The Role of Adjuvant Intravesical BCG Therapy for Medium/High Risk Non-Invasive Bladder Tumours

Introduction and Objectives: To assess the role of one single-shot Epirubicin instillation associated with intravesical BCG therapy after transurethral resection in order to prevent recurrence and progression in medium/high risk, non-invasive bladder tumours.

Materials and Methods: Between 2000-2012, 146 patients with non-invasive bladder tumours were treated by the same surgeon (Dr. G. Glück). **Group A** included 75 patients and were treated between August 2002-January 2012 according to the 2011 EAU protocol, with one single-shot Epirubicin instillation associated with intravesical BCG therapy after TUR-BT. There were 16 patients with intermediate risk and 59 patients with high risk bladder tumor (16 Ta and 59 T1). Stratifications according to the grading was: 26 G1, 43 G2 and 6 G3. From the total of 75 patients, 21 were female and 54 male. The mean age in this group was 62 years (ranged between 16-82 years) with a mean follow-up of 58 months (range between 3-113 months). The control group (group B) consisted of 71 patients treated between 2000-2002 with TUR-BT only. Retrospectively, we found in this group 40 patients with intermediate risk tumours and 31 with high risk non-invasive bladder tumours. Stratification according to the stage was: 36 pTa and 35 pT1, while stratification according to the grading was as follows: 42 patients with G1, 25 patients with G2 and 4 patients with G3. Regarding the gender, there were 16 female and 55 male patients. Mean age was 67 years, ranged between 41-84 years. The mean follow-up was 86 months, ranged between 76-108 months. The criterias for BCG administration were the following: multiple tumors at first presentation, tumour size more than 3 cm, associated Cis, high grade, early recurrency, high rate of reccurency. All patients received one instillation with 50 mg of Epirubicin in the first 6 hours post TUR-BT. The BCG therapy began at 14 days post TUR-BT, using 150 mg BCG instillation. All patients received 6 BCG instillations. If a patient developed reccurence, the tumour was resected followed by another cycle of 6 BCG instillations. In selected cases (30 patients) was used the maintenance therapy. In 17 cases re-TURB-BT was performed.

Results: In group A, 17 patients (22.7%) had 23 recurrencies and 5 patients developed tumor progression (6.7%). A number of 5 patients (6.7%) developed complications like cystitis, arthritis, vasculitis or gonarthritis. There were 4 deaths recorded in this group of study (none of oncological cause). In group B 33 patients (46.4%) developed recurrencies (36 recurrencies), while 14 patients (19.7%) developed tumor progression. There were 28 deaths recorded (11 oncological).

Conclusions: It was confirmed that intravesical BCG insillation can be an efficient tool in the adjuvant treatment of non-muscle invasive bladder tumours. The recurrence rate was reduced by 23.7%, with a reduction in the progression rate of 13% during follow up.