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Effect of heart failure reversal treatment as add-on therapy in patients with chronic heart failure: A randomized, open-label study

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Objectives: Present study was designed to evaluate the effect of heart failure reversal therapy (HFRT) using herbal procedure (Panchakarma) and allied therapies, as add-on to standard CHF treatment (SCT) in chronic heart failure (CHF) patients.

Methods: This open-label, randomized study conducted in CHF patients (aged: 25-65 years, ejection fraction: 30-65%), had 3-phases: 1-week screening, 6-week treatment (randomized [1:1] to HFRT + SCT or SCT-alone) and follow-up (12-week). Twice weekly HFRT (60-75 min) consisting of snehana (external oleation), swedana (passive heat therapy), hrudaydhara (concoction dripping treatment) and basti (enema) was administered. Primary endpoints included evaluation of change in metabolic equivalents of task (MET) and peak oxygen uptake (VO₂peak) from baseline, at the end of the 6-week treatment and follow-up at week-18 (non-parametric rank ANCOVA analysis), safety and quality of life (QoL) was assessed.

Results: 70 CHF patients (n=35, each treatment-arm; mean [SD] age: 53.0 [8.6], 80% men) were enrolled in the study. All patients completed treatment phase. Add-on HFRT caused a significant increase in METs (least square mean difference [LSMD], 6-week: 1.536, p=0.0002; 18-week: 1.254, p=0.0089) and VO₂peak (LSMD, 6-week: 5.52, p=0.0002; 18-week: 4.517, p=0.0089) as compared with SCT alone. Results suggested improved functional capacity in patients with HFRT (QoL; Mean [SD] HFRT+SCT vs. SCT-alone; 6-week: 0.44 [0.34] vs. 0.06 [0.25], p<0.0001 and 18-week: 0.53 [0.35] vs. 0.29 [0.26], p=0.0013). Seven treatment-emergent adverse events (mild severity) were reported in HFRT-arm.

Conclusion: Findings of this study highlight therapeutic efficacy of add-on HFRT vs. SCT-alone in CHF patients. The non-invasive HFRT showed no safety concerns.

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