

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 (Abstract LBA10502)

エリブリンは進行脂肪肉腫および平滑筋肉腫の患者の全生存期間を延長する

Eribulin extends overall survival for patients with advanced liposarcoma and leiomyosarcoma

第51回American Society of Clinical Oncology年次集会で報告されたランダム化第III相トライアルの結果、2ライン以上の前治療歴の後に増悪した中等度または高度進行脂肪肉腫または平滑筋肉腫患者に対する新たな治療の有効性が示された。スタディにおいて、進行平滑筋肉腫または脂肪肉腫とも呼ばれる脂肪細胞性肉腫の患者452人が、エリブリンまたはダカルバジン治療を疾患が増悪するまで行う群にランダムに割り付けられた。全ての患者のがんは過去に2回以上の治療を受けたが増悪した。全生存期間中央値はエリブリン群で13.5か月であり、ダカルバジン群で11.5か月であった($p=0.0169$)。エリブリンの最も多い副作用は白血球減少、倦怠感、嘔気、脱毛、および便秘であり、8%の患者が副作用のために治療を中止した。筆者によると、この進行の速い疾患群の全生存期間改善を示した、これは初めての第III相試験である。彼らは、まれで悪性度の高いこの疾患群におけるアンメット・メディカルニーズを考えると、今回の結果は臨床的に重要なものである、と結論付けている。

Full Text

Findings from a randomized phase III trial reported at the American Society of Clinical Oncology's 51st Annual Meeting point to a promising new therapy for patients with advanced intermediate or high grade liposarcoma or leiomyosarcoma whose disease worsened after two or more lines of initial therapies. Patients treated with the chemotherapy drug eribulin had a two-month increase in median overall survival compared to those treated with the standard drug dacarbazine.

According to the authors, this is the first randomized phase III study to show an improvement in overall survival in patients with this aggressive family of diseases.

"Soft-tissue sarcomas are relatively rare and can be very difficult to treat. The efficacy of available drugs for initial therapy is very unsatisfactory, and patients whose disease progresses despite two or more lines of treatment have a very poor prognosis," said lead study author Patrick Schöffski, M.D., MPH, Head of Department of General Medical Oncology, University Hospitals Leuven in Leuven, Belgium. "For a disease where such few treatment options exist, a two-month improvement in survival is significant. The more treatments our patients have access to, the better their chances of improving life expectancy."

Soft-tissue sarcoma is a diverse family of rare diseases, and liposarcomas and leiomyosarcomas are among the more common types. Patients with advanced, metastatic soft-tissue sarcoma have poor outcomes, typically with survival of one year or less. There are currently few treatment options available, particularly at the point the disease worsens or further spreads to other parts of the body despite prior therapy.

In the study, 452 patients with advanced leiomyosarcoma or adipocytic sarcoma, which is also called liposarcoma, were randomly assigned to treatment with eribulin or dacarbazine until disease progression. All patients had cancers that had worsened upon receiving two or more prior treatments.

The median overall survival was 13.5 months in the eribulin group and 11.5 months in the dacarbazine group ($p=0.0169$). The authors conclude that this is a clinically meaningful result given the unmet need in this rare, hard-to-treat family of diseases.

The most common side effects associated with eribulin were low white blood cell counts, fatigue, nausea, hair loss, and constipation, and 8% of patients stopped treatment due to side effects. Low platelet counts were more common in the dacarbazine group compared to the eribulin group. Grade 3 and 4 treatment-related side effects occurred more frequently with eribulin than dacarbazine.

Eribulin belongs to a class of anticancer drugs known as microtubule inhibitors, which block cell division. It was originally derived from a natural source — a sea sponge.

Several additional analyses are ongoing, including quality of life analysis, subgroup analysis and biomarker tests. The results of those analyses will be reported at a later date.

ASCO Expert Gary K. Schwartz, M.D. commented on the study: "In a disease that has been notoriously difficult to treat, even small steps forward are worthwhile. These findings also remind us that our work is far from finished. The survival gain seen with eribulin must be weighed against the burden of side effects patients experienced."

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