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Original research

Long-term survival benefit of ramipril in patients with acute myocardial infarction complicated by heart failure

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ABSTRACT

Aims ACE inhibition reduces mortality and morbidity in patients with heart failure after acute myocardial infarction (AMI). However, there are limited randomised data about the long-term survival benefits of ACE inhibition in this population.

Methods In 1993, the Acute Infarction Ramipril Efficacy (AIRE) study randomly allocated patients with AMI and clinical heart failure to ramipril or placebo. The duration of masked trial therapy in the UK cohort (603 patients, mean age=64.7 years, 455 male patients) was 12.4 and 13.4 months for ramipril (n=302) and placebo (n=301), respectively. We estimated life expectancy and extensions of life (difference in median survival times) according to duration of follow-up (range 0–29.6 years).

Results By 9 April 2019, death from all causes occurred in 266 (88.4%) patients in placebo arm and 275 (91.1%) patients in ramipril arm. The extension of life between ramipril and placebo groups was 14.5 months (95% CI 13.2 to 15.8). Ramipril increased life expectancy more for patients with than without diabetes (life expectancy difference 32.1 vs 5.0 months), previous AMI (20.1 vs 4.9 months), previous heart failure (19.5 vs 4.9 months), hypertension (16.6 vs 8.3 months), angina (16.2 vs 5.0 months) and age >65 years (11.3 vs 5.7 months). Given potential treatment switching, the true absolute treatment effect could be underestimated by 28%.

Conclusion For patients with clinically defined heart failure following AMI, ramipril results in a sustained survival benefit, and is associated with an extension of life of up to 14.5 months for, on average, 13 months treatment duration.

INTRODUCTION

Survival following acute myocardial infarction (AMI) remains a key objective for healthcare professionals and governments throughout the globe. Despite major advances in the emergency treatment and secondary prevention of AMI, a substantial proportion of patients with AMI develop heart failure,¹ which in turn is associated with high morbidity, mortality and healthcare expenditure.^{2–4}

Moreover, therapeutic inhibition of ACE has become an established strategy in the care of patients with AMI and heart failure.⁵ ACE inhibition reduces death and disease in patients with left ventricular systolic dysfunction, and coronary artery disease.^{6–8} In the Acute Infarction Ramipril

Efficacy (AIRE) study, ACE inhibition at an average follow-up time of 15 months after randomisation significantly reduced all-cause mortality, and continued to confer a survival benefit at 3 years following study closure in the AIRE Extension (AIREX) study.^{9–12} Further placebo-controlled survival studies testing the efficacy of ACE inhibition in patients with AMI and clinical heart failure are unlikely because withholding a treatment of accepted clinical value would be unethical. Therefore, in the AIRE survival (AIRE-S) study, we aimed to assess the long-term (29.6 years after randomisation) magnitude of impact on length of survival observed after treatment with ramipril (target dose 5 mg twice daily) when compared with placebo.

METHODS

Patients and design

The rationale, design, organisation, outcome definitions and results of the AIRE study have been published previously.^{10–12} This was an independent, multinational, multicentre, double-blind, randomised, placebo-controlled, parallel-group investigation into the potential benefits from treatment with the lipophilic ACE inhibitor ramipril (target dose 10 mg/day) following AMI complicated by clinical evidence of heart failure. When the trial was conducted, in 1993, all patients had an ECG and cardiac enzyme confirmation of AMI, and also evidence of transient or persisting heart failure as judged by the attending physician (chest X-ray evidence of left ventricular failure, or auscultatory evidence of pulmonary oedema, or a third heart sound in the presence of persistent tachycardia), usually sufficient to justify diuretic or vasodilator therapy. Patients were excluded if they had evidence of clinical instability, contraindications to the use of ACE inhibitor therapy, heart failure of primary valvular or congenital origin or overt heart failure deemed to require treatment with an open-label ACE inhibitor. After applying these entry criteria to consecutive patients admitted to the UK centres (30 centres), 44% of patients approached declined to give their consent to take part in the study. All 603 of the remaining patients were then randomised by telephone to receive masked treatment with either ramipril (titrated over 4 days to 5 mg twice daily) or a matching placebo. Treatment was started between 2 and 9 days after the onset of AMI. Patients initially received either 1.25 or 2.5 mg ramipril or

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Table of Contents Longterm Management Of Patients After Myocardial Infarction

1. Understanding the eBook Longterm Management Of Patients After Myocardial Infarction
 - The Rise of Digital Reading Longterm Management Of Patients After Myocardial Infarction
 - Advantages of eBooks Over Traditional Books
2. Identifying Longterm Management Of Patients After Myocardial Infarction
 - Exploring Different Genres
 - Considering Fiction vs. Non-Fiction
 - Determining Your Reading Goals
3. Choosing the Right eBook Platform
 - Popular eBook Platforms
 - Features to Look for in an Longterm Management Of Patients After Myocardial Infarction
 - User-Friendly Interface
4. Exploring eBook Recommendations from Longterm Management Of Patients After Myocardial Infarction
 - Personalized Recommendations
 - Longterm Management Of Patients After Myocardial Infarction User Reviews and Ratings
 - Longterm Management Of Patients After Myocardial Infarction and Bestseller Lists

5. Accessing Longterm Management Of Patients After Myocardial Infarction Free and Paid eBooks
 - Longterm Management Of Patients After Myocardial Infarction Public Domain eBooks
 - Longterm Management Of Patients After Myocardial Infarction eBook Subscription Services
 - Longterm Management Of Patients After Myocardial Infarction Budget-Friendly Options
6. Navigating Longterm Management Of Patients After Myocardial Infarction eBook Formats
 - ePub, PDF, MOBI, and More
 - Longterm Management Of Patients After Myocardial Infarction Compatibility with Devices
 - Longterm Management Of Patients After Myocardial Infarction Enhanced eBook Features
7. Enhancing Your Reading Experience
 - Adjustable Fonts and Text Sizes of Longterm Management Of Patients After Myocardial Infarction
 - Highlighting and Note-Taking Longterm Management Of Patients After Myocardial Infarction
 - Interactive Elements Longterm Management Of Patients After Myocardial Infarction
8. Staying Engaged with Longterm Management Of Patients After Myocardial Infarction
 - Joining Online Reading Communities
 - Participating in Virtual Book Clubs
 - Following Authors and Publishers Longterm Management Of Patients After Myocardial Infarction
9. Balancing eBooks and Physical Books Longterm Management Of Patients After Myocardial Infarction
 - Benefits of a Digital Library
 - Creating a Diverse Reading Collection Longterm Management Of Patients After Myocardial Infarction
10. Overcoming Reading Challenges
 - Dealing with Digital Eye Strain
 - Minimizing Distractions
 - Managing Screen Time
11. Cultivating a Reading Routine Longterm Management Of Patients After Myocardial Infarction
 - Setting Reading Goals Longterm Management Of Patients After Myocardial Infarction
 - Carving Out Dedicated Reading Time
12. Sourcing Reliable Information of Longterm Management Of Patients After Myocardial Infarction
 - Fact-Checking eBook Content of Longterm Management Of Patients After Myocardial Infarction
 - Distinguishing Credible Sources
13. Promoting Lifelong Learning

- Utilizing eBooks for Skill Development
- Exploring Educational eBooks

14. Embracing eBook Trends

- Integration of Multimedia Elements
- Interactive and Gamified eBooks

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