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CASE REPORT

A restless night's sleep

A 76 year old woman presented to her general practitioner with a four year history of uncomfortable sensations in her legs like "swarms of biting and crawling ants." These would occur in the evenings and were worse when she was sitting still or lying in bed at night. Relief could be obtained only by moving her legs or getting out of bed. This caused severe insomnia and was adversely affecting her quality of life. She had no family history of movement disorders but had osteoarthritis and gout, and was taking allopurinol plus calcium and vitamin D supplements.

She was started on co-beneldopa 25/100 (benserazide 25 mg, levodopa 100 mg) and ropinirole 2 mg nightly for her leg symptoms and nitrazepam 5 mg for her insomnia. She initially had some mild relief, but because her symptoms were not fully controlled the doses were increased. After one month of dose escalation, her symptoms became more severe, lasted longer during the night, and affected her sleep more severely than before. In an attempt to control her symptoms, her doses were increased further until she was taking co-beneldopa and ropinirole four hourly. However, she then developed severe symptoms during the daytime, from the mornings onwards, which were exacerbated by taking long car journeys. She was referred to the neurology clinic for a further opinion.

- 1 What is the cause of her initial symptoms?
- 2 How should this condition be managed?
- 3 Why did her symptoms get worse when she started treatment?
- 4 How should this phenomenon be managed?

Submitted by Dilan Athauda and Guy Leschziner

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STATISTICAL QUESTION

External and internal validity in clinical trials

Researchers investigated the efficacy of a probiotic drink containing *Lactobacillus* for the prevention of antibiotic associated diarrhoea in patients over 50 years. A randomised double blind placebo controlled trial study design was used. The intervention consisted of consumption of a probiotic drink twice a day during a course of antibiotics and for one week after the course finished. The placebo was a long life sterile milkshake. The primary outcome was occurrence of antibiotic associated diarrhoea.

Participants were recruited from three London hospitals. A total of 1760 patients were assessed for eligibility, 1625 of whom were not recruited because they did not meet the inclusion criteria (n=1263), refused to participate (n=148), or could not be included for practical reasons (n=214). The remaining 135 patients were recruited to the trial and randomised to intervention (n=69) or placebo (n=66). In total, 12 patients receiving the intervention and 10 in the placebo group did not complete their treatment protocol because they were lost to follow-up, withdrew consent, or died during the study period. The trial was analysed using a per protocol analysis. The researchers reported that consumption of the probiotic drink reduced the incidence of antibiotic associated diarrhoea.

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

- a) The random allocation of patients promoted external validity
- b) The random allocation of patients promoted internal validity
- c) The per protocol analysis promoted internal validity

Submitted by Philip Sedgwick

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PICTURE QUIZ

A blistering eruption after a holiday in India



A 33 year old woman presented with an intensely itchy, erythematous, blistering eruption bilaterally on the distal upper and lower limbs a week after coming back from a holiday in India. The rash was associated with oedema. She had attended a friend's wedding while in India, and as part of the festivities she took part in the ritual of "mehndi," which involved having an intricate henna design painted on her hands and feet. Five days after this ritual she developed a sharply demarcated erythematous, itchy, papulovesicular swelling in the proximal distribution of the tattoo design, which spread distally (figure). Other than the skin irritation, she had no other symptoms and was systemically well.

- 1 What is the diagnosis?
- 2 What investigations should be performed?
- 3 How is this condition managed?

Submitted by FS Worsnop, EE Craythorne, and Anthony W P du Vivier

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