



図5 本邦で行われた、進展型小細胞肺癌に対するPCIの第III相試験

おわりに

小細胞肺癌におけるPCIについて述べた。PCIというアイデア自体は非常に斬新であり、化学療法の弱点を補うよい手段と考えられるが、進展型については本邦からの臨床試験結果が実地に沿った解答を与えてくれるだろう。今後は適切なフォローアップの方法やより有効性が期待される対象の選別などに焦点が当たると思われ、大いに注目が集まると思われる。

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- (PCI) in patients with limited-stage small-cell lung cancer in complete remission after chemotherapy and thoracic radiotherapy (PCI 99-01, EORTC 22003-08004, RTOG 0212, and IFCT 99-01): a randomised clinical trial. *Lancet Oncol* 2009 ; 10 : 467.
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Prophylactic cranial irradiation (PCI) has a detrimental effect on the overall survival (OS) of patients (pts) with extensive disease small cell lung cancer (ED-SCLC): Results of a Japanese randomized phase III trial.

Meeting:

2014 ASCO Annual Meeting

Category:

Lung Cancer - Non-Small Cell Local-Regional/Small Cell/Other Thoracic Cancers

Subcategory:

Small Cell Lung Cancer

Session Type and Session Title:

Oral Abstract Session, Lung Cancer - Non-small Cell Local-regional/Small Cell/Other Thoracic Cancers

Abstract Number:

7503

Citation:

J Clin Oncol 32:5s, 2014 (suppl; abstr 7503)

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Background: A previous study has shown that PCI reduced the risk of brain metastases (BM) and prolonged the OS of patients with ED-SCLC (Slotman B et al, NEJM 2007). There were, however, several concerns that arose in association with that study, including the lack of magnetic resonance imaging (MRI) assessment to confirm the absence of BM before enrollment, the use of induction chemotherapy other than platinum, and variations in the radiation doses. **Methods:** From March 2009, pts with ED-SCLC who had any response to first-line platinum doublet chemotherapy were randomized to either PCI (25Gy/10 fractions) or observation (Obs) alone. The patients were required to prove the absence of BM by MRI prior to enrollment. The primary endpoint was OS and a planned sample size of 330 was determined to detect the hazard ratio (HR)

of 0.75 at a significance level of 0.05 and a power of 80%. Secondary endpoints included time to BM (evaluated every 3 months by imaging), progression-free survival (PFS), and adverse effects (AEs). **Results:** In July 2013, a preplanned interim analysis was conducted for the survival data of 163 pts from 41 centers. The study was terminated because of futility; with a median follow-up of 9.4 months and 111 observed deaths, the median OS was 10.1 and 15.1 months for PCI ($n=84$) and Obs ($n=79$), respectively (HR=1.38, 95%CI= 0.95-2.01; stratified log-rank test, $P=0.091$). Bayesian predictive probability of showing superiority of PCI over Obs was 0.01%. PCI significantly reduced the risk of BM as compared to Obs (32.4% vs 58.0% at 12 months; Gray's test, $P<0.001$), whereas PFS was comparable between the two arms (median, 2.2 vs. 2.4 months; HR=1.12, 95%CI=0.82-1.54). No significant difference in AEs greater than Grade 2 was observed between the two arms. **Conclusions:** PCI after response to chemotherapy had a negative impact on OS in pts with ED-SCLC. Clinical trial information: 000001755.

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