Making Heart Failure trials accessible and convenient for everyone, everywhere.

Jodi J. Akin

Abstract

Cardiological diseases represents a major growing health problem in the developed world. Clinical research is the cornerstone of continuous improvement in prevention and treatment of heart diseases. An average pivotal trial evaluating novel cardiovascular therapies can require more than10,000 visits and the collection of millions of data points. An important factor of success in clinical trials is the accessibility and diversity of participants and the quality and completeness of data. In order to collect all the data, the follow-up examinations are particularly relevant. A significant problem is that 79% published clinical trials have significant missing data resulting in issues of interpretability and generalizability of results. This causes incongruities of health burden to population which costs trillions and therefore the number of studies on new preventions and therapies in heart failure is kept low. Hawthorne Effect is a novel decentralized, patient-centric clinical trial platform that enables clinical trials to be accessible to patients anywhere, anytime via a convergence of digitization, home health and a gig work force. With a community, consisting physicians and healthcare professionals, as well as a novel integrated technology solution it is possible transform the future of healthcare. By enabling remote in home or virtual visits. This decreased patient burden, increases participation and quality data collection and improves interpretability, costs and timing of clinical trials. Focusing on enabling participation through comprehensive clinical trial follow-up may enable clinical trials design to advance to a new level of impact as well as close the inequity gap for more generalized populations to participate in innovative clinical trials. The aim of this meta-analysis was to assess the evidence from rigorous clinical trials of the use of hawthorn extract to treat patients with chronic heart failure. We searched the literature using MEDLINE, EMBASE, the Cochrane Library, CINAHL, CISCOM, and AMED. Experts on and manufacturers of commercial preparations containing hawthorn extract were asked to contribute published and unpublished studies.

There were no restrictions about the language of publication. Two reviewers independently performed the screening of studies, selection, validation, data extraction, and the assessment of methodological quality. To be included, studies were required to state that they were randomized, double-blind, and placebo controlled, and used hawthorn extract mono preparations. Thirteen trials met all inclusion criteria.

In most of the studies, hawthorn was used as an adjunct to conventional treatment. Eight trials including 632 patients with chronic heart failure (New York Heart Association classes I to III) provided data that were suitable for meta-analysis. For the physiologic outcome of maximal workload, treatment with hawthorn extract was more beneficial than placebo (weighted mean difference, 7 Watt; 95% confidence interval [CI]: 3 to 11 Watt; $P < 0.01$; $n = 310$ patients). The pressure-heart rate product also showed a beneficial decrease (weighted mean difference, -20; 95% CI: -32 to -8; $n = 264$ patients) with hawthorn treatment. Symptoms such as dyspnea and fatigue improved significantly with hawthorn treatment as compared with placebo. Reported adverse events were infrequent, mild, and transient; they included nausea, dizziness, and cardiac and gastrointestinal complaints. In conclusion, these results suggest that there is a significant benefit from hawthorn extract as an adjunctive treatment for chronic heart failure.

consisting physicians and healthcare professionals, as well as a novel integrated technology solution it is possible transform the future of healthcare. By enabling remote in home or virtual visits. This decreased patient burden, increases participation and quality data collection and improves interpretability, costs and timing of clinical trials.

Bottom Note: *This work is partly presented at 9th International Conference on Interventional Cardiology at August 09-10, 2021 | Webinar*

Jodi J. Akin

Founder, Chairman and CEO, Hawthorne Effect, Inc, California, E-mail: christian.dopp@hawthorne-effect.com