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Eculizumab Therapy for Antibody-Mediated Injury in Kidney Transplant Recipients

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Objectives: We evaluated the efficacy and safety of eculizumab in comparison with plasmapheresis (PP) and intravenous immunoglobulin (IVIG) therapy in renal transplant recipients diagnosed with antibody-mediated rejection (AMR).

Methods: This was a multi-center, open-label, prospective, randomized analysis. The patients were randomized as to therapy type (eculizumab infusions or standard of care, SOC: PP/IVIG). The patients were evaluated for the continuing presence of donor-specific antibodies (DSAs) and C4d (staining on biopsy), as well as histological evidence, using repeat renal biopsies after treatment.

Results: The allograft biopsies revealed that eculizumab did not prevent the progression to transplant glomerulopathy. Only 2 patients in the SOC arm experienced rejection reversal, and no graft losses occurred in either group. Following AMR treatment, the DSA titers generally decreased compared to titers taken at the time of AMR diagnosis. There were no serious adverse effects in the eculizumab arm.

Conclusions: Eculizumab alone is not sufficient to treat AMR and does not prevent acute AMR from progressing to chronic AMR or to transplant glomerulopathy. However, it should be considered as a potential alternative therapy because it may be associated with decreased DSA levels.

Table1.Clinical and laboratory characteristics of cases

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Case	Sex(F/M)	Age(y)	Treatment of AMR	No. of RT	Cytotoxic XM	Induction Therapy	IS	Duration of RT-AMR (days)	DSA	No. of Biopsy	C4d	*PTC	*ACR	Additional Rejection Therapy	Graft loss	Last Cr Level (mg/dL)
*1	F	59	Eculizumab arm	0	Negative	ATG	FK, MMF, P	2912	Negative	4	Positive	1	Positive	BS, CAMPATH	...	1.34
2	F	50	Eculizumab arm	0	Negative	Basiliximab	FK, MMF, P	5495	Positive	3	Positive	0	Negative	VELCADE, PP/IVIG	...	1.04
4	F	36	Eculizumab arm	0	Negative	Basiliximab	FK, MMF, P	3004	Positive	2	Positive	3	Negative	none	...	Not tested
5	F	28	Eculizumab arm	0	Negative	ATG	FK, MMF, P	1257	Positive	3	Positive	3	Negative	BS, IVIG	...	1.31
8	F	52	Eculizumab arm	0	Negative	ATG	FK, MMF, P	24	Positive	2	Positive	2	Negative	BS,PP/IVIG,RITUX, VELCADE	...	2.01
9	F	32	Eculizumab arm	1	Negative	ATG	FK, MMF, P	2100	Positive	3	Positive	2	Negative	BS,PP/IVIG	...	2.14
11	M	45	Eculizumab arm	0	Negative	ATG	FK, MMF, P	564	Positive	3	Positive	1	Negative	PP/IVIG	...	Not tested
3	M	63	Standard of Care Arm	0	Negative	Basiliximab	FK, MMF, P	334	Positive	3	Positive	2	Positive	BS, ATG	...	1.73
6	F	33	Standard of Care Arm	0	Negative	Basiliximab	FK, MMF, P	976	Negative	1	Positive	1	Positive	NA (withdrawal)	...	NA (withdrawal)
7	F	26	Standard of Care Arm	1	Negative	Basiliximab	FK, MMF, P	1243	Positive	3	Positive	1	Negative	BS,PP/IVIG	...	1.69
10	M	61	Standard of Care Arm	1	Negative	ATG	FK, MMF, P	1	Positive	4	Positive	1	Negative	Ecu	...	1.66

Table2.Patient characteristics by treatment received

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	Overall (n=11)	**Eculizumab arm (n= 7)**	**Standard of Care arm (n = 4)**
Age at transplant	44.4	43.1	45.7
Female	8	6	2
Black race	2	1	1
DSA strength at the time of AMR			
Luminex positive	9	7	2
DSA strength after treatment of AMR			
Luminex positive	6	5	1
HLA antibody class			
None	2	1	1
Class I	1	1	0
Class II	3	2	1
Class I and II	5	3	2
Induction agent			
Antithymocyte globulin	6	5	1
Basiliximab	5	2	3
Median posttransplant PP session	6.4	4.5	8.3
Days until AMR diagnosis	1415	2193	638
Mean serum creatinine at 6 month, mg/dL	1.68	1.87	1.49
Mean serum creatinine at 1 year, mg/dL	1.62	1.56	1.69
Rejection reversal	2	0	2
Graft loss	0	0	0
DSA, donor specific antibody, PP, plasmapheresis, AMR, antibody mediated rejection			