A 21 year old man presented to his general practitioner with intermittent left sided pain in the anterior chest wall associated with neck discomfort. The pain was reported as “stabbing” in nature and had arisen suddenly while watching television. He had no history of trauma before the onset of symptoms, and the pain was not exacerbated by inspiration or effort. His medical history and physical examination were unremarkable. His GP referred him for outpatient cardiology assessment and prescribed simple analgesia.

Several days later he attended the local emergency department with worsening chest pain and dyspnoea. On examination, chest expansion was equal and breath sounds were normal, although there was crepitus on auscultation of the precordium. Palpation of the neck and supraclavicular fossae detected subcutaneous emphysema. His respiratory rate was 25 breaths/min and his oxygen saturations were 100%. A chest radiograph (figure) was abnormal and he was admitted for computed tomography of the chest. No abnormalities were seen on a water soluble oral contrast swallow. His full blood count and inflammatory markers were within normal limits.

The effectiveness of topical chloramphenicol in preventing wound infection after minor dermatological surgery was evaluated. A randomised placebo controlled double blind superiority trial was performed. The intervention was a single application of topical chloramphenicol ointment applied to the sutured wound immediately after suturing. Participants were patients with high risk sutured wounds who had undergone minor surgery.

The primary outcome was infection on the agreed day of removal of sutures or sooner if the patient re-presented with a perceived infection. The required sample size was based on a projected infection rate of 0.0% in the placebo group. The smallest effect of clinical interest was an absolute decrease in the incidence of infection of 5%. To achieve this difference with a power in excess of 80% and a critical level of significance of 0.05, 473 patients were needed in each treatment group. In total, 972 patients were recruited and randomised to topical chloramphenicol ointment (n=488) or placebo (n=484).

The proportion of participants with an infection in the topical chloramphenicol group was statistically significantly lower than for placebo (6.6% vs 11.0%; difference −4.4%, 95% confidence interval −7.9% to −0.8%; P=0.010).

Which of the following statements, if any, are true?

a) The derived sample size was based on clinical significance
b) The derived sample size was based on statistical significance
c) It can be inferred that the reduction in infection rate for the intervention compared with placebo was clinically significant because it was statistically significant

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