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Third Party Mesenchymal Stromal Cell Infusion in Kidney Transplant Recipient: 6-Month Safety Interim Analysis

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Session Information

Date: [Sunday, May 3, 2015](#)

Session Time: 5:30pm-6:30pm

Session Name: [Poster Session B: Cell Transplantation and Cell Therapies](#)

↳ **Presentation Time:** 5:30pm-6:30pm

Location: Exhibit Hall E

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[A Prospective Pilot Study Evaluating the Safety and Efficacy of Everolimus for the Prevention of CMV and BK Viral Infection \(BKV\) in Broadly Sensitized Kidney Transplant Recipients Following Desensitization With IVIG and Rituximab: Interim Analysis](#)

Back-ground

Mesenchymal stromal cell (MSC) have immunomodulating properties and could be used as immunosuppressive agents.

We report the 6-month safety results for the 5 first patients treated with MSC after kidney transplantation (KTx). Here, we address 3 specific safety issues:

– Immunization against MSC

– Engraftment syndrome defined as acute graft dysfunction not related to rejection

– Over-immunosuppression.

Patients and method

MSC production was carried out locally. MSC were not matched with kidney recipients' HLA. Included patients were non-immunized, first transplant recipient from deceased donors. MSC (1.5 – 3.0 x 10⁶/kg) infusion was planned 3 to 5 days post KTx. Patients with cardiovascular instability post KTx were excluded. All patients were treated with Basiliximab induction, Tacrolimus, Mycophenolate Mofetil and Steroid. We prospectively screened for anti-HLA antibodies at month 1, 3 and 6. Informed consent was obtained from all participants. The local ethical committee approved the protocol.

Results

Collectively there were 23/50 and 29/50 HLA mismatches (MM) with kidney and MSC donor respectively, out of which 5 were shared MM.

Baseline characteristics

Recipient	Age at Tx (years)	63 ± 6
	Gender (M/F)	4/1
	BMI (kg/m ²)	27 ± 3
	Dialysis vintage (days)	373 ± 564
Kidney donor	Age (years)	51 ± 18
	Gender (M/F)	3/2
	BMI (kg/m ²)	26 ± 5
	DBD/DCD	4/1
Transplantation	CIT (min)	737 ± 219
	WIT (min)	46 ± 16
	HLA mismatches (n)	
	A (0/1/2)	0/5/0

	B (0/1/2)	1/4/0
	Cw (0/1/2)	1/3/1
	DR (0/1/2)	1/4/0
	DQ (0/1/2)	
MSC donor	HLA mismatches (n)	
	A (0/1/2)	1/2/2
	B (0/1/2)	1/3/1
	Cw (0/1/2)	0/4/1
	DR (0/1/2)	1/3/1
	DQ (0/1/2)	0/3/2

DB/CD: donor after brain /cardiac -death; C/WIT: cold/warm ischemic time

One patient developed de novo DSA, 2 patients anti-HLA antibodies against shared kidney/MSK MM and 1 patient developed 2 specific antibodies against MSC (MSCSA) at month 6. All antibodies were anti HLA class I except for 1.

We did not observe any “engraftment” syndrome.

Three patients experienced non-severe opportunistic infections: 1 CMV reactivation and 2 polyoma-BK virus viremia.

Conclusion

We did not observe any strong safety signal. We did however observe some degree of immunization in 3 patients: 2 developed antibodies against shared kidney/MSK donor HLA MM and 1 MSCSA.

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