SP717 DE NOVO REGIMEN FOR RENAL TRANSPLANTATION USING EVEROLIMUS AND TACROLIMUS-ER.

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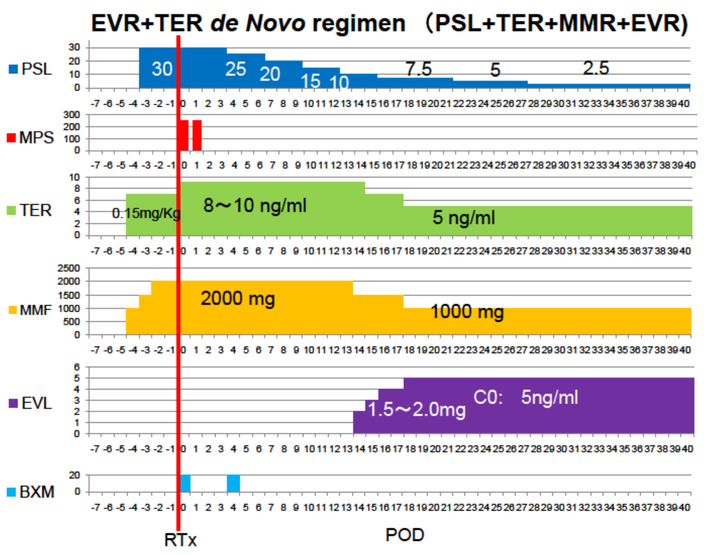
OBJECTIVES

Everolimus (EVR) is a mTOR inhibitor recently available immunosuppressive drug, which expect to reduce dosage of CNIs to avoid nephrotoxity. It inhibits the IL-2-stimulated T-cell, but also suppresses viral activity and carcinogenesis. These actions expect to elongate the graft survival. We conduct de novo regimen with EVR and tacrolimus-extended release (TER) expecting stable renal graft function and little incidence of viral infection. We compared the result of this regimen with that of previous graft regimen without EVR.

- EVR add-on to TER/MMF/PSL
- TER as CNI
- Steroid reduction
- Maintenance level of TER from 2 wk post RTx
- Maintenance level of MMF from 2 wk post RTx
- Same other immunosuppression
  - BXM, RXM
  - DGF case: (EVR stared from 2 wk post graft function recovery)

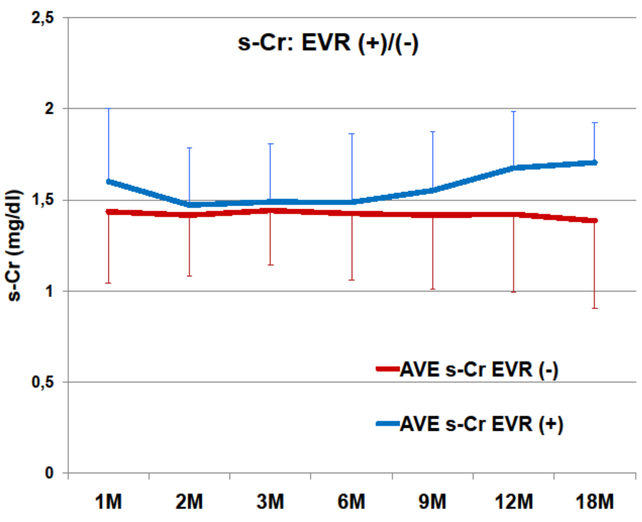
METHODS

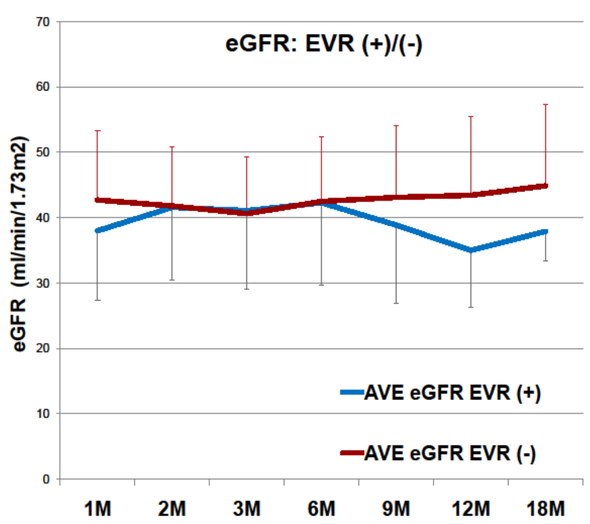
- We initiated EVR of 1.5-2.0 mg/day from 14 days after transplantation and control at the C0 of 5 ng/ml. PSL is started with 30 mg and gradually reduced to 2.5 mg by POD 30. TER is administrated with 0.15 mg/Kg and maintained with C0 level of 8 ng/ml until POD 14, then reduced to 5ng/ml after EVR initiation. MMF is also reduced from 2000 to 1000 mg at same time. Other immunosuppressions are same as usual. In the previous regimen without EVR, TER was maintained at C0 level of 8 ng/ml and MMF was 1500mg.
- We evaluated and comparing the results between the groups with and without EVR in terms of the graft and patient survival, graft function, incidence of biopsy proven acute rejection, and adverse events such as CMV infection, proteinuria and dyslipidemia.

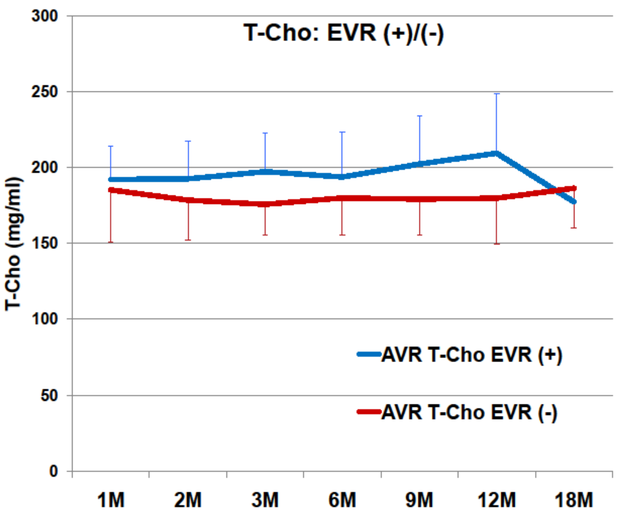


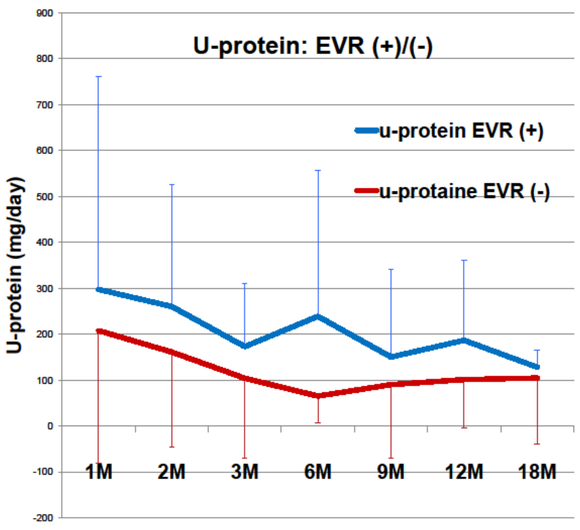
		age	sex	primary disease	L/C	D age	D sex	ABO	Ab MM	DR MM	D/C	Ref
KM	1	53	M	CGN、gout	LRD	59	F	comp	3	1		
SY	2	62	M	nephrosclerosis	LRD	58	M	comp	1	0	D/C wound trouble	
TTt	3	27	M	drug nephrotoxity	LRD	52	F	comp	1	1		
MF	4	51	M	unknown	LRD	47	F	incomp	2	1		
WS	5	52	M	DM nephropathy	LRD	58	F	comp	2	1	D/C pancytopenia	HBV HCV
OC	6	58	F	IgA nephropathy	LRD	64	F	comp	3	0		
TTm	7	26	F	fibril nephritis	LRD	57	F	incomp	1	1		
SK	8	52	M	CGN	LRD	55	F	comp	1	0	D/C folliculitis, gurunculosis	
MO	9	53	M	IgA nephropathy	LRD	51	F	incomp	4	1		
IG	10	46	M	CGN	LRD	46	F	comp	2	1	delayed start 2 mo	UC past Hx
TK	11	39	M	IgA nephropathy	LRD	65	M	comp	2	1		
KT	12	40	M	CGN	BDD	41	M	comp	1	1		
EM	13	47	F	viral infection	DCD	60	M	comp	1	1	delayed start 1 mo	DGF
UJ	14	33	M	IgA nephropathy	LRD	60	F	comp	1	1		
GH	15	64	M	DMN	LRD	49	F	mr-inco	3	2	D/C pancytopenia	HBV HCV
NR	16	59	M	Alport	LRD	59	M	comp	2	1		
	AVE	47.6				55.1			1.9	0.9		

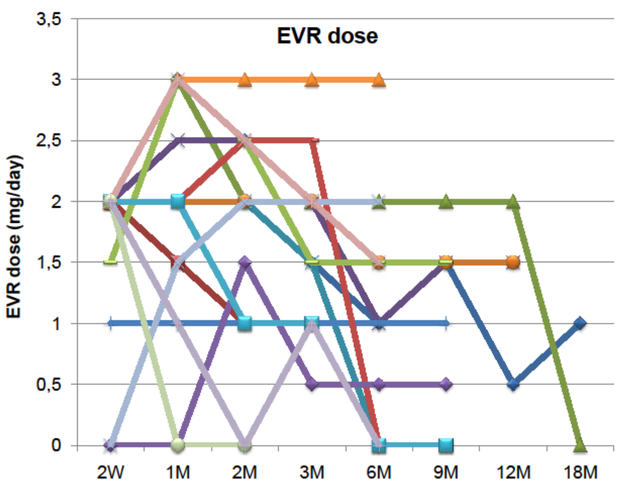
RESULTS

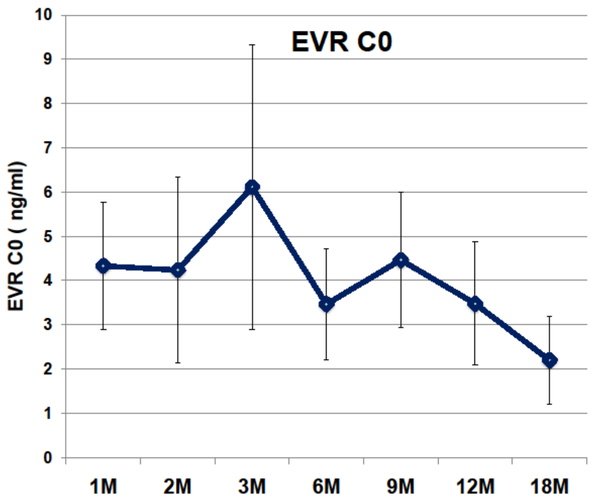












- We experienced 16 cases for 16 months. Mean age of the recipients was 47.6 years, M/F was 13/3. Two were from deceased donor. Mean follow-up period was 8.1 months (2.3-17.6). Mean donor age was 55.1 years (table 1).
- Three cases were ABO incompatible transplantation.
- Both patient and graft survival were 100%.
- In all cases graft function resulted in good. The average sCr at 1, 2, 3, 6, 9 and 12 months post-transplant were 1.60, 1.47, 1.47, 1.49, 1.62 and 1.67mg/dl respectively, and eGFR were 39.9, 43.9, 42.8 and 40.6, 31.7 and 39.7 ml/min/1.73m respectively.
- The graft function of the EVR group is not significantly different from that of without EVR.
- No Biopsy Proven Acute Rejection was observed in EVR group.
- No CMV infection was encountered in EVR group except in CMV IgG positive to negative transplant cases.
- We had better results than those in the group without EVR in terms of rejection and CMV infection. However we observed several adverse events; 7 cases (43.8%) had stomatitis, 5 cases (33.3%) of hyperlipidemia, 2 cases of pancytopenia, and 2 of proteinuria>1g/day (13.3%). Some of cases should discontinue EVR because of adverse events.
- The dose of EVR was unstable (1-3mg/day) at beginning, but settled at 1-1.75 after two months. We had difficulty to control EVR and TER dose, because C0 of EVR and TER were certainly unstable (mean C0 of EVR: 4.78±1.76(1.3~8.99) ng/ml),and C0/dose: 2.48±1.08 ng/ml/mg).

CONCLUSIONS

EVR+TER de novo regimen for renal transplantation resulted in good graft function, little incidence of rejection and viral infection, but we encountered some risks of stomatitis, dyslipidemia, pancytopenia and proteinuria, which sometimes become severe. We need attention to control dose of EVR and TER with frequent drug monitoring.

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