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Development of De Novo Anti-HLA Abs in Kidney Transplant Recipients: Final Analysis of the NIH CTOT02 Study

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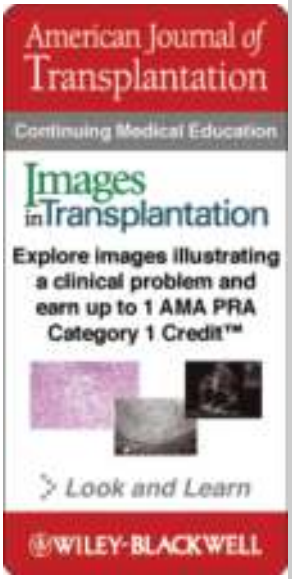

The NIH CTOT02 is the first large multi-center prospective study to examine the causes and effects of development of post-transplant de novo anti-HLA Ab in unsensitized kidney transplant recipients. This analysis is based on the completed data set from the CTOT02 study.

Data were analyzed for the 653 subjects enrolled in the screening phase of the study from 17 centers, who were followed for development of de novo HLA-Ab for up to 60 months post- transplant. 79 (12%) subjects developed de novo HLA-Ab.

The interval to development of HLA-Ab following transplantation was fairly constant, with no difference between those who developed Abs early (≤12 months post transplant) and those who developed Ab later (>12 months post transplant) with respect to patient characteristics or clinical outcomes. Among the 79 subjects with de novo Ab, 17 (21.5%)

had class I only, 51 (64%) had class II only, and 11 (13.9%) had both. Multivariate analysis of factors associated with increased risk of developing HLA-Ab identified age of subject, type of induction therapy and HLA mismatching. The mean age of HLA-Ab positive subjects was significantly younger, 36.8 vs 43.2 years (p=0.001). Use of anti-IL2R Ab as induction therapy was independently protective against development of anti-HLA Abs (p=0.002).

Anti-HLA Ab positive subjects were significantly more likely to develop rejection (22.8% vs 5.4%, p<0.001), with in-vitro complement binding anti-HLA Ab being more highly associated with rejection. Samples from 74 of 79 anti-HLA positive subjects were available for in vitro C1q binding studies: 36 (48.6%) were C1q positive and 38 (51.4%) were C1q negative, with complement binding Ab being significantly more likely to be directed against donor specific antigens (p=0.007), and associated with rejection (33.3% vs 10.5 %, p=0.024) Despite this and in contradiction to previously reported retrospective studies there was no difference in allograft survival in subjects who developed anti-HLA Abs.

This multi-center prospective analysis describes the characteristics and risks of de novo HLA-Ab development in kidney transplant recipients, and indicates that development of de novo HLA-Ab is rather an uncommon event that in contrast to the prevailing dogma may not be associated with long term worse outcomes.

Chandraker, A.: Other, Sanofi, Consultant, Novartis, DSMB, Tolera, DMB.

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