

2. Cancer (Condition after Cancer Surgery and Unspecified Adverse Drug Reactions of Anti-cancer Drugs)**Reference**

Fukui I, Gotoh S, Kihara K, et al. Adjuvant chemotherapy for invasive bladder cancer. Multicenter study. *Nippon Hinyokika Gakkai Zasshi (Japanese Journal of Urology)* 1992; 83: 1633-9 (in Japanese with English abstract).

1. Objectives

To evaluate the effect of postoperative adjuvant chemotherapy for bladder cancer on survival (the efficacy of the combination with jumentaihoto (十全大補湯) was assessed in patients stratified into 3 groups).

2. Design

Randomized controlled trial (RCT).

3. Setting

One university hospital (Tokyo Medical and Dental University) and 9 other institutions, Japan.

4. Participants

Forty-eight patients undergoing total cystectomy for bladder cancer.

5. Intervention

Arm 1: chemotherapy + TSUMURA Jumentaihoto Extract Granules (十全大補湯) 7.5 g/day (n=16).

Arm 2: chemotherapy + Picibanil (OK432) (n=15).

Arm 3: chemotherapy only (n=17).

Patients received chemotherapy with one of three cis-platinum-based combinations (5-fluorouracil + adriamycin + cis-platinum [FAP], cyclophosphamide + vincristine + methotrexate [COM] alternating with FAP, or ifosfamide + 5-fluorouracil + cis-platinum [IFP]) for at least 3 cycles, and 6 to 8 cycles if possible.

6. Main outcome measures

Survival.

7. Main results

There was no significant difference between groups.

8. Conclusions

The combination with jumentaihoto for patients with bladder cancer had no effect on their survival.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

None.

11. Abstractor's comments

Since the main objective of this multicenter study was to examine the effect of adjuvant chemotherapy for invasive bladder cancer, main analysis was not conducted on the combination with or without jumentaihoto, and the sample size was too small (17 patients) to draw firm conclusions on the efficacy of jumentaihoto. Investigation with a larger sample size is expected.

12. Abstractor and date

Oikawa T, 19 September 2008, 6 January 2010, 1 June 2010.