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Exploring Coronary Sinus Downsizing for Angina Treatment: Lessons from the ORBITA-COSMIC Experience

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The paper "Coronary sinus reducer for the treatment of refractory angina (ORBITA-COSMIC), published in The Lancet on April 20, 2024: a randomised, placebo-controlled trial", Written by Michael J. Foley, Christopher A. Rajkumar, F. Ahmed-Jushuf, et al. From Imperial College London, Midlands and South Essex NHS Foundation Trust, Anglia Ruskin University, etc. In this study, the researchers investigated the effects of coronary sinus reducers (CSR) in the treatment of refractory angina pectoris through the ORBITA-COSMIC trial. The study was conducted in six UK hospitals using a double-blind, randomized, placebo-controlled approach to assess the effectiveness of CSR compared to placebo in improving myocardial ischemia and angina symptoms. The study was conducted in patients over 18 years of age with stable coronary artery disease and myocardial ischemia who had no other treatment options. The results of the study showed that although the effect of CSR in improving myocardial blood flow was not significant, it had a significant effect compared to placebo in reducing the frequency of angina attacks. These findings provide a scientific basis for CSR as a new treatment option against angina pectoris.

1 Interpretation Experimental Data

In the trial, 61 patients were enrolled in the study and 51 eligible patients were randomly assigned to the CSR and placebo groups. The results of the study showed that patients treated with CSR had a lower frequency of angina attacks six months after treatment. Specifically, the reduction ratio for daily angina attacks was 1.40, with a 95% confidence interval of 1.08 to 1.83, suggesting that CSR had a significant effect in reducing angina relative to placebo. In addition, major measures of myocardial blood flow did not differ significantly between the CSR group and the placebo group, suggesting that the benefits of CSR may be primarily reflected in improvements in angina symptoms.

Figure 2 details the two main findings of the ORBITA-COSMIC trial. Figure A shows that there was no significant difference between the CSR group and the placebo group in terms of stress myocardial flow (MBF) at the site of myocardial ischemia. Figure B reveals the daily frequency of angina attacks in the CSR and placebo groups after random assignment, showing a significant reduction in angina attacks in the CSR group. Figure C shows a gradual increase in the odds ratio of CSR to placebo in reducing angina attacks over time, particularly at the end of the trial period, showing the long-term effect of CSR in reducing angina.

2 Insights of Research Findings

Although the coronary sinus miniator failed to significantly improve myocardial blood flow, its results in significantly reducing angina attacks indicate its potential effectiveness as an anti-angina treatment. The Bayesian statistical approach in the study further confirms the potential benefits of CSR in reducing angina, particularly in patients who have no other treatment options. For these patients, CSR can be used as a complementary treatment, especially when traditional drug therapy is no longer effective.

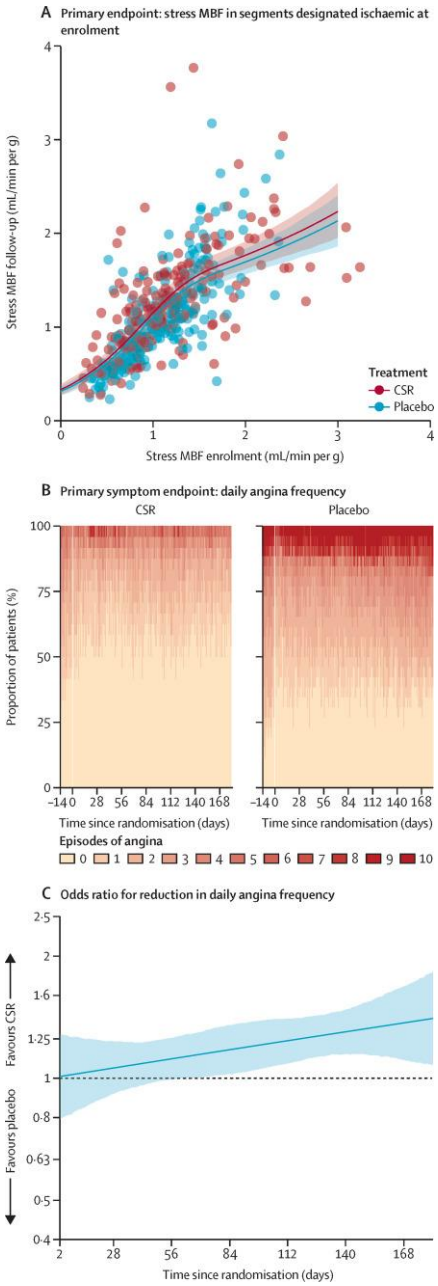

Figure 2 The ORBITA-COSMIC test primary outcomes

Note: (A) Individual patient data for the primary endpoint (stress MBF) in segments designated ischaemic at enrolment; (B) Individual patient data for the primary symptom endpoint (daily angina episodes), reported via the ORBITA smartphone symptom application; (C) Odds ratio for reduction in daily angina episodes for CSR versus placebo. CSR=coronary sinus reducer. MBF=myocardial blood flow

3 Evaluation of the Research

This study demonstrates the high standards of clinical trials with its sophisticated design and execution, particularly in the search for innovative therapies in the field of cardiovascular disease. By using a double-blind, randomized controlled approach, the study ensured the objectivity and reliability of the data, minimizing bias. Despite the rigorous design, the results of the study did not show an effect of CSR in improving myocardial blood flow, which may be related to the small sample size of the study and the short follow-up period. The study was limited to a specific patient population (i.e., those with no other treatment options), which may limit the general applicability of the results. Overall, this study provides important preliminary data for the cardiovascular field and supports further evaluation of the value of CSR in broader clinical practice.

4 Concluding Remarks

The ORBITA-COSMIC trial provides preliminary evidence that coronary sinus miniators (CSR) may have clinical benefits in patients with refractory angina, particularly in terms of improving patients' symptoms, rather than in improving myocardial blood flow. Although there was no significant improvement in the main physiological measures, the effect in reducing angina attacks suggests that CSR can be used as a useful supplement to existing treatment options. These results underscore the importance of continuing to explore the role of CSR in cardiovascular therapy and point to directions for future research, including expanding sample sizes, extending follow-up, and exploring its mechanisms of action. The study also raises the possibility of a broader application of CSR strategies, especially for patients whose symptoms have not been effectively alleviated by traditional treatments.

5 Access Original Paper

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