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### Introduction & Objectives:

Axitinib is used as second or further-line agent for metastatic renal cell carcinoma(mRCC). Axitinib is a drug recommended to adjust the dose according to side effects such as high blood pressure. We analyzed how much drug withdrawal and dose adjustment were performed in the real world and how they contribute to overall survival.

### Materials & Methods:

We retrospectively analyzed the cases of 53 mRCC patients who received treatment with Axitinib between 2012 and 2018 at Kanagawa Cancer Center. Overall survival (OS) and progression free survival (PFS) from the initiation of axitinib were assessed. Relative dose intensity: RDI (%) = total dose (mg) / 10 × total administration days (mg) × 100.

### Results:

The study group comprised 53 patients. Median age was 65-year-old (34-79). The median OS and PFS from the initiation of Axitinib were 32.9 months and 8.5 months, respectively. 29 patients received Axitinib as second line treatment, in whom the median OS and median PFS were 32.9 and 8.5 months, respectively, 24 patients received as third or later lines, in whom the median OS and PFS were 37.4 and 12.9 months, respectively. The median RDI was 79% (18%-199%). When the median of RDI was set as cut off value, the OS were 37.3months (<RDI:79%) and 18.3months (>RDI:79%) respectively. (p=0.575) More than half of the patients administered Axitinib without drug withdrawal.

### Conclusions:

Axis trial demonstrated clinical efficacy, the median OS and PFS were 20.1 and 6.7 months respectively. In our hospital, Axitinib outperforms clinical trials not only in the second line, but also in the later lines. The median RDI was 79. More than half of the cases was below the standard dose. It is not necessary to keep RDI high, it is important to set the dose suitable for the individual patient. In the future, Axitinib in combination with immune checkpoint inhibitor may be considered in the first line, dose adjustment of Axitinib may be required depending on side effects.