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**Efficacy of integrated risk score using omics-based biomarkers for the prediction of acute rejection in kidney transplantation: A randomized prospective pilot study**

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**Objectives :** Acute rejection (AR) is critical for long-term graft survival in kidney transplant recipients (KTRs). This study aimed to evaluate the efficacy of the integrated risk score of omics-based biomarkers in predicting AR in KTRs.

**Methods :** This prospective, randomized, controlled, multicenter, pilot study enrolled 40 patients who newly underwent high-immunologic-risk kidney transplantation (KT). Five omics biomarkers were measured, namely, blood mRNA (three-gene signature), urinary exosomal miRNA (three-gene signature), urinary mRNA (six-gene signature), and two urinary exosomal proteins (hemopexin and tetraspanin-1), at 2 weeks and every 4 weeks after KT for 1 year. An integrated risk score was generated by summing each biomarker up. The biomarker group was informed about the integrated risk scores but not the control group. The outcomes were graft function and frequency of graft biopsy.

**Results :** Sixteen patients in the biomarker group and nineteen in the control group completed the study. The mean estimated glomerular filtration rate after KT was  $55.3 \pm 17.5 \text{ mL/min/1.73m}^2$  and did not differ between the groups. Graft biopsy was performed in two patients (12.5%) and nine (47.4%) in the biomarker and control groups, respectively, with the proportion being significantly lower in the biomarker group ( $P=0.027$ ). One patient (6.3%) in the biomarker group and two (10.5%) in the control group were diagnosed with AR, and the AR incidence did not differ between the groups. The tacrolimus trough level was significantly lower in the biomarker group than in the control group at 1 year after KT ( $P=0.006$ ).

**Conclusions :** Integrated omics biomarker monitoring can help prevent unnecessary or high-complication-risk biopsy and enables tailored immunosuppression by predicting the risk of AR in KTRs.

Figure 2.jpg

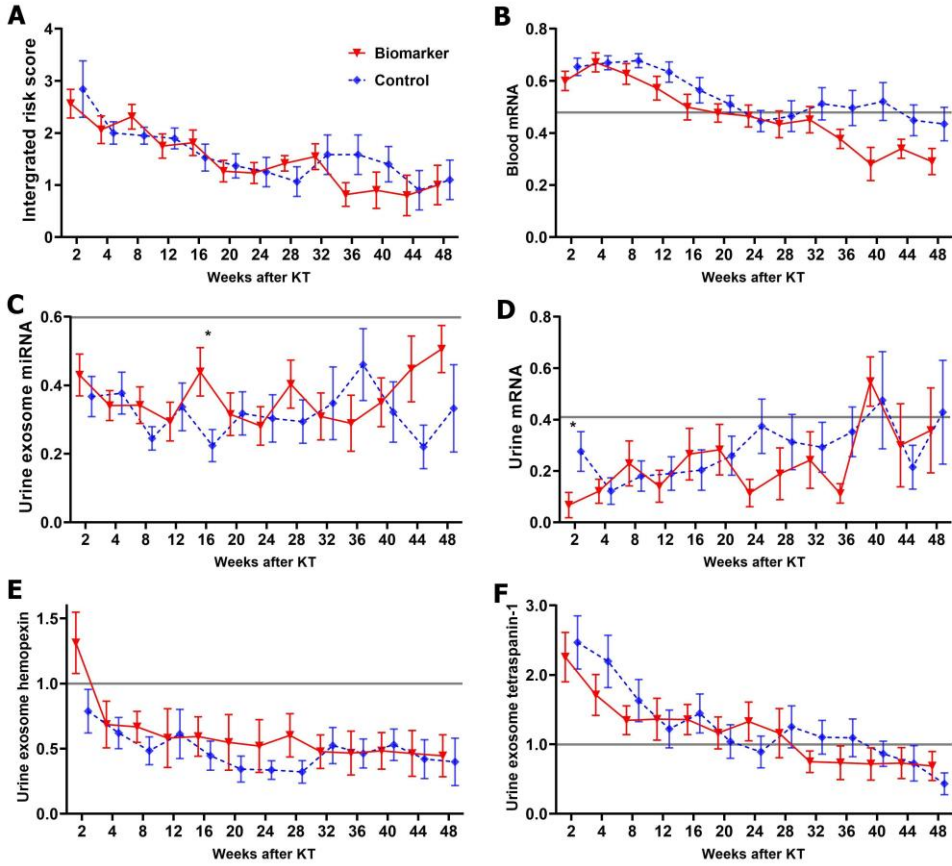


Figure 2.jpg

