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## Heat Targeted Drug Delivery (COMBAT) in Superficial TCC: First Midterm Results in a Cohort of High-Risk Patients Scheduled for Cystectomy

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**Background:** Due to the suboptimal outcomes in recurrent superficial TCC over the last 30 years the search for new treatments continues. We report the first mid term results of a high risk cohort of heavily pretreated patients by a circulating device for intravesical thermochemotherapy. It is known that the effect of mitomycin increases at a temperature over 40°C.

**Methods:** 58 patients with different failed methods of former intravesical therapy and recurrent TCC (21 intermediate risk and 37 high risk patients) were treated with the COMBAT device which facilitates irrigation of the bladder with mitomycin 40 mg at exactly 43 degrees Celsius for 1 hour/6 courses weekly. Side effects were monitored prospectively, and success of the treatment was controlled by ReTUR whenever possible and afterwards by 3 monthly cystoscopy and cytology.

**Results:** 22 patients had dysuria during treatment and 9/58 suffered from hematuria but without intervention. In 6 cases urinary tract infection occurred and 3 patients had allergic reaction. In one patient thermochemotherapy must be terminated due to pain and discomfort, no long term morbidity was recorded over the whole period. The FU was 14 months (3-29) for the entire cohort, 17 patients had a FU of over 2 years. One patient had recurrent pTaGIII Tumor managed successfully by TUR. 2 patients underwent cystectomy because of invasive recurrence early after intravesical therapy, one patient developed bone metastasis 2 years after therapy without intravesical tumor.

**Conclusions:** Thermochemotherapy with heated mitomycin is a well tolerated new option for patients with superficial TCC who are at high risk of recurrence or progression. The toxicity is acceptable and no long term morbidity was observed. The rate of cystectomies in this heavily pretreated group of patients including 18 BCG failures was very low with N = 2 respective 1,9%. Intravesical thermochemotherapy seems to be a new therapeutic bladder preserving option in high risk patients with superficial TCC. It is of note that thermochemotherapy has now been included in the European Guidelines.