PATIENT-REPORTED OUTCOMES WITH NIVOLUMAB ACROSS LUNG CANCERS : A SYSTEMATIC LITERATURE REVIEW

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Conclusion

Nivolumab showed improved quality of life as compared to docetaxel and chemotherapy alone. The addition of ipilimumab to a combination of nivolumab ± chemotherapy did not provide an extra benefit in terms of PROs.

Background

- For several decades, lung cancer has been the leading cause of cancer death Globally[1]
- In 2018, an estimated 2.1 million lung cancer diagnoses were reported, accounting for 12% of cancer deaths worldwide[2]
- In the management of lung cancer, Nivolumab has emerged as a promising immunotherapeutic agent
- However, measuring the impact of Nivolumab on patient quality of life (QoL) requires a comprehensive assessment beyond traditional clinical analysis
- There is unmet need in terms of precise analyses of the longitudinal effects of Nivolumab on patient-reported outcomes (PROs)

Objective

- The systematic literature review aims to evaluate the existing literature on patient-reported outcomes with Nivolumab across lung cancers.

Methodology

- The review followed the standard methodology for conducting reviews as per National Institute for Health and Care Excellence[3] (NICE), Cochrane Handbook[4], and PRISMA guidelines[5]
- Embase® and MEDLINE® were searched from database inception to June 2023 for all randomized controlled studies reporting PROs with Nivolumab across lung cancers. The SLR followed two review and quality control process as recommended by various HTAs

Figure 1: Presents the eligibility criteria for the selection of evidence

Results

- A PRISMA diagram for the screening process is presented in Figure 2.
- Out of 1278 screened publications, seven studies assessing advanced non-small cell lung cancer (NSCLC) met the inclusion criteria

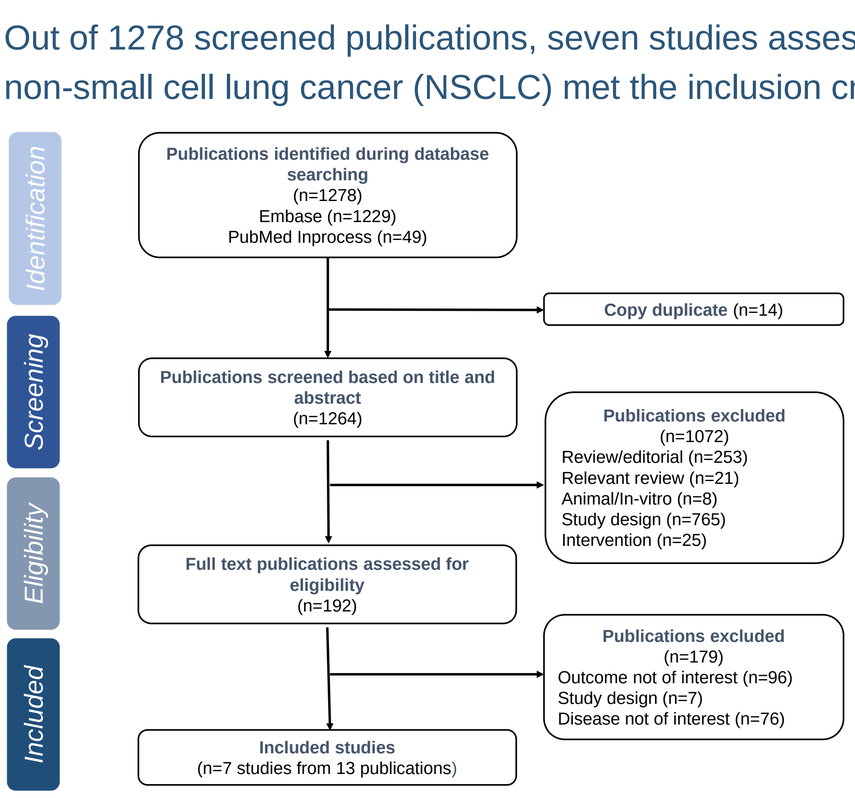

Figure 2: Flow of studies through the systematic literature review

Results (Cont'd)

- Sample size of the included studies ranged from 272 to 1739

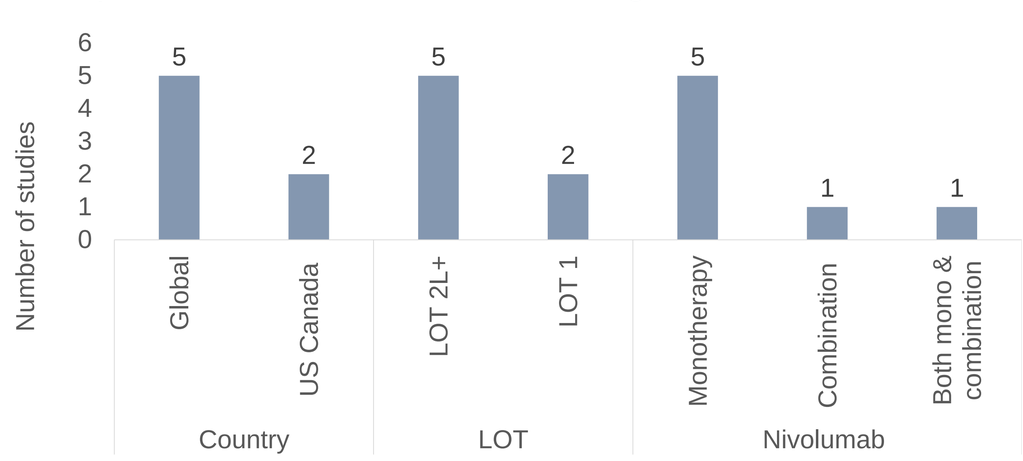

Figure 3: Study details reported across the included studies

- Time points of assessment were 102 weeks for LOT1 and ranged from 42-84 weeks for LOT≥2
- LCSS ASBI (n=6), LEQ5D VAS (n=6), CSS 3-IGI (n=5), EQ-5D UI (n=5) were the commonly assessed QoI instruments.
- Clinically meaningful improvement (CMI) in EQ-5D VAS (cut-off 7) and EQ-5D UI (cut-off 0.08) was observed with nivolumab (LOT≥2: 2 studies each) and nivolumab + ipilimumab (LOT1: n=1 each)
- Three studies showed CMI (cut-off 10) in LCSS ASBI and delayed time to first symptom deterioration with nivolumab ± ipilimumab against chemotherapy/docetaxel. Similar findings were observed with LCSS 3-IGI scale (cut-off 30)
- Significant differences in QoI scores between nivolumab and chemotherapy groups were observed at very few time points across the studies.

PRO Scale	Trial	Nivolumab Monotherapy	Nivolumab + IPI	Nivolumab + IPI + CT	Placebo/CT	Docetaxel
LCSS-Meso ASBI (CMI: 10)	CheckMate 227	-	-14.64 (-28.36, -1.95)	-	0.30 (-6.99, 6.64)	-
	CheckMate 9LA	-	-	-7.93 (-3.96, -11.83)	-8.99 (-2.60, -15.27))	-
	CheckMate 057	-5.8 (-11.14, -0.79)	-	-	-	1.63 (-7.13, 10.14)
	CheckMate 017	-14.49 (-1.57, -27.41)	-	-	-	10.41 (-17.89, 38.59)
	CheckMate 153	-4.41 (-6.61, -2.64)	-	-	-	-
LCSS-3IGI (CMI: 30)	CheckMate 227	-	55.96 (38.14, 73.62)	-	8.24 (-10.37, 26.69)	-
	CheckMate 9LA	-	-	27.16 (42.68, 11.64)	5.50 (-23.91, 35.28)	-
	CheckMate 057	9.17 (-10.85, 29.19)	-	-	-	-26.24 (-65.65, 14.01)
	CheckMate 017	36.04 (-15.42, 88.99)	-	-	-	-70.46 (-140.07, -1.14)
EQ-5D UI (CMI: 0.08)	CheckMate 227	-	0.16 (-0.02, 0.35)	-	0 (-0.14, 0.15)	-
	CheckMate 9LA	-	-	0.04 (-0.04, 0.12)	0.05 (-0.02, 0.11)	-
	CheckMate 057	0.03 (-0.05, 0.10)	-	-	-	0.09 (-0.31, 0.49)
	CheckMate 017	0.13 (0, 0.25)	-	-	-	-0.07 (-0.32, 0.17)
EQ-5D VAS (CMI: 7)	CheckMate 227	-	12.06 (7.22, 12.06)	-	3.17 (-3.22, 8.89)	-
	CheckMate 9LA	-	-	4.44 (-0.58, 9.45)	2.05 (-3.45, 7.3)	-
	CheckMate 057	4.94 (-3.40, 12.85)	-	-	-	-7.57 (0.68, -16.09)
	CheckMate 017	24 (15.95, 31.68)	-	-	-	-6.52 (-28.14, 15.02)
	CheckMate 153	8.76 (11.50, 6.2)	-	-	-	-

Table 1: Change from baseline (mean (95% CI)) values for various PRO scales with nivolumab mean (95% CI)

ASBI: Average Symptom Burden Index; CI: Confidence interval; CMI: Clinical meaningful improvement; CT: Chemotherapy; EQ-5D: Euro Qol-5 dimension; IPI: Ipilimumab; LCSS: Lung cancer symptom scale; PRO: Patient-reported outcomes; UI: Utility Index; VAS: Visual analogue scale; 3IGI: Three-item global index

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Disclosure

GK, GB, BS, the authors, declare that they have no conflict of interest

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