# 学位論文の要旨

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Antibiotic Prophylaxis in Transcatheter Treatment of Hepatocellular Carcinoma: an Open Randomized Prospective Study of Oral Versus Intravenous Administration

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#### 論文内容の要旨

## INTRODUCTION

Transcatheter arterial chemoembolization (TACE) and transcatheter arterial infusion chemotherapy (TAI) are increasingly used to treat inoperable liver malignancies. It has not been determined whether standard oral and intravenous administration of antibiotics have different prophylactic effects against post-TACE/TAI infection. We compared the efficacy of oral levofloxacin (LVFX) and intravenous cephazolin (CEZ) in patients receiving TACE/TAI for hepatocellular carcinoma (HCC) using a prospective design.

## **MATERIALS AND METHODS**

One hundred eighty-three subjects with HCC were scheduled to undergo transcatheter arterial therapy at Hyogo Prefectural Awaji Hospital between October 2007 and March 2009. Thirty-three patients did not agree to participate. Six subjects were excluded from the protocol

because of the presence of some of these exclusion criteria (three were over 85 years old, and the others had drug allergy). Therefore, 144 subjects were enrolled in this prospective study and randomly assigned to two groups. Fifteen patients were excluded for breach of the protocol. Then, one hundred twenty-nine eligible subjects with HCC treated by TACE/TAI were analyzed in this study. Patients were randomly assigned by the envelope method to groups who received either intravenous infusion of CEZ at 2 g/day or oral administration of LVFX at 300 mg/day for 5 days. Laboratory data, changes in antibiotic administration from the standard ones, duration of hospital stay, side effects of antibiotics, and infectious complications were assessed. Using a questionnaire, we asked each enrolled patient whether they preferred oral or intravenous administration of antibiotics, and if they had previously received transcatheter therapy and/or had been given either of the antibiotics used in this study.

#### RESULTS AND DISCUSSION

There were no significant differences between the two groups in terms of baseline characteristics before and after exclusion of these 15 cases. The peak WBC counts (day 4) of CEZ group vs. LVFX group were 5799±408 vs. 5626±417 /μL, peak serum CRP levels (day 4) were 3.67±0.52 vs. 3.29±0.48 mg/dL, infectious complications were 1 vs. 1 patient (p=0.483), adverse events were 3 vs. 4 patients (p=0.483), prolongation/dose escalation of antibiotics were 6 vs. 3 patients (p=0.474), period of antibiotic administrations were 5.3±1.4 vs. 5.1±1.1 days (p=0.507), and length of hospital stay were 10.1±4.2 vs. 10.1±5.8 days(p=0.139).

There were no significant differences in the change of WBC counts (p=0.587; repeated measure ANOVA) and serum CRP levels (p=0.820; repeated measure ANOVA) between the groups; there were also no significant inter-group differences in the numbers of infectious and other adverse events.

We investigated whether the patients preferred oral or intravenous administration of antibiotics. The patients who had previously received transcatheter therapy, and had already been exposed to these two antibiotics were investigated. We were able to obtain 48 replies from the 56 applicable patients, among whom 36 (75%) stated that they preferred oral administration of prophylactic antibiotics

## **CONCLUSION**

Our study findings suggest that the results of peroral administration of LVFX for the prevention of post-procedure infectious complications in patients receiving TACE/TAI for HCC are not inferior to those of intravenous administration of CEZ.

These observations suggest that peroral administration of LVFX and intravenous drip-infusion of CEZ have roughly equivalent effectiveness for prophylaxis against post-procedural infectious complications of HCC. Therefore, for easier prophylaxis, peroral administration of antibiotics is preferable, as might be expected.