

# Phase III research represents potential shift in standard of care for bladder cancer

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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 here 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."

### **More information:**

#### **Abstract**

A randomized phase III study comparing the efficacy of Bacillus Calmette Guérin strain Tice versus Connaught for immunotherapy of non-muscle invasive bladder cancer

Introduction: For almost forty years now, adjuvant immunotherapy with intravesical Bacillus Calmette Guérin (BCG) is standard of care in the treatment of non-muscle invasive bladder cancer (NMIBC). The

question whether the choice of the different available BCG strains used for treatment influences treatment outcome is still under debate. We report on a randomized phase III study comparing the two most commonly used strains in Europe and the USA.

**Patients and Methods:** This study was performed under approval of the Cantonal Ethical Committee of Bern, Switzerland, to evaluate recurrence free survival in patients treated with BCG as the primary end-point.

Between 1998 and 2010 149 patients (n=149) were recruited. Patients underwent transurethral resection of all visible bladder tumors or random bladder biopsies in case of a solely positive bladder wash cytology. TaG3 and T1G3 tumors underwent a second resection to confirm non-muscle invasive disease. Two to 15 days after surgery, patients were either randomized to receive six weekly intravesical instillations with 2-8x10<sup>8</sup> CFU OncoTice ® (BCG Tice) or 6.6-19.2 x10<sup>8</sup> CFU ImmuCyst ® (BCG Connaught) dissolved in 50 ml of saline according to manufacturers recommendations. Patients were followed in 3-monthly intervals for 3yrs, then in 6-monthly intervals by cystoscopy and bladder wash cytology. Relapses were confirmed by histology after transurethral surgery. Cox regression analysis and Log rank tests served for statistical analysis.

**Results:** Gender, age, tumor stage and grade were well balanced between the two treatment arms (p=0.38). Median follow up was 25 months (range: 0.3-136). Side effects did not differ between the two treatment arms (p=0.42). Age and gender did not have an impact on treatment response (p=0.71). Five year recurrence-free survival for all patients was 61%. Patients treated with Connaught had significantly less recurrences than patients treated with OncoTice (p

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