免疫療法はほとんどの一般的な肺がんにおいて生存期間を延長する (Abstract LBA109)

Nivolumabは非扁平上皮非小細胞肺がんに対する標準的なセカンドライン治療選択となり得る

Nivolumab as a possible standard second-line treatment option for non-squamous non-small cell lung cancer

第51回American Society of Clinical Oncology年次集会で発表された研究の結果、非扁平上皮、非小細胞肺がん（NSCLC）患者に対し、PD-1免疫療法は有効な治療であることが示された。プラチナ製剤ベースの化学療法後に悪化した進行肺がん患者において、nivolumab治療を受けた患者の生存期間はドセタキセルで治療された患者よりも3か月長かった。この第III相スタディでは進行非扁平上皮NSCLC患者582人をnivolumabまたはドセタキセルで治療する群にランダムに割り付けた。奏効率はnivolumab群においてドセタキセル群よりも高かった（19.2%対12.4%）。またnivolumab群において有意に長い持続的な奏効が得られた（平均17.1か月対5.6か月）。全生存期間中央値はnivolumab群で12.2か月であり、ドセタキセル群では9.4か月であった。特筆すべきことに、腫瘍内PD-L1が高レベル（≥1%細胞）のサブグループにおいては、nivolumab治療群の生存期間中央値は17か月を超えたのに対しドセタキセル群では9か月であった。Nivolumabの忍容性は全般的に良好であった。Nivolumabは治療歴のあるNSCLC患者の新たな標準治療となり得る、と研究者らは述べている。

Full Text

Findings from a phase III study presented at the American Society of Clinical Oncology's 51st Annual Meeting indicate that PD-1 immunotherapy is an effective treatment option for patients with non-squamous, non-small cell lung cancer (NSCLC). Among patients with advanced disease that worsened after receiving platinum-based chemotherapy, those treated with nivolumab lived on average three months longer than those treated with docetaxel chemotherapy.

"This is the first phase III study to show that immunotherapy is effective against non-squamous cell NSCLC, and appears to be particularly active in patients with PD-L1-positive tumors," said lead study author Luis Paz-Ares, M.D., Ph.D., a professor of medicine at Hospital Universitario 12 de Octubre in Madrid, Spain. "While nivolumab appears to be more potent against this most common lung cancer, it is important to note that it is also far easier on patients compared to the standard second-line treatment, docetaxel."

Lung cancer is the most common cancer worldwide, with more than 1.8 million new cases diagnosed in 2012. NSCLC is the most common form of lung cancer, accounting for 85% of all lung cancers. More than two-thirds of those are non-squamous cell cancers.

The study randomly assigned 582 patients with advanced non-squamous NSCLC to treatment with nivolumab or docetaxel. Response rates were higher in the nivolumab group compared to the docetaxel group (19.2% vs. 12.4%). Responses also lasted significantly longer in the nivolumab group (17.1 months vs. 5.6 months, on average).

The median overall survival was 12.2 months in the nivolumab group compared to 9.4 months in the docetaxel group. Of note, in the subgroup of patients with high levels of PD-L1 in their tumor (≥1% cells), the median survival with nivolumab exceeded 17 months as compared to 9 months for those treated with docetaxel.

Nivolumab was well tolerated overall, with only one in 10 patients experiencing serious side effects, compared to more than half of patients in the docetaxel arm. There was one treatment-related death in the docetaxel arm and none in the nivolumab arm. Due to toxic side effects, 4.9% patients stopped nivolumab, and 14.9% patients stopped docetaxel.

Nearly half of the patients who stopped treatment subsequently received systemic therapy.

The researchers pointed out that patients with higher levels of the biomarker PD-L1 experienced the greatest degree of benefit from nivolumab. Overall, patients who received nivolumab had a 27% lower risk of death compared to those who received docetaxel. However, the subgroup of patients with the high levels of PD-L1 had a 41- 60% reduction in risk of death, which was not observed in cases of low or undetectable PD- L1 levels.

Dr. Paz-Ares stated that nivolumab could potentially become a new standard therapy for patients with previously treated NSCLC.

ASCO Expert Gregory A. Masters, MD, FACP, FASCO noted that "Even five years ago, an effective immunotherapy for lung cancer was largely considered impossible. Today, we have such a treatment, and it surpasses the standard therapy both in terms of efficacy and patient quality of life."

This study received funding from Bristol-Myers Squibb.

ASCO2015特集