ORGAN PRESERVING, QUADRIMODAL TREATMENT OF T1-2N0M0 BLADDER CANCER: RESULTS AFTER TRANS-URETHRAL RESECTION AND SIMULTANEOUS RADIOCHEMOTHERAPY COMBINED WITH REGIONAL DEEP HYPERTERMIA.

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Purpose:
Evaluation of the safety and effectiveness of a quadrimodal treatment of T1-2N0M0 transitional cell cancer of the bladder with trans-urethral resection (TUR) followed by simultaneous radiochemotherapy combined with regional deep hyperthermia.

Patients and method:
Between 11/2003 and 09/2006, 37 consecutive patients were enrolled in this phase II-study. After trans-urethral resection the patients received external beam radiotherapy of the bladder and the pelvic lymph nodes up to 50.4 Gy (SD 1.8 Gy, range 50.4-54); followed by a local boost of the bladder up to a median total dose of 57.6 Gy (SD 1.8 Gy; range 54-61.3). The medium overall treatment time was 45 days (range 41-56). 95% (35/37) of the patients received a radiosensitizing chemotherapy, usually cisplatin and 5-fluorouracil during the first and fifth irradiation week. During radiotherapy, regional deep hyperthermia was performed once weekly with the BSD 2000•3D/PC-hyperthermia system. Acute toxicity was graded with the Common Terminology Criteria for Adverse Events, Version 3.0. The remission rate was re-evaluated 6 weeks after treatment by re-TUR, local control was assessed by periodical follow-up cystoscopies.

Results:
The median follow-up was 20 months (range 4-39). The median age was 67 years (range 38-82). 76% (28/37) received more than 3 hyperthermia-fractions. Because of co-morbidities or request 21% (8/37) of the patients received ≤ 2 hyperthermia fractions. The median number of hyperthermia treatments was 5 (range 1-7). Acute toxicity was low: Grade 3 gastrointestinal toxicity 5% (2/37), grade 3-4 hematotoxicity 16% (6/37). At the time of re-TUR the complete response rate was 94% (33/35). The local relapse free survival probability was 90.2% at 2 years. At the time of the last follow-up examination the bladder preserving rate was 100%.

Conclusion:
The quadrimodal treatment of T1-2N0M0 bladder carcinoma was feasible and well tolerated. Local control and bladder preserving rates were encouraging. However, for a conclusive appraisal of the results longer follow-up is necessary. To clarify the additional effect of deep regional hyperthermia randomised trials are required.