

Neoadjuvant Chemohyperthermia (CHT) for the Treatment of High-Risk Non-Muscle Invasive Bladder Cancer: A Phase I Study

Introduction and Objective: Chemohyperthermia, using microwaves technology, has demonstrated its efficacy as adjuvant and neoadjuvant treatment on medium-high risk bladder tumors or after failure of other therapies. We believe that the best way to evaluate toxicity and antitumoral efficacy of a new system, which performs bladder chemohyperthermia through a recirculative hot solution, was a Phase I study of neoadjuvancy in high-risk patients. The objectives were: *main*: to evaluate the tolerancy and side effects of this new neoadjuvant recirculative chemohyperthermia; *secondary*: to evaluate the antitumoral effect of the treatment.

Materials and Methods: Between November 2010 and May 2011 a controlled prospective study was performed including 11 patients with medium-high grade non-muscle-invasive bladder tumors to evaluate the efficacy and security of an intravesical neoadjuvant treatment with 80 mgr. of mytomicyn C applied through a new recirculating system of hot fluids (43 °C) during 60 minutes.

Results: The side effects of the 87 evaluable doses were mild and transitory (CTC: grade I). Its antitumoral efficacy was high, among the 9 patients finally evaluable 6 (66.6%) showed tumoral absence (pT0) -RC- and other 3 (33.3%) showed tumoral reduction > 50% on number/side of the lesions -RP-.

Conclusion: It was demonstrated that this new external hot recirculating system of chemohyperthermia has a high antitumoral efficacy and that side effects during treatment were mild and transitory

Table 1: Treatment scheme and data recovery

Suspect	Confirm	Day 1	Day 8	Day 15	Day 22	Day 29	Day 36	Day 43	Day 50	Day 57-64
Cystoscopy + Biopsy	- Inform. Consent	CHT	CHT	CHT	CHT	CHT	CHT	CHT	CHT	TUR
		VAS IPSS	VAS IPSS	VAS IPSS	VAS IPSS	VAS IPSS	VAS IPSS	VAS IPSS	VAS IPSS	Pathology

Table 2: Side effects of the CHT administered with the BRS

Significative haematuria	1 (1.1%)
Mild & transient haematuria	8 (9.1%)
Mild pain needing oral NEAIs	3 (4.4%)
Mild pain not needing treatment	11 (12.6%)
Dysuria (following 24 hs)	21 (24.1%)
Bladder spasms	17 (19.5%)
Malaise	7 (8%)
Bacterial cystitis	0 (0%)
Fever (>37.5 °C)	0 (0%)
MMC Allergy	0 (0%)
Urethral stenosis (<i>de novo</i>)	0 (0%)