

膵がんに対する術後補助化学療法 (Abstract LBA4006)

カペシタビンを用いた併用化学療法は膵がん術後の生存期間を延長させる

Chemotherapy combination with capecitabine extends survival after pancreatic cancer surgery

2016年American Society of Clinical Oncology年次集会で発表されたランダム化第III相試験の結果、ゲムシタビンによる化学療法にカペシタビンを上乗せすることにより、膵がんの術後予後が改善することが示された。この2剤併用療法は、毒性を大幅に増加させることなく、推定5年生存率が16.3%から28.8%に上昇させた。全生存期間中央値は、併用療法群で28.0か月であったのに対し、ゲムシタビン単独群では25.5か月であった。生存期間中央値の差はわずかに見えるかもしれないが、このがんにとって長期生存期間の改善は大幅な改善である、と筆者らは指摘している。

Full Text

A European phase III trial, one of the largest ever conducted in pancreatic cancer, showed that adding the oral drug capecitabine chemotherapy to gemcitabine prolongs survival without increased toxicity. Adjuvant gemcitabine chemotherapy is currently the standard of care worldwide after surgical removal of pancreatic cancer.

The study was presented at the 2016 American Society of Clinical Oncology (ASCO) Annual Meeting.

"Unfortunately, most patients are not candidates for surgery when they are diagnosed with pancreatic cancer," said lead study author John P. Neoptolemos, MA, MB, BChir, MD, FMedSci, the chair of surgery in the Department Molecular and Clinical Cancer Medicine at the University of Liverpool in Liverpool, United Kingdom. "These findings are significant because they show that those patients who can undergo surgery have a fighting chance of surviving this cancer with the combination of two commonly used chemotherapies."

With 732 patients, the European Study Group for Pancreatic Cancer (ESPAC) 4 trial is the second-largest clinical trial ever conducted in patients with pancreatic cancer who had undergone surgery. Within 12 weeks of surgery, patients with early-stage pancreatic ductal adenocarcinoma were randomly assigned to receive either gemcitabine alone or gemcitabine with capecitabine for 24 weeks.

The median overall survival was 28.0 months with the combination regimen vs. 25.5 months with gemcitabine alone. The estimated 5-year survival rates were 28.8% vs. 16.3% in the two groups. "The difference in median survival may seem modest, but the improvement in long-term survival is substantial for this cancer," said Dr. Neoptolemos. "We've gone from a five-year survival rate of 8% with surgery alone to nearly 30% with adjuvant therapy."

According to the authors, the patient characteristics were representative of a real-world pancreatic cancer population. A large proportion of patients had unfavorable prognostic factors, such as locally advanced or aggressive disease, large tumor size, or incomplete removal of the tumor.

The survival advantage with the combination regimen was similar irrespective of such factors. Patients who had been smokers but stopped smoking after their diagnosis had better outcomes than those who continued smoking.

Overall, there were no major differences in the types and severity of side effects between the two groups. Severe diarrhea was slightly more common with the combination regimen (14 vs. 5 patients), as was fatigue (16 vs. 14 patients). Quality of life was also comparable between the two groups.

The safety of this new gemcitabine-capecitabine chemotherapy regimen opens the opportunity to add other treatments to this combination, which might further improve outcomes for patients. Future research efforts will focus on developing tests to predict which patients would benefit most from a particular adjuvant therapy.

In 2012, 338,000 people were diagnosed with pancreatic cancer worldwide.

"Pancreatic cancer remains one of the most hard-to-treat cancers. It is a major win to find that adding a generic chemotherapy not only improves survival for these patients, but does so with little effect on patients' quality of life," said Smitha Krishnamurthi, MD, ASCO Expert in pancreatic cancer.

This study received funding from Cancer Research UK.

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[News 01]

切除不能進行・再発大腸がんにおいて原発巣部位が予後を予測する

[News 02]

進行期メラノーマにおいてPD-1阻害薬は生存期間を改善する

[News 03]

多発性骨髄腫に対する幹細胞移植は依然として望ましい治療法である

[News 04]

早期臨床試験であっても個別化治療は治療成績を改善する

[News 05]

新規レジメンは多発性骨髄腫の進行を緩徐にする

[News 06]

卵巣がん進行の緩徐化

[News 07]

化学放射線療法は高齢の神経膠芽腫患者の生存期間を延長する

[News 08]

新たな抗体は小細胞肺がんにおける有効性を示した

[News 09]

膀胱がん免疫療法による生存に関する有益性が認められた

[News 10]

血液検査は組織生検に対する非侵襲的な代替法である

[News 11]

小児神経芽腫の有望な治療法

[News 12]

乳がんに対するホルモン療法の延長は良好な結果をもたらす

[News 13]

膵がんに対する術後補助化学療法

[News 14]

希少脳腫瘍治療を変化させる可能性

[News 15]

Claudin 18.2 - 胃がんの新たな標的

[News 16]

モバイルフレンドリーなウェブアプリケーションが肺がんの生存期間を延長する

[News 17]

個別化医療によりがんの治療選択肢が広がる可能性がある

[News 18]

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