

# FragilitySynth: Deconstructing the Coronary Sinus Reducer Controversy via Systems Engineering and Bayesian Decision Theory

The Coronary Sinus Reducer (CSR) is an implantable device for refractory angina. Sham-controlled randomized clinical trials (RCTs) show modest improvements, whereas open-label registries report dramatic symptomatic benefit, raising concerns that much of the apparent effect reflects contextual and placebo responses rather than the device itself. Traditional meta-analysis, which treats studies as static and independent, provides limited insight into this certainty gap. We developed FragilitySynth v1.0, a simple browser-based tool that treats the CSR evidence base as a dynamic system. The framework combines: (1) random-matrix inspired measures of how many truly independent studies exist and how concentrated authorship is; (2) Kalman filtering to track how the estimated effect changes as trials accumulate; and (3) Bayesian decision theory to compute an Adaptive Minimum Risk estimate under asymmetric penalties for recommending an ineffective invasive device. Applied to 17 CSR datasets, FragilitySynth finds several independent information streams, a stable effect above a minimally clinically important difference, and a decision-optimal effect size well above this threshold even when over-treatment is heavily penalised.

## References

1. Sham-controlled randomised trials of the Coronary Sinus Reducer for refractory angina (COSIRA).