Switching of bacillus Calmette-Guérin (BCG) strain at second course of BCG therapy may reduce BCG-related side effects in patients with BCG relapsing tumor

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Introduction

• To investigate the clinical efficacy and safety of switching of BCG strain at the second course of BCG therapy in patients with BCG-relapsing non-muscle-invasive bladder cancer.

Patients characteristics

<table>
<thead>
<tr>
<th></th>
<th>Non-switching</th>
<th>Switching</th>
<th>Switching p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of patients.</td>
<td>69 (100)</td>
<td>28 (100)</td>
<td>0.18</td>
</tr>
<tr>
<td>Age, n(%)</td>
<td>&lt;65 yrs</td>
<td>34 (49)</td>
<td>18 (64)</td>
</tr>
<tr>
<td></td>
<td>≥65 yrs</td>
<td>35 (51)</td>
<td>18 (64)</td>
</tr>
<tr>
<td>Sex, n(%)</td>
<td>Male</td>
<td>56 (84)</td>
<td>23 (82)</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>11 (16)</td>
<td>23 (82)</td>
</tr>
</tbody>
</table>

Clinicopathological findings at initial BCG therapy

Tumor grade

- G1: 32 (46)
- G3: 37 (54)

Stage

- Ta/is: 45 (65)
- T1: 24 (35)

Multiplicity

- Single: 22 (32)
- Multiple: 47 (68)

Concurrent CIS

- Negative: 55 (80)
- Positive: 14 (20)

BCG relapse

- ≤24 mo: 21 (75)
- >24 mo: 16 (60)

Clinicopathological findings of BCG-relapsing tumors

Tumor grade

- G1: 33 (48)
- G3: 36 (52)

Stage

- Ta/is: 49 (71)
- T1: 20 (29)

Multiplicity

- Single: 34 (49)
- Multiple: 35 (51)

Concurrent CIS

- Negative: 58 (84)
- Positive: 11 (16)

BCG-related side effects

- Hematuria, n(%): 3 (6)
- LUTS, n(%): 1 (2)
- Fever, n(%): 1 (2)
- All, n(%): 7 (14)

Conclusions

• To investigate the clinical efficacy and safety of switching of BCG strain at the second course of BCG therapy in patients with BCG-relapsing non-muscle-invasive bladder cancer.

Patients and methods

138 NMIBC patients were treated with a second induction course of BCG therapy for tumor recurrence after initial BCG therapy.

Connaught to Tokyo-172

- N=71
- 18 patient had BCG-resistance
- 97 patient had BCG-relapsing

Connaught to Connaught

- N=26

Tokyo-172 to Connaught

- N=56
- Non-switching
- Switching

Tokyo-172 to Tokyo-172

- N=13

Oncological outcomes

- Recurrence-free survival
- Progression-free survival

BCG-related major side effects were defined according to our previous study (Takeda et al. Urology 2009)

- Macroscopic hematuria and lower urinary tract symptoms (LUTS) that persisting more than 48 hours
- Fever persisting beyond 2 days or a fever ≥ 38°C
- Other side effects such as epididymitis, prostatitis, and systemic infection were classified as major side effects.

Conclusions

• In patients with a BCG-relapsing tumor after the initial BCG therapy, the same BCG strain as that administered at the initial BCG therapy could be utilized effectively for the second BCG therapy.
• Patients treated with BCG Tokyo-172 for an initial tumor had a higher incidence of side effects during the second BCG therapy using the same strain.