

Abstract 20-942

Prospective randomized clinical trial of chemohyperthermia with mitomycin-C prior to transurethral resection of the bladder and its relationship with the rate of early recurrence in non-muscle invasive bladder cancer: intermediate

Plata Bello A., Garcia Alvarez C., Plata Bello J., Tamayo Jover M.A., Concepción Masip T.
University Hospital of Canary Islands, Spain



**I have no conflicts of interest for
this presentation**

BACKGROUND AND OBJECTIVE

The recurrence rate for NMIBC varies from 50-70%. Single immediate postoperative instillation of mitomycin-C (iPOP-MMC) is considered mandatory as it may prevent recurrence in some NMIBC. Despite this, 30% of patients are not suitable for it due to hematuria or deep TURB. We propose that the use of chemohyperthermia (CH-MMC) immediately prior to TURBT should be a safe and effective alternative available for every patients independently of postoperative complications.

MATERIALS AND METHODS

***Single center prospective randomized control clinical trial:**

INTENTION TO TREAT ANALYSIS (n=134) // PROTOCOL ANALYSIS (n=76)

*Primary analysis after a follow-up period of 12 months: **non-inferiority study, safety and tolerability of pre-operative instillation of CH-MMC** in 134 patients: 71 in control arm (CA: postoperative normothermia MMC) and 63 in the experimental arm (EA: pre-operative hyperthermia MMC).

- *Inclusion Criteria: Low to intermediate risk NMIBC, single tumor <30mm or multiple <8 lesions and <30mm. Patients with a history of bladder TURBT <1 year were excluded.*

- Follow up with cystoscopy, cytology and image test.

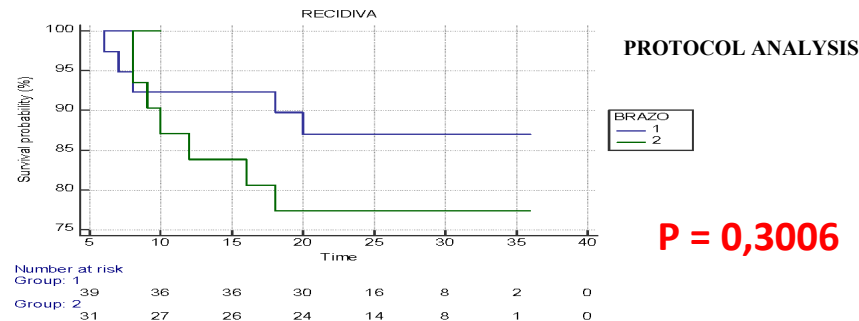
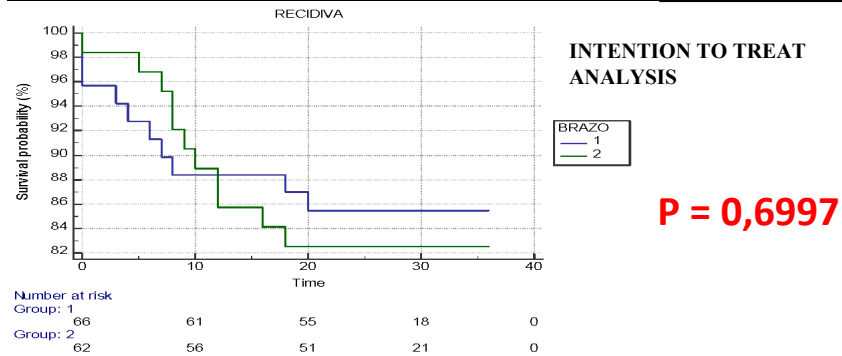
- Assessment tools for tolerability of the instillation procedure (pain scale analogue–visual) and global satisfaction questionnaire.

RESULTS

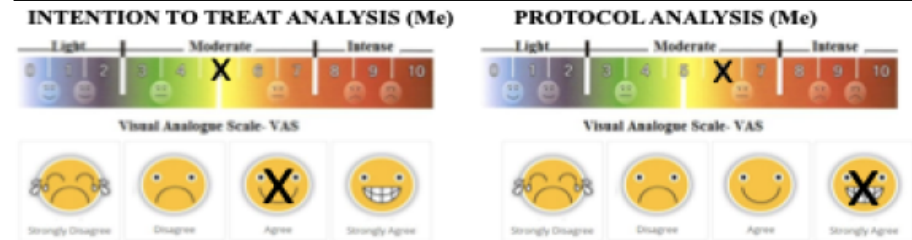
INTENTION TO TREAT ANALYSIS	CA (N-MMC)	EA (CH-MMC)
GENDER (Male/Female)	59 (83.1%) / 12 (16.9%)	52 (82.5%) / 11 (17.5%)
AGE (Me)	74	73
INSTILLATIONS (YES/NO)	50 (70.4%) / 21 (29.6%)	60 (95.2%) / 3 (4.8%)
PATHOLOGICAL ANATOMY		
*Number of tumors (Me)	1	1
*Tumor size mm (Me)	10	10
*TNM		
- pTa	40 (58.8%)	32 (54.2%)
*Grade		
- 1 & 2	32 (47.8%)	26 (44.1%)
- 3	23 (34.3%)	19 (32.2%)
Adverse drug reaction (YES/NO)	3 (4.3%) / 67 (95.7%)	7 (11.7%) / 53 (88.3%)
RECURRENCE 12m	3 (4.2%)	3 (4.8%)
Months to recurrence (Me)	8	9

PROTOCOL ANALYSIS	CA (N-MMC)	EA: CH-MMC
GENDER (Male/Female)	32 (78%) / 9 (22%)	26 (74.3%) / 9 (25.7%)
AGE (Me)	72	72
INSTILLATIONS (YES/NO)	32 (78%) / 9 (22%)	35 (100%) / 0 (0%)
PATHOLOGICAL ANATOMY		
*Number of tumors (Me)	1	1
*Tumor size mm (Me)	10	12
*TNM		
- pTa	37 (94.9%)	32 (100%)
*Grado		
- 1	31 (79.5%)	26 (81.3%)
- 3	7 (17.9%)	6 (18.8%)
Adverse drug reaction (YES/NO)	1 (2.5%) / 39 (97.5%)	5 (15.6%) / 27 (84.4%)
RECURRENCE 12m	3 (7.3%)	3 (8.6%)
Months to recurrence (Me)	8	9

Recurrence analysis



Global tolerability/satisfaction to MMC-CH instillation



CONCLUSION

- Chemohyperthermia treatment with mitomycin-c pre-TURBT seems to be a safe and well tolerated alternative.
- After a follow-up period of 12 months, the recurrence rate in both arms seems to be equivalent.