BONE MARROW MESENCHYMAL STROMAL CELLS INFUSION IN CKD PATIENTS: SAFTEY AND FEASIBILITY STUDY WITH ONE YEAR FOLLOW-UP

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Introduction

Chronic Kidney Disease (CKD) is a progressive loss of kidney function and structure that affects approximately 7% of the population worldwide[1].
Endogenous & exogenous stem cells give the regeneration capacity to kidney, although it decreases by CKD progression. A recent meta-analysis revealed that cell-based therapies improved impaired renal function and structural morphology in preclinical models of CKD [2].
We assessed the safety and potential efficacy of the Bone Marrow Mesenchymal Stromal cells(BMMSCs) injection in Chronic Kidney Disease(CKD) patients.

Methods

A single arm safety & feasibility study was carried out at one center with 12-month follow-up among 7 patients with CKD due to HTN, Nephrotic Syndrome & CIN.
Fifty-five CKD patients evaluated for participation in the trial, 7 eligible patients with eGFR 25-60 enrolled the study between June 2014 and January 2015. We infused a single intravenous injection (2 million cells per kilogram) of autologous cultured BMMSCs to the patients.(figure 2). The Primary endpoint was the safety issue and was measured by number and the severity of adverse events related to cell injection. Secondary endpoint was changes in eGFR. We evaluated eGFR by MDRD (IDMS traceable) formula and DMSA scan. We compared kidney function during the follow-up visits to baseline and a year prior to the intervention.

Results

Follow-up visit of all 7 patients are completed and demographic data is listed in Table 1. We didn't observe any cell related adverse events after 12 months following the intervention.
Although The DMSA scan was being used in all 7 patients before the enrolment, just two patients were scanned in follow-up visits.
Serum creatinine and eGFR changes were not remarkable except one patient. One patient used a single dose Gelofen three month after the intervention and experienced creatinine rise which reached to previous level after 2 weeks.

Table 1. Demographic Data

Patient Number	1	2	3	4	5	6	7
Sex	M	F	M	M	M	M	F
Age	29	60	34	29	29	51	42
Race	Caucasian	Caucasian	Caucasian	Caucasian	Caucasian	Caucasian	Caucasian
Dx	Unknown CKD	HTN	CIN	N.S	FSGS	HTN	HTN
DM	-	-	-	-	-	-	-
HTN	-	+	-	-	-	+	+
Smoking	-	-	-	-	-	-	-
Controlled Diet	+	+	+	+	+	+	+
Baseline GFR	25	30	37	25	29	42	25

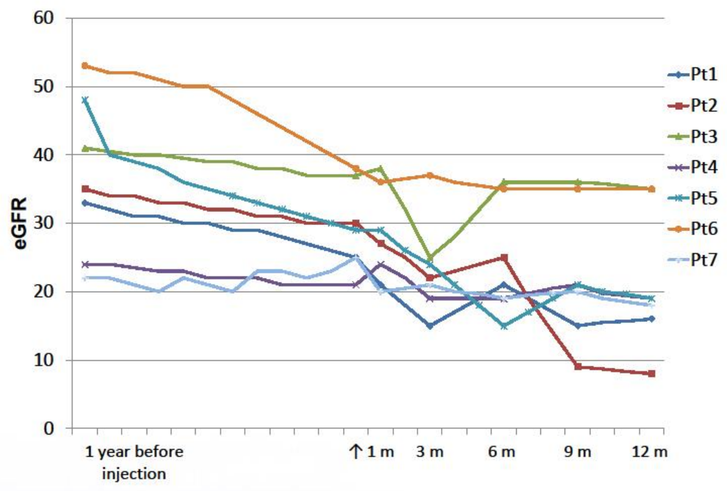

Figure 1. eGFR changes of CKD patients in 2 years, from a year before up to one year after single dose autologous BMMSC injection

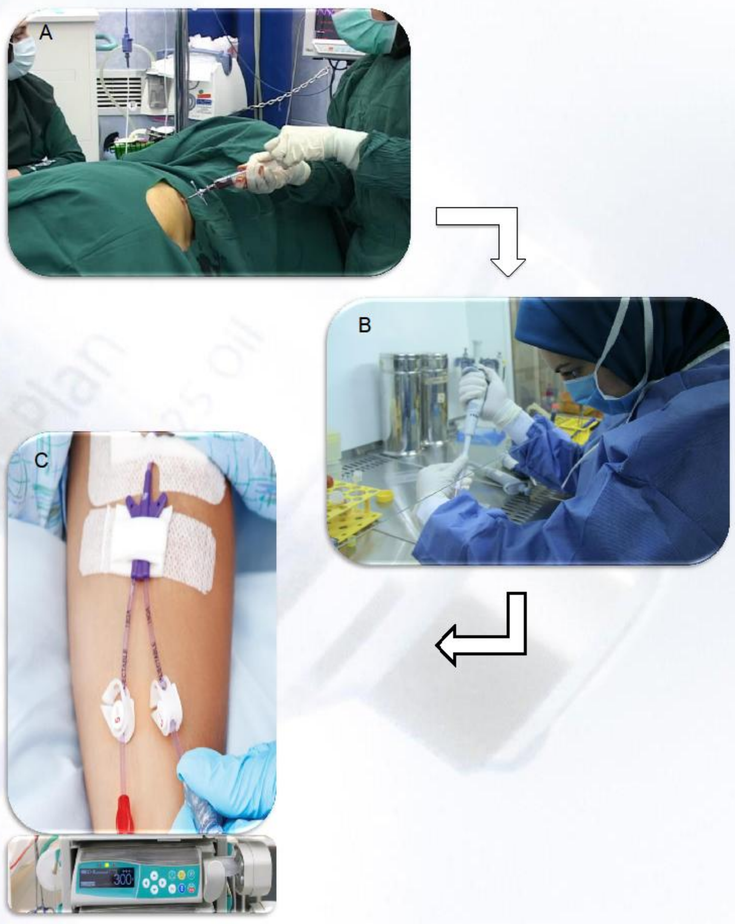

Figure 2. Cell transplantation steps:
A. Bone marrow aspiration
B. Cell processing
C. Intravenous cell infusion

Conclusions

We showed safety and tolerability of a single dose infusion of autologous BM-MSCs in CKD patients. The efficacy of the BMMSCs infusion should be tested by a larger sample size trial.

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