

## Proposal for a two-tier re-classification of stage IV/M1 renal cell carcinoma into M1 (oligometastatic) and M2 (polymetastatic) sub stages

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**Introduction & Objectives:** Advancements in tumor biology and therapeutics have led to increased understanding of the heterogeneous potential of stage 4 Renal Cell Carcinoma (RCC). We hypothesized that a two-tier classification may more rationally risk stratify stage 4 RCC than the current monolithic classification.

**Materials & Methods:** Multicenter retrospective analysis of patients from the REMARCC (REgistry of MetAstatic RCC) database. Patients were stratified by tumor size into two groups, M1 (Oligometastatic) and M2 (Polymetastatic) sub stages. Primary outcome was overall survival (OS). Secondary outcomes were cancer specific survival (CSS) and progression free survival (PFS). Multivariable regression analysis (MVA) and Kaplan-Meier analysis (KMA) were utilized for outcomes.

**Results:** 431 patients were stratified into proposed M1 and M2 groups (M1=217, M2=214; median follow-up 19.18 months). 59 (13.8%) were Motzer low risk, 273 (63.6%) were Motzer intermediate risk, and 97 (22.6%) were Motzer high risk mRCC. Mean age was (M1=62.37 vs. M2=63.16, p=0.454), Mean Charlson score was M1=5.27 vs. M2=4.83 (p=0.212), and median ECOG was M1=1.00 vs. M2=1.00 (p=0.577). MVA revealed M2 classification (OR=2.536, p<0.001) as a predictive factor for OS. MVA revealed M2 classification (OR=2.233, p<0.001) and male sex (OR=1.63, p=0.033) as predictive factors for CSS. KMA revealed 5 year OS of 36% vs. 21% (p<0.001), 5 year PFS of 35% vs. 22% (p<0.001), and 5 year CSS of 39% vs. 23% (p<0.001) (Figure).

**Conclusions:** Sub-classification of stage IV/M1 RCC into two clinical sub stage categories corresponds to distinctive tumor groups whose oncological potential varies significantly. Division into two distinct categories may enhance risk stratification, refine counseling, and augment clinical trial design by delineating a lower risk and higher risk subset of mRCC.

