LONG-TERM EFFICACY AND SAFETY OF EVEROLIMUS BASED IMMUNOSUPPRESSION ON DE NOVO KIDNEY TRANSPLANTATION WITH 7 YEARS FOLLOW-UP

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OBJECTIVES

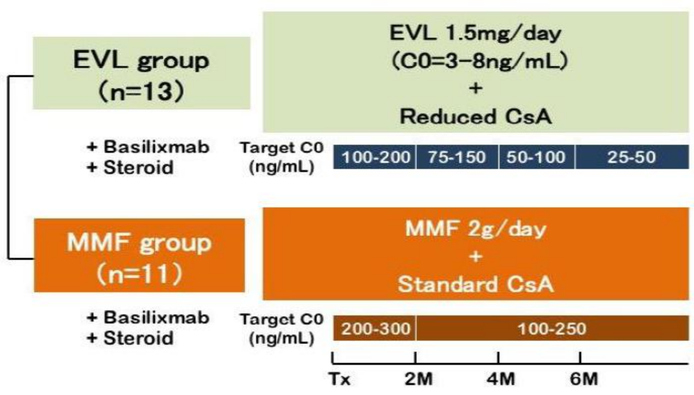
Long-term efficacy and safety of everolimus (EVR) based immunosuppression for de novo kidney transplant recipient who were involved in A1202 study from our institute was evaluated in clinical outcomes as well as protocol biopsies findings and donor specific antibody (DSA) production.

METHODS

During March 2008 and August 2009, twenty-four recipients prospectively randomized into two groups to compare clinical outcome of kidney transplantation between EVR based and mycophenolate mofetile (MMF) based immunosuppression. EVR group received reduced-exposure cyclosporine (CsA; target C0 25-50ng/ml after 6 months) + steroid, and EVR-C0 were adjusted 3-12ng/ml. MMF group received standard-exposure cyclosporine (CsA; target C0 100-250ng/ml after 6 months) + steroid. Both group received basiliximab induction. Follow-up data until March 2016 are desribed.

RESULTS

Study Protocol



Patient's Demography

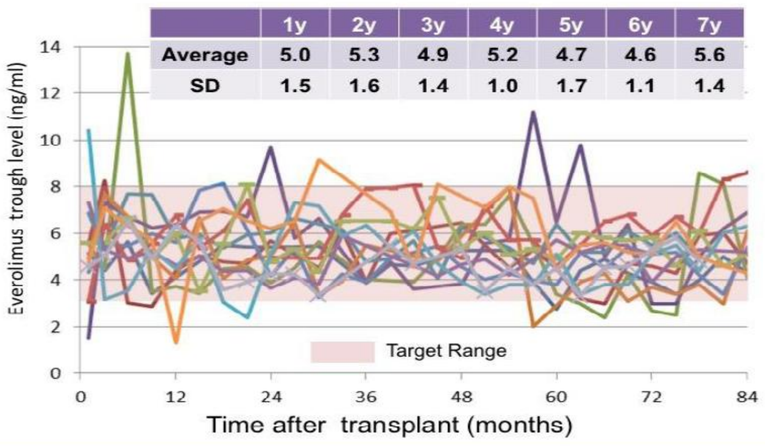
	EVR group	MMF group
Patients	13	11
Age	22-61 (44±15)	22-49 (35±9)
Male/Female	8/5	7/4
Disease	CGN 4 IgA nephropathy 4 Renal sclerosis 1 Interstitial nephritis 1 ADPKD 1 Medullary sponge kidney 1 Reflux N 1	CGN 3 IgA nephropathy 4 Diabetes mellitus 2 FSGS 1 Reflux N 1
Body Mass Index	17.5-27.7 (21.7±3.1)	17.0-30.0 (21.0±3.1)
Dialysis (month)	0-118 (20±32) Preemptive 4/13 (30.8%)	0-153 (28±43) Preemptive 3/11 (27.3%)
Observation (month)	80 – 96 (88 ± 6)	80 – 97 (89 ± 6)
Patient & Graft Survival	100% / 100%	100% / 90.9% (one graft loss at 5.5y PO)

Donor's Demography

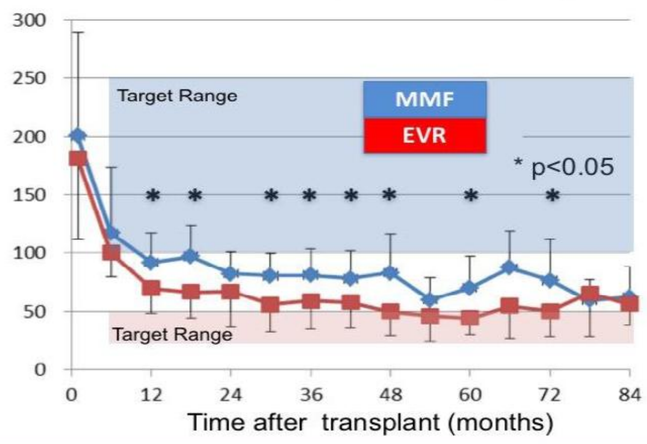
	EVR group	MMF group
Sex (M/F)	7/6	4/7
Age	34-63 (52±8)	43-62 (55±6)
Relationship	Spouse 5 Sibling 6 Parents 2	Spouse 2 Parents 2 Sibling 1
HLA mismatch Class I	1.9±0.7 (1 – 3)	1.6±0.7 (0 – 2)
HLA mismatch Class II	1.2±0.6 (0 – 2)	0.8±0.6 (0 – 2)
CMV serology	D+/R+ 9 (69.2%) D-/R+ 1 (7.7%) D+/R- 3 (23.1%)	D+/R+ 10 (92.3%) D- /R+ 1 (7.7%) D+ /R- 0 (0%)

EVR Trough

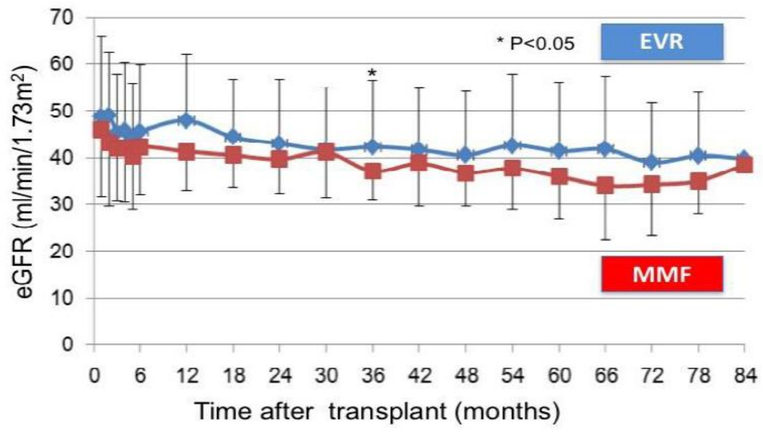
	1y	2y	3y	4y	5y	6y	7y
Average	5.0	5.3	4.9	5.2	4.7	4.6	5.6
SD	1.5	1.6	1.4	1.0	1.7	1.1	1.4



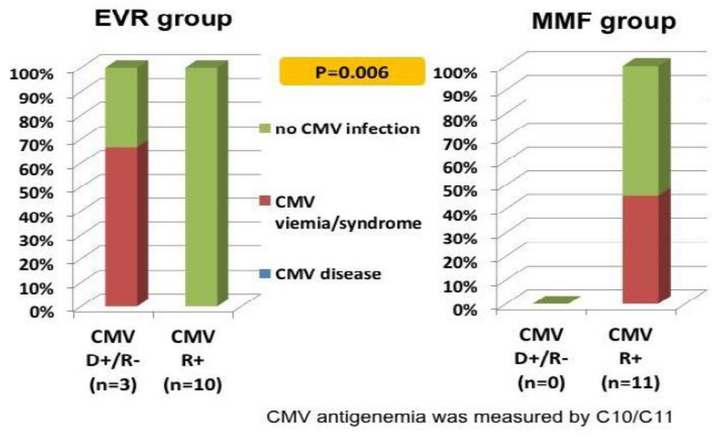
CSA Trough Level (Co)



eGFR

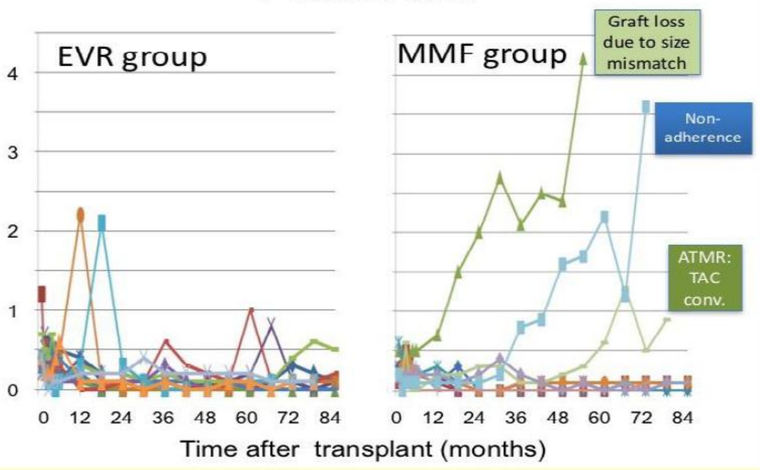


CMV viremia/disease

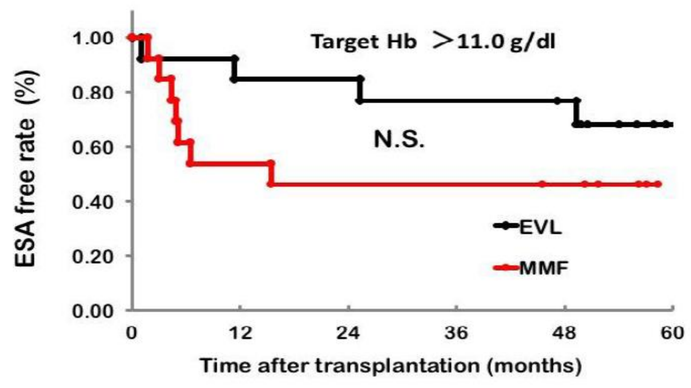


CMV antigenemia was measured by C10/C11

Proteinura



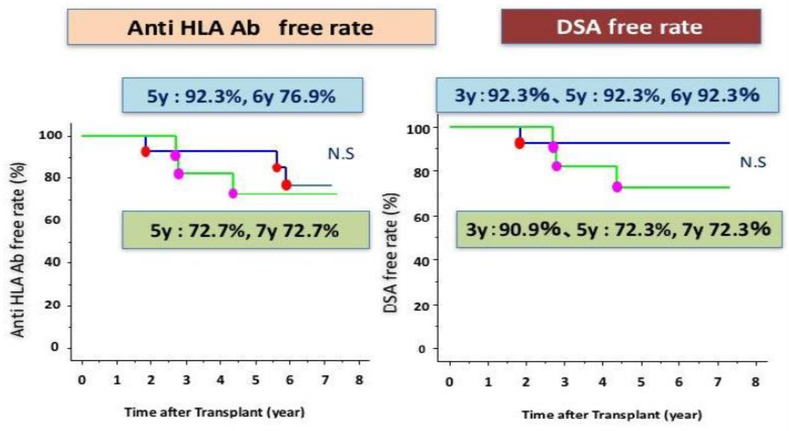
Erythropoietin Stimulating Agent Free Rate



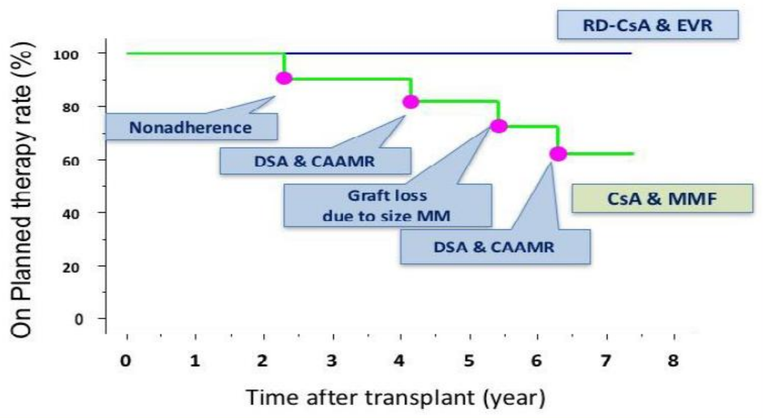
Adverse Effects

	EVR group	MMF group	P value
Proteinuria >300mg/day	10/13(76.9%) Treated with ARB	6/11(54.5%) Treated with ARB	N.S.
Viral infection Other than CMV	Hemorrhagic cystitis 1 HCV infection 1	Herpes Zoster 2	N.S.
Lymphocele	0/13 (0%)	2/11 (18.2%)	N.S.
Aphthous ulceration	2/13 (15.4%)	0/11 (0%)	N.S.
Joint pain, Edema Interstitial pneumonia	0/13 (0%)	0/11 (0%)	N.S.
NODAT	3/13 (23.1%) on medication, but not insulin therapy	0/11 (0%)	P=0.09

Anti HLA Ab or DSA free rate



On Therapy Rate



CONCLUSIONS

EVR based immunosuppression provides equivalent clinical outcomes as well as the incidence of De Novo DSA production with MMF based immunosuppression with 7 years follow-up.
CNI can be safely minimized with good graft function as well as a favorable outcome for incidence of CMV.
Proteinuria, even nephrotic, could be treated with ARB without graft dysfunction.

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