 (0.46, 0.88)	0.66 (0.46, 0.94)	**PLAT+NAB/PAC**

Note: None of the Meta-Regression models showed an improved model fit to the base case, and estimated regression coefficients were all non-significant

SUCRA Plots



Sensitivity Analysis Results

Overall Survival	Basecase*	Sensitivity 2*	Sensitivity 3*	Sensitivity 4*
	SINT+PEM+PLAT	SINT+PEM+PLAT	SINT+PEM+PLAT	SINT+PEM+PLAT
PEM+PLAT	0.65 (0.50,0.85)	0.65 (0.50,0.85)	0.66 (0.50,0.85)	0.65 (0.50,0.85)
BEV+PLAT+NAB/PAC	0.68 (0.49,0.94)	0.70 (0.49,1.00)	0.70 (0.49,1.00)	0.65 (0.44,0.97)
ATEZO+BEV+PLAT+NAB/PAC	0.85 (0.59,1.23)	0.88 (0.59,1.31)	0.88 (0.59,1.30)	0.82 (0.53,1.26)
ATEZO+PLAT+NAB/PAC	0.81 (0.56,1.17)	0.83 (0.56,1.24)	0.83 (0.56,1.24)	0.78 (0.50,1.20)
PEMBRO+PEM+PLAT	1.08 (0.79,1.47)	1.08 (0.79,1.47)	1.07 (0.78,1.46)	1.08 (0.79,1.47)
BEV+PLAT+PAC	0.61 (0.37,1.01)	0.61 (0.37,1.01)	0.61 (0.37,1.01)	0.61 (0.37,1.01)
PLAT+NAB/PAC	0.64 (0.42,0.98)	0.66 (0.42,1.03)	0.66 (0.42,1.03)	0.61 (0.38,0.99)
NIVO+IPI+PEM+PLAT	0.95 (0.67,1.34)	NA	0.95 (0.67,1.34)	0.95 (0.67,1.34)
NIVO+IPI	0.83 (0.61,1.13)	NA	0.83 (0.61,1.13)	0.83 (0.61,1.13)
DIC	21.65	15.55	18.48	21.52
Number of Data Points	12	9	10	11
Residual Deviance	11.66	8.55	9.47	11.53

*Fixed Effect independent baseline model, Sensitivity 2= Exclude Studies with mixed populations, Sensitivity 3= Exclude studies with sample sizes <50 per arm, Sensitivity 4= Exclude studies with unclear EGFR/ALK mutation status. Green indicates significance.

CONCLUSIONS

- The equivalence and the use of new ICIs is an emerging question for which only indirect comparisons among trials are available
- With the limits of the NMA, this work showed comparable efficacy and safety between sintilimab+pemetrexed+platinum and U.S. FDA-approved and NCCN-recommended ICI combinations for untreated advanced or metastatic nonsquamous NSCLC regardless of PD-L1 status although the patient populations differ in ethnicity
- No meaningful difference in results between base case and sensitivity analyses, including the meta-regression, which demonstrates the strength of the NMA results that were observed
- These results confirm and strengthen available direct and indirect evidence showing a favorable benefit/risk profile with the addition of ICIs to chemotherapy
- The results disclosed here were generally consistent with other NMAs conducted recently[14,15,16]
- In the absence of head-to-head evidence from RCTs, our findings may help support future treatment decisions, evidence evaluation, and health technology assessment of NCCN-recommended first-line therapy of advanced or metastatic nonsquamous NSCLC

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