#2606 Endovascular Ablation Of The Right Greater Splanchnic Nerve For The Treatment Of Heart Failure With Reduced Ejection Fraction: A First-in-human Pilot Clinical Study

Sponsor: axon therapies

Marat Fudim[1,2], Teona Zirakashvili[3], Nikoloz Shaburishvili[3], Giorgi Shaishmelashvili[3], Zoar J. Engelman[4], Tamaz Shaburishvili[3], Sanjiv J. Shah[5]. Vivek Y. Reddy[6]

Splanchnic Ablation for Volume Management

In heart failure with reduced ejection fraction (HFrEF), a sympathetic nerve mediated increase in cardiac preload is thought to significantly contribute to intra-cardiac pressure elevations at rest and with exertion [1]. Temporary blockade (24 hours) of the splanchnic nerves in HFrEF has been shown to reduce resting central venous pressures (CVP), pulmonary capillary wedge pressure (PCWP), and improve exercise capacity [2]. We previously demonstrated the feasibility of right sided greater splanchnic nerve (GSN) ablation to reduce right-sided filling pressure and relieve symptoms in HF patients with preserved ejection fraction in an open-label study [3].

Objectives

To assess the feasibility of transvenous right sided GSN ablation for the treatment of HFrEF.

Methods

In a non-randomized, open-label trial, HFrEF patients on maximal GDMT underwent right GSN ablation with the novel ablation catheter (Satera Ablation System, Axon Therapies Inc.). The procedure was performed under conscious sedation via right femoral venous access, with an overnight stay post procedure. Follow-up assessments included 6MWT, KCCQ, NTproBNP and echocardiography. Changes from baseline to each follow-up were compared using paired Wilcoxon rank-sum tests. Data shown as mean ± standard deviation, unless otherwise noted.

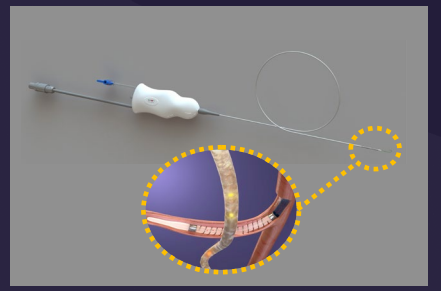
Results

Six HFrEF patients were enrolled: 60±10 years, 6/6 male, 6/6 non-ischemic cardiomyopathy, 3/5 hypertension, 3/5 atrial fibrillation, 1/6 diabetes mellitus, 6/6 NYHA class III, LVEF 34±4%, and median NTproBNP 959 pg/ml (IQR 835-1022). Use of GDMT at baseline included 6/6 renin-angiotensin inhibitors, 6/6 beta blockers and 5/6 mineralocorticoid receptor antagonists. There were no device related adverse cardiac events or unanticipated adverse device effects. Acute invasive hemodynamic changes (immediately pre to 1 hour post-ablation) were: CVP pre 10.5±6 mmHg to post 8.2±4 mmHg; PCWP pre 23.8±10 mmHg to post 19.8±8.1 mmHg and systolic blood pressure pre 164±34 mmHg to post 141±33 mmHg (all $p>0.05$). There were no significant changes in systolic blood pressure, heart rate or body mass index from baseline to 3 months (all $p>0.05$). Efficacy results (Table) demonstrated improvements and/or favorable trends in quality of life (KCCQ), exercise capacity (6MWT), and NTproBNP. * $p<0.05$, † $p<0.01$

Parameter	Baseline (n=6)	1 Month (n=6)	3 Months (n=6)
NYHA Class	3.0 ± 0.0	3.0 ± 0.0	3.0 ± 0.0
KCCQ Overall Summary Score	22 ± 4	29 ± 4*	36 ± 4†
6MWT Distance (m)	214 ± 28	270 ± 30† (n=5)	359 ± 42*
NTproBNP (pg/mL) Median [IQR]	959 [835,1022]	728 [658,803]†	619 [519,662]†
Office Systolic Blood Pressure	133 ± 8	128 ± 10	126 ± 6

Satera Ablation System

The Satera™ Ablation System is an implant-free, transvenous, frontline HF intervention that unilaterally ablates the greater splanchnic nerve In order to restore volume balance and improve patient outcomes.



Conclusions

These results demonstrate, for the first time, the feasibility of treating HFrEF with endovascular right-sided GSN ablation. The encouraging safety and efficacy results provide rationale for a phase 2 randomized controlled trial.

Author Affiliations

1 Duke University Medical Center, Durham, NC;
2 Duke Clinical Research Institute, Durham, NC;
3 Tbilisi Heart and Vascular Clinic, Tbilisi, Georgia;
4 Axon Therapies, New York City, NY;
5 Northwestern University Feinberg School of Medicine, Chicago, IL;
6 Icahn School of Medicine at Mount Sinai, New York, NY;

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