

# メラノーマ患者においてリンパ節全郭清は生存率を改善しない (Abstract LBA9002)

センチネルリンパ節生検陽性のメラノーマ患者に対する拡大リンパ節郭清術は不要である可能性がある

Extensive lymph node dissection may not be necessary for patients with melanoma with a positive sentinel node biopsy

リンパ節転移陽性患者のメラノーマ腫瘍周囲のリンパ節郭清は生存率を改善しない、と第51回American Society of Clinical Oncology年次集会で発表された。原発腫瘍を外科的に切除した後、ステージIIIメラノーマ患者483人が経過観察のみの群または完全リンパ節郭清 (CLND) 群にランダムに割り付けられた。微小転移を有する患者のみがスタディに含まれた。患者らの追跡期間中央値は35か月であった。経過観察群では、14.6%の患者がリンパ節局所転移を来したのに対し、CLND群では8.3%であった。しかし、スタディ対象者全体において、5年無再発率 ( $p=0.72$ )、無遠隔転移率 ( $p=0.76$ ) またはメラノーマ特異的生存率 ( $p=0.86$ ) に関しては治療による有意差はなかった。センチネルリンパ節にがんが認められた患者は、メラノーマ再発および転移のリスクが高いと考えられている。世界的に、これらの患者にはCLNDを行うことが推奨されている。今回のスタディは、治療を変え不要な手術やそれによる副作用から何千人もの患者を救うのに役立つ可能性が高い。

## Full Text

A randomized study presented by researchers at the American Society of Clinical Oncology's 51st Annual Meeting finds that surgical removal of the lymph nodes surrounding a melanoma tumor after a positive lymph node biopsy does not improve survival. The study will likely change practice and conclude a long-standing debate about the role of this approach, called complete lymph node dissection (CLND). More importantly, the new knowledge gained from this study will help spare thousands of patients with melanoma from unnecessary surgery and its significant side effects.

Patients who have cancer detected in the sentinel lymph node upon biopsy are deemed to be at increased risk of melanoma recurrence and metastasis. Worldwide, it is recommended that such patients undergo CLND.

CLND is an extensive surgical procedure that involves removal of entire groups of lymph nodes. It carries the risk of debilitating side effects, including infection, nerve damage and lymphedema. According to the authors, lymphedema can occur in more than 20% of patients and persist long-term in 5-10% of patients.

"I think that our study is the beginning of the end of a general recommendation of complete lymph node dissection for patients with positive sentinel nodes," said senior study author Claus Garbe, MD, a professor of dermatology at the University of Tübingen in Tübingen, Germany. "However, it is possible that this surgery may provide a smaller survival advantage than this study could detect. So, doctors may want to discuss this finding with their patients to help them decide whether this procedure is right for them."

Following surgery to remove the primary tumor, 483 patients with stage III melanoma and a positive lymph node biopsy were randomly assigned to observation only or CLND. Patients in the observation group were closely monitored for signs of disease recurrence – they underwent a lymph node ultrasound exam every three months and CT/MRI or PET scans every six months. Patients in the CLND group followed the same schedule of check-ups after CLND.

Patients had a median follow-up of 35 months. In the observation group, 14.6% of patients developed lymph node regional metastases, compared to 8.3% in the CLND group. However, the differences in three and five-year recurrence-free survival, distant metastases-free survival, and melanoma-specific survival were not statistically significant between the two groups. In this study, a survival difference of 10% or higher between the two treatment groups was considered statistically significant based on the study design.

Only patients with micrometastases were included in this study. According to the authors, CLND will continue to be recommended for patients with larger macrometastases.

Another analysis of this study is planned in three years; however, Dr. Garbe stated it is unlikely that the overall findings of the study will change, because prior research has shown that the majority (roughly 80%) of melanoma recurrences happen in the first three years of initial diagnosis.

Another ongoing CLND randomized trial, MSLT-II, is much larger and designed to detect an even smaller (5%) difference in survival. However, the final results from MSLT-II are not expected until 2022.

ASCO Expert Lynn Schuchter, MD, FASCO noted that "This is the first study to offer solid evidence that many patients with melanoma don't need extensive lymph node surgery. The findings should reduce the use of an approach that we have long assumed to be optimal. This is great news for patients, who can forego extensive surgeries without compromising their survival chances."

This study received funding from German Cancer Aid.

## ASCO2015特集

### [News 01]

前立腺がんに対する初めての有効な術後補助化学療法

### [News 02]

免疫療法はほとんどの一般的な肺癌において生存期間を延長する

### [News 03]

一部のがんにおいてゲノム異常は抗PD-1反応の予測因子となる

### [News 04]

再発CLLの予後改善

### [News 05]

ビタミンB3による化学予防

### [News 06]

再発多発性骨髄腫に対する新たな免疫療法の選択肢

### [News 07]

治療によりメラノーマの進行が半減する

### [News 08]

DCISに対する他の良い治療選択肢

### [News 09]

メラノーマ患者においてリンパ節全郭清は生存率を改善しない

### [News 10]

口腔がんにおける頸部リンパ節手術の最良のタイミング

### [News 11]

モノクローナル抗体は非ホジキンリンパ腫の寛解を2倍にする

### [News 12]

骨髄線維症の新規治療薬は血小板減少症を伴っていても有効である

### [News 13]

治療により進行乳がんの進行が抑制される

### [News 14]

進行肝臓がんに対する免疫療法

### [News 15]

進行の速い軟部組織肉腫に対する生存の有益性が認められた

### [News 16]

脳転移治療中の認知機能改善

### [News 17]

小児腎がんの予後改善

### [News 18]

治療により進行前立腺がんの生存期間が延長する