

膀胱がん治療としてのより優れたアジュバント免疫療法

phase III試験の結果、筋層非浸潤性膀胱がんに対する標準治療が変わる可能性が示された

Phase III research represents potential shift in standard care for non-muscle-invasive bladder cancer

筋層非浸潤性膀胱がん治療として使用されるアジュバント免疫療法カルメット・ゲラン桿菌 (BCG) のConnaught株の使用により、カルメット・ゲラン桿菌のTice株と比較し、がん再発が有意に減少したとのデータが2012年AACR学会で発表された。このphase IIIスタディにおいて研究者らは、Connaught株およびTice株のがん再発および進行予防効果を前向きに比較した。149人の患者を組み入れ、週1回のTice株またはConnaught株の注射を6回施行する群に無作為に割り付けた。全ての患者が可視の膀胱腫瘍の除去術を受けた。追跡期間中央値25か月後、全ての患者における5年無再発生存率は61%であった。Connaught株を用いて治療された患者はTice株で治療された患者よりも有意に再発が少なかった。Connaught株で治療された患者の5年無再発生存率は75%であったのに対し、Tice株で治療された患者では46%であった。この結果は筋層非浸潤性膀胱がんの標準治療が変わる可能性を示している、と筆者らは述べている。

Full Text

Use of the Connaught strain of bacillus Calmette-Guérin, an adjuvant immunotherapy used in the treatment of non-muscle-invasive bladder cancer, significantly reduced cancer recurrence compared with the Tice strain of bacillus Calmette-Guérin, according to data presented at the AACR Annual Meeting 2012, held in Chicago, March 31 - April 4.

Cyrill A. Rentsch, M.D., Ph.D., of the division of urology at the University of Basel in Switzerland, presented the phase III data, which represent the potential for a shift in the standard-of-care treatment for non-muscle-invasive bladder cancer.

Bacillus Calmette-Guérin (BCG) was originally developed as a vaccine for tuberculosis but has also been the standard of care for the treatment of noninvasive bladder cancer for more than 30 years. Currently, at least eight strains of BCG are used in treating bladder cancer.

"This is the first study demonstrating that different BCG strains lead to different clinical outcomes in the treatment of bladder cancer," Rentsch said.

He and his colleagues prospectively compared the efficacy of the Connaught and Tice strains in preventing recurrences and progression of cancer. They recruited and randomly assigned 149 patients to six weekly injections of Tice or Connaught. All patients had undergone surgery to remove visible bladder tumors.

After a median follow-up of 25 months, the five-year recurrence-free survival rate for all patients was 61 percent. Patients who underwent treatment with Connaught had significantly fewer recurrences compared with patients treated with Tice. The five-year recurrence-free survival for patients treated with Connaught was 75 percent compared with 46 percent for patients treated with Tice.

"At five years, this results in a more than twofold improvement in the recurrence rate in favor of BCG Connaught," Rentsch said. "Based on its common use, we estimate that more than 20 percent of the worldwide population is at risk to receive treatment with BCG Tice, a treatment that, based on our findings, is less effective in reducing recurrences than BCG Connaught."

These results have the potential to substantially improve the course of disease in many patients with non-muscle-invasive bladder cancer, according to Rentsch.

"As an example of clinically successful immunotherapy, it is a must to further dissect and understand the specific mechanisms underlying BCG immunotherapy," Rentsch said. "The genetic differences identified between the two strains might represent a start for further studies."

The study was funded clinically by the department of urology at the University Hospital of Bern, Switzerland, and the Swiss Group for Clinical Cancer Research. Translational funding included the Swiss National Foundation, Inserm, La Ligue contre le Cancer and Institute Pasteur in Paris.

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