

進行腎臓がんに対する腎摘出術回避 (Abstract LBA3)

CARMENA: 転移性腎細胞がん患者の多くが手術を必要としない CARMENA: Many people with metastatic renal cell carcinoma do not need surgery

2018 ASCO Annual Meetingで発表されたランダム化第III相臨床試験の結果、同時発症転移性腎細胞がんの患者の多くが生存期間を短縮することなく手術を回避できることが示された。このCARMENA試験対象患者の全生存期間は、スニチニブによる標的療法のみの群で18.4か月であったのに対し、現在の標準治療である手術後にスニチニブ投与群では13.9か月であった。治療奏効率はこれら2つの群で同等であり、がん増悪までの期間中央値はスニチニブのみを投与された患者でやや長かった(8.3か月対7.2か月)。

Full Text

A randomized phase III clinical trial showed that many people with advanced kidney cancer can avoid a nephrectomy, without compromising survival. The median overall survival for people who received only the targeted therapy sunitinib was 18.4 months, compared to 13.9 months for those who received surgery followed by sunitinib, the current standard of care.

These findings will be presented in ASCO's Plenary Session, which features four studies deemed to have the greatest potential impact on patient care, out of the more than 5,800 abstracts featured as part of the 2018 American Society of Clinical Oncology (ASCO) Annual Meeting.

"Until now, nephrectomy has been considered the standard of care for patients with kidney cancer who have metastatic disease when the cancer is first diagnosed. These cases account for about 20% of all kidney cancers worldwide," said lead study author Arnaud Mejean, MD, a urologist at the Department of Urology, Hôpital Européen Georges-Pompidou - Paris Descartes University in Paris, France. "Our study is the first to question the need for surgery in the era of targeted therapies and clearly shows that surgery for certain people with kidney cancer should no longer be the standard of care."

In addition to putting patients at risk for complications, including blood loss, infection, pulmonary embolism, and heart problems, nephrectomy delays medical treatment for people with advanced kidney cancer for weeks. In some cases, the cancer worsens so rapidly during this delay that there is no time to start systemic treatment.

The CARMENA trial enrolled 450 patients with synchronous metastatic renal cell carcinoma (mRCC). An estimated 40,000 to 50,000 people each year are diagnosed with this type of cancer.

The patients were randomly assigned to receive surgery followed by sunitinib or sunitinib alone. In the surgery group, patients started sunitinib 4-6 weeks after surgery to allow time for recovery from surgery.

Patients were followed for a median time of 50.9 months. Survival was not worse with sunitinib alone than with surgery and sunitinib. This was true for the study population as a whole (median survival was 18.4 months without surgery vs. 13.9 months with surgery), as well as for subgroups with an intermediate (median survival was 23.4 months vs. 19 months) and poor prognosis (median survival was 13.3 months vs. 10.2 months) groups.

The difference in median survival seems to suggest a greater benefit with sunitinib alone. However, this cannot be concluded, as this trial was not designed to prove that one treatment is superior to the other, noted Dr. Mejean.

The rate of tumor response to therapy was the same in the two treatment groups (27.4% and 29.1%) and the median time until the cancer worsened was slightly longer for patients who received sunitinib alone compared with those who also had surgery (8.3 months vs. 7.2 months). Clinical benefit was experienced by 47.9% of patients treated with sunitinib only, compared with 36.6% of patients treated by surgery and sunitinib

The authors remarked that kidney surgery is still the gold standard for people who do not need systemic therapy, such as those with only one metastasis. Those patients were not included in this clinical trial.

"Thanks to this research, many patients with advanced kidney cancer can be spared unnecessary surgery and a host of severe side effects that often accompany it. These findings will likely lead to a dramatic change in treatment for people who are diagnosed with metastatic kidney cancer," said ASCO Expert Sumanta K. Pal, MD.

Some patients in the study had a very good response to sunitinib alone and received surgery after completing systemic treatment. The researchers plan to continue following outcomes in these patients, as well as in other subgroups of study participants. Genomic research on tumor tissue collected on the study is underway.

This study received funding from PHRC (French governmental grants for clinical research).

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