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BRIEF REPORT

Transendocardial Injection of Expanded Autologous CD34+ Cells After Myocardial Infarction

Results of the EXCELLENT Trial

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Reparative therapy based on the injection of stem cells like CD34+cells has been considered an attractive approach to improve patient outcomes after an acute myocardial infarction (AMI).[1] Prior trials suggested that the benefits of cell therapy may be dependent on the number of injected CD34+ cells[2] and route of administration.[3]

What is the clinical question being addressed?
What is the safety and feasibility of transendocardial injections of expanded autologous CD34+ cells in patients presenting with a recent large acute myocardial infarction?

What are the main findings?
Transendocardial injections of expanded autologous CD34+ cells in patients with recent large myocardial infarction were feasible but resulted in procedural complications following the injections. Changes in LV remodeling and viability in the active group over 6 months suggest a possible benefit that warrants further investigation in larger studies.

METHODS

The prospective, multicenter, international, open label, randomized, controlled EXCELLENT (Expanded Cell Endocardiac Transplantation; NCT02669810) phase I/IIb trial has been developed to assess the safety and feasibility of transendocardial injections of expanded autologous CD34+ cells (ProtheraCytes, CellProthera) in patients presenting with a recent large AMI. The detailed design and methodology have been published previously.[4] The trial was conducted in accordance with the Declaration of Helsinki and was approved by local research ethics committees.

RESULTS

The trial was performed between January 2016 and September 2023. A total of 146 participants were eligible for the study, of whom 69 were subsequently excluded due to the presence of left ventricular (LV) thrombus or recovered LV ejection fraction. Seventy-seven participants were randomized to receive the standard of care (SoC) and cell injections (active group, n = 61) or SoC alone (SoC group, n = 16), but 28

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ABBREVIATIONS AND ACRONYMS

AMI = acute myocardial infarction

CMR = cardiac magnetic resonance

HF = heart failure

LV = left ventricular

MVO = microvascular obstruction

NT-proBNP = N-terminal pro-B-type natriuretic peptide

SoC = standard of care

patients of the active group did not receive expanded autologous CD34+ cells, mainly due to the cell product being out of specification or the development of LV thrombus. The withdrawal of these patients was associated with a reduction of the mean age in the active group (54.8 ± 10.6 vs 58.6 ± 10.6 years in intention-to-treat). Other baseline characteristics were similar in both groups (Table 1). Most participants had microvascular obstructions (MVO) at baseline, which generally extended over 5 cardiac segments.

Patients in the active group received the granulocyte colony-stimulating factor lenograstim 29 ± 11 days after AMI and 17 days before cell injections, which induced a transient leukocytosis that was reversible within 48 to 72 hours. The average number of CD34+ cells obtained after expansion was 20 × 10^6, corresponding to a 15.9 ± 7.7-fold expansion rate. The mean purity and viability of CD34+ cells after expansion were found to be 90.0 ± 3.7% and 97.5 ± 2.0%, respectively.

Eleven major adverse cardiac events were reported in 10 participants of the active group (30% [95% CI: 16%-49%]) which included 1 heart failure (HF)-associated hospitalization, 1 AMI, and 9 procedure-related complications: 4 cardiac tamponades, 2 pericarditis, 2 ischemic strokes, and 1 ventricular fibrillation. All recovered with appropriate care except 1 patient with stroke who recovered with partial visual acuity impairment. There were no deaths or sudden unexpected serious adverse reactions. Five HF-related hospitalizations were reported in 3 participants in the SoC group (19%), 1 of whom underwent subsequent heart transplantation.

Changes over the 6-month follow-up period in parameters associated with LV remodeling and infarct size were observed (Table 2). The ratios at 3 and 6 months to baseline in N-terminal pro-B-type natriuretic peptide (NT-proBNP) concentrations, assessed as a post hoc endpoint, were 0.30 (95% CI: 0.22-0.41) and 0.24 (95% CI: 0.17-0.33) in the active group (n = 19), and 0.49 (95% CI: 0.29-0.85) and 0.34 (95% CI: 0.20-0.59) in the SoC group (n = 7), respectively.

DISCUSSION

This prospective randomized controlled trial with blinded endpoint evaluation is the first to investigate the safety and feasibility of transendocardial injections of expanded autologous mobilized CD34+ cells in patients with a recent large AMI who are at risk of developing subsequent HF. The expansion of CD34+ cells allowed the injection of a higher mean number of cells than in the PreSERVE-AMI (A Prospective Randomized Double Blind Placebo Controlled Phase II Trial of Intra-coronary Infusion of AMR-001, a Bone Marrow Derived Autologous CD34+ Selected Cell Product, in Patients With Acute Myocardial Infarction) study, which used intracoronary administrations of bone marrow-derived CD34+ cells to AMI patients.[3]

The population included was at high risk of incident HF as demonstrated by the marked elevation in baseline troponin (inclusion criterion) and NT-proBNP concentrations, the low baseline LV ejection fraction, and the extent of transmurality and MVO. The high proportion of screen failures reflected the reversal of myocardial stunning justifying selection of delayed (8 days) timing for screening cardiac magnetic resonance (CMR) to target patients with a persistent high risk of subsequent adverse remodeling. The presence of LV thrombus was the other main reason for screen failure and is consistent with expectations in patients with large AMI. Despite preprocedural CMR imaging, 2 stroke events of embolic origin occurred in the hours after the injection procedure. Although independent central reading of CMR imaging may minimize the risk of false negative

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The authors attest they are in compliance with human studies committees and animal welfare regulations of the authors' institutions and Food and Drug Administration guidelines, including patient consent where appropriate. For more information, visit the Author Center.

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TABLE 1 Baseline Characteristics

	Active Group (n = 33)	Standard of Care Group (n = 16)	Total (N = 49)
Demographic characteristics			
Age, y	54.8 ± 10.6	62.0 ± 13.5	57.2 ± 12
Male, %	88	81	86
Female, %	12	19	14
Body mass index, kg/m^2	29.6 ± 4.6	27.7 ± 4.0	27.18 ± 4.4
Current/former smokers	26 (79)	7 (44)	33 (67)
NYHA functional class			
I	15 (45)	3 (23)[a]	18 (39)
II	17 (52)	9 (69)[a]	26 (57)
III	1 (3)	1 (8)[a]	2 (4)
Time from AMI			
Randomization, d	15.4 ± 6.6	16.0 ± 6.0	15.6 ± 6.4
Cell injection, d	42.9 ± 10.8	–	–
Hemodynamic variables			
Systemic BP, mm Hg	108.2 ± 15.7[b]	106.4 ± 16.6	107.6 ± 15.9
Diastolic BP, mm Hg	68.8 ± 11.4[b]	66.7 ± 10.6	68.1 ± 11.1
Heart rate, beats/min	68.0 ± 10.6	70.4 ± 8.2	68.8 ± 9.9
Natriuretic peptide			
NT-proBNP, pg/mL	1,938 (1,366-3,192)[c]	3,759 (1,045-4,353)[d]	1,939 (1,341-3,613)
Renal function			
eGFR, mL/mn/1.73 m^2	78.3 ± 16.9	75.9 ± 21.0	77.5 ± 18.1
Cardiac magnetic resonance			
LV end-systolic volume index, mL/m^2	63.3 ± 20.6	65.4 ± 18.8	64.0 ± 19.9
LV end-systolic volume, mL	125.0 ± 47.0	129.8 ± 36.3	126.6 ± 43.4
LV end-diastolic volume index, mL/m^2	98.2 ± 23.7	91.3 ± 23.5	95.9 ± 23.6
LV end-diastolic volume, mL	193.6 ± 56.2	181.7 ± 47.4	189.67 ± 53.2
LV ejection fraction, %	36.3 ± 7.6	32.8 ± 7.4	35.2 ± 7.6
Viability parameters			
Number of segments with			
LGE ≥75%	3.2 ± 2.2	3.1 ± 1.9	3.2 ± 2.1
MVO	4.6 ± 2.2	5.1 ± 2.9	4.8 ± 2.4
Number of patients with MVO	31 (94)	15 (94)	46 (94)
Main concomitant medications at randomization			
Antiplatelet therapy	33 (100)	16 (100)	49 (100)
Anticoagulant therapy	9 (27)	3 (19)	12 (25)
ACEI	24 (73)	14 (88)	38 (78)
Sacubitril/valsartan	7 (21)	3 (19)	10 (20)
Angiotensin receptor blocker	3 (9)	1 (6)	4 (8)
Mineralocorticoid receptor antagonist	27 (82)	14 (88)	41 (84)
Beta-blocker	30 (91)	15 (94)	45 (92)
Diuretic	5 (15)	5 (31)	10 (20)
Statin	32 (97)	15 (94)	47 (96)
SGLT2 inhibitor	15 (46)	7 (44)	22 (45)
Other diabetes therapy	4 (12)	5 (31)	9 (18)

Values are presented as n (%), mean ± SD, or median (Q1-Q3), unless otherwise indicated. [a]n = 13. [b]n = 32. [c]n = 29. [d]n = 10.

ACEI = angiotensin-converting enzyme inhibitor; AMI = acute myocardial infarction; BP = blood pressure; eGFR = estimated glomerular filtration rate; LGE = late gadolinium enhancement; LV = left ventricular; MVO = microvascular obstructions; NT-proBNP = N-terminal pro-B-type natriuretic peptide; SGLT2 = sodium-glucose cotransporter 2.

diagnosis of LV thrombus, small areas of LV thrombus may still be missed.

The high proportion of events related to cardiac tamponade in comparison with previous studies of transendocardial injections of stem cells in patients with AMI[2] may reflect the severity of infarction with large regions of friable myocardium that are expected to be more susceptible to perforation. Even though

TABLE 2 Changes in LV Remodeling Parameters and Infarct Size Over the 6-Month Follow-Up Period

	Active Group (n = 31)[a]		Standard of Care Group (n = 15)[b]	
	Month 3	Month 6	Month 3	Month 6
CMR LV remodeling[c]				
LV end-systolic volume index, mL/m^2[,d]	−5.4 (−11.8 to 1.0)	−5.7 (−12.1 to 0.7)	−4.0 (−13.5 to 5.4)	0.2 (−9.3 to 9.6)
LV end-systolic volume, mL/m^2	−11.7 (−23.8 to 0.3)	−11.8 (−23.9 to 0.2)	−10.4 (−27.7 to 6.9)	−0.3 (−17.6 to 17.0)
LV end-systolic volume index, mL[d]	−1.6 (−8.5 to 5.4)	−3.2 (−10.1 to 3.8)	4.8 (−5.5 to 15.1)	8.6 (−1.7 to 18.9)
LV end-diastolic volume, mL/m^2	−4.9 (−18.3 to 8.5)	−7.5 (−20.9 to 5.9)	9.7 (−9.5 to 28.9)	17.4 (−1.8 to 36.7)
LV end-diastolic volume, mL	5.0 (1.7-8.3)	4.4 (1.1-7.7)	5.3 (0.5-10.0)	2.9 (−1.9 to 7.6)
CMR infarct size[c,e]				
LGE ≥75% segments, n	−1.3 (−2.2 to −0.4)	−1.7 (−2.6 to 0.9)	−0.9 (−2.2 to −0.3)	−1.0 (−2.2 to 0.2)

Values are adjusted mean changes from baseline (95% CI) from repeated measures analysis of covariance (age and baseline value as covariates). Patient exclusion from the analysis: [a]1 recurrent MI and 1 lost to follow-up. [b]1 heart transplant. [c]1 CMR contraindicated in the active group due to implantable cardioverter device. [d]1 body surface area missing data. [e]2 unexploitable LGE-CMR.

CMR = cardiac magnetic resonance; other abbreviations as in Table 1.

all participants in the present study recovered promptly, there is a need for a risk mitigation strategy to optimize the safety of the procedure, likely based on enhanced procedure planning with central review of CMR wall thickness and infarct area, intraoperative navigation, and additional operator training to address the endocardial injection learning curve. In addition, a relationship between cell mobilization and an increase in cardiac proteinase activity that could have contributed to adverse events in the active group cannot be totally excluded, and serum biomarkers of enzyme activity and immune cell activation will have to be monitored in future studies.

Although the trial was not powered to assess efficacy, changes in LV remodeling and viability in the active group over 6 months suggest a possible benefit that warrants further investigation in larger studies.

STUDY LIMITATIONS. The main limitation of the trial is the low number of participants that is inherent to this type of proof-of-concept study. Additionally, patients of the active group were younger after the postrandomization exclusion, likely because of an age-related insufficient cell mobilization. This possible bias will be addressed in future comparative trials by relying on drugs like plerixafor, which are used to increase the mobilization of CD34+ cells in various settings. Finally, one may postulate that lenograstim administration in the active group contributed to some of the findings. However, the largest available trial recently published did not support the efficacy of the mobilization alone.[5]

CONCLUSIONS

We showed that transendocardial injections of expanded autologous CD34+ cells in patients with recent large myocardial infarction were feasible but resulted in procedural complications following the injections. Optimization of treatment delivery and establishing whether there is potential for long-term benefit warrant an evaluation in an adequately sized, long-term, randomized comparative trial.

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The EXCELLENT trial is sponsored by CellProthera. Dr Henon is a founder and shareholder of CellProthera. Dr Trebuchet, Mr de Kalbermatten, and Dr Ibon Garitaonandia are staff members of CellProthera. Drs Roncalli, Marie, Bhatt, Solomon, Montalescot, and Zannad have received fees from CellProthera as members of the steering committee of the EXCELLENT trial. Dr Roncalli has been an advisory board member and has received consulting fees from CellProthera. Dr Zannad has received personal fees from Applied Therapeutics, Bayer, Biopeutics, Boehringer Ingelheim, Bristol-Myers Squibb, CVRx, Cardior, Cereno Pharmaceutical, CellProthera, Merck, Northsea, Novartis, NovoNordisk, Otsuka, Owkin, has stock options at G3Pharmaceutical and equities at Cereno Pharmaceutical, Cardiorenal, Eshmoun Clinical Research, and is the founder of Cardiovascular Clinical Trialists (CVCT). Dr Bhatt is on the advisory boards of AngioWave, Bayer, Boehringer Ingelheim, CellProthera, Cereno Scientific, Elsevier Practice Update Cardiology, High Enroll, Janssen, Level Ex, McKinsey, Medscape Cardiology, Merck, MyoKardia, NirvaMed, Novo Nordisk, PhaseBio, PLx Pharma, and Stasys; is on the board of directors of the American Heart Association-New York City; is on the board of directors and has stock options with AngioWave, Bristol Myers Squibb, and DRS.LINQ; is on the board of directors and owns stock in High Enroll; has served as a consultant for Broadview Ventures, GlaxoSmithKline, Hims, SFJ, and Youngene; has been on

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APPENDIX For a list of the investigators, please see the online version of this paper.