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STATISTICAL QUESTION

Non-inferiority trials

Researchers investigated the efficacy and safety of oral pristinamycin for the treatment of erysipelas in patients admitted to hospital. A multicentre, randomised controlled non-inferiority trial was performed. The control treatment was penicillin, the standard treatment for erysipelas in adults. Penicillin is given intravenously until body temperature returns to normal, after which it is given orally. Unfortunately, intravenous treatment is painful, time consuming, requires hospital admission, and not uncommonly has side effects. If pristinamycin could be shown to be as effective as penicillin it could be used as first line treatment, with the advantage that it is given orally.

The primary end point was proportion of adults cured of erysipelas at follow-up (days 25-45). A non-inferiority margin of 10% was proposed. In total, 139 adults were randomised to oral pristinamycin and 150 to the standard treatment of penicillin. Using an intention to treat analysis, the cure rate at follow-up was 65% for pristinamycin and 53% for penicillin (difference favouring pristinamycin 12%). Pristinamycin was shown not to be statistically inferior to penicillin in effectiveness.

Which one of the following statements best describes the null hypothesis for the statistical test of the comparison of pristinamycin with penicillin in the primary end point?

a) In the population, the cure rate for pristinamycin is greater than for penicillin
b) In the population, the cure rates for pristinamycin and penicillin are equal
c) In the population, the cure rate for penicillin is greater than for pristinamycin by 10% or more
d) In the population, the cure rate for pristinamycin was no more than 10% below that for penicillin

Submitted by Philip Sedgwick
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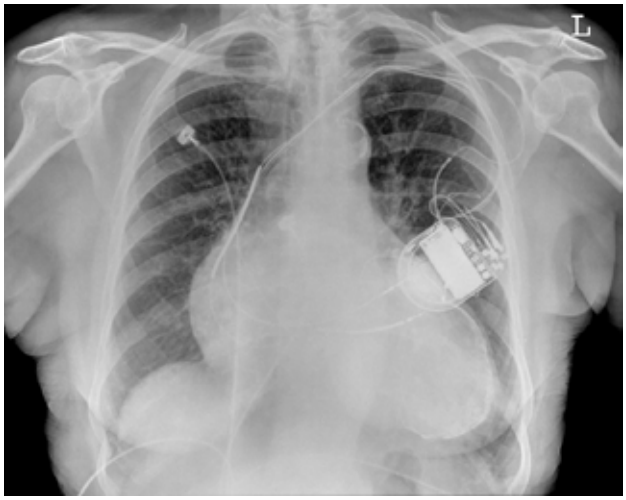
PICTURE QUIZ

A case of recurrent ventricular tachycardia



Submitted by C Inglis, F Chedgy, and D C Howlett
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A 76 year old woman collapsed at home after feeling ill and faint, with central chest pain radiating to both arms. She was found to be in pulsatile ventricular tachycardia by paramedics and her arrhythmia was converted to sinus rhythm with 100 mg of intravenous lidocaine. Her medical history included an anteroapical myocardial infarction eight years previously and subsequent New York Heart Association class III heart failure with moderate to severe systolic dysfunction. Before this admission she had been maintained on lisinopril 20 mg once daily, isosorbide mononitrate 40 mg once daily, frusemide 40 mg twice daily, warfarin, atorvastatin 20 mg once daily, digoxin 250 µg once daily, carvedilol 6.25 mg once daily, and glyceryl trinitrate as needed. In the months before this episode she had experienced recurrent attacks of dizziness and palpitations and occasional episodes of anginal chest pain. Serial electrocardiographs showed sinus rhythm, QRS duration of 125 ms, septal Q waves, and non-dynamic 1 mm ST elevation unchanged from previous electrocardiographs. Cardiac enzymes were not raised. She had more episodes of ventricular tachycardia on the coronary care unit, however, and she underwent further treatment. Chest radiography (figure) was performed before she was discharged.

1 What abnormalities are seen on the chest radiograph and what are the most likely causes?
2 What is the most likely explanation for her arrhythmia?
3 How should such patients be managed?

ANATOMY QUIZ

Coronal computed tomography of the chest

Identify the structures labelled A, B, C, D, and E in this coronal computed tomogram of the chest.

Submitted by A Nair
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