ENGAMES

STATISTICAL QUESTION

Number needed to harm

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Last week's question described a trial that assessed the efficacy and safety of varenicline, a smoking cessation aid for users of smokeless tobacco.[1] A double blind, placebo controlled, randomised controlled trial was performed. In total, 213 participants were allocated to varenicline and 218 to placebo. Treatment was for 12 weeks, with 14 weeks of follow-up after treatment.[2]

The primary end point was continuous abstinence from smoking for four weeks at the end of treatment (weeks 9 to 12). Secondary end points included adverse events. One of the most common adverse events was headaches, which were reported by 10% of the varenicline group and 9% of the placebo group.

Which one of the following is the number needed to harm for the comparison of varenicline with placebo in the adverse event of headaches?

  a) 100

  b) 10

  c) 0

  d) −10

  e) −100

Answers

Answer *a* is the value of the number needed to harm for the comparison of varenicline with placebo in the adverse event of headaches. Number needed to harm is calculated as the reciprocal of the absolute risk difference between varenicline and placebo in the reported adverse event of headaches. The percentage difference between varenicline and placebo is 1%, that is, a difference in risks of 0.01. Therefore, number needed to harm equals 1÷0.01; that is, 100. The value of number needed to harm is always positive.

The number needed to harm quantifies the harm caused by an intervention compared with the control, so it usually describes adverse advents. In the study described, the number needed to harm of 100 indicates that 100 participants need to be treated with varenicline for one more person to experience the adverse event of a headache than if those 100 participants had been treated with placebo. Number needed to harm is obviously based on an estimated long term average.

Number needed to harm is calculated in a similar way to number needed to treat, described in previous questions.[1][3] The smaller the value of the number needed to treat, the greater the therapeutic benefit of the intervention compared with the control. However, for the number needed to harm, the larger the value the better, because it is less likely that the adverse event will occur.

The value of number needed to harm depends only on the difference in risks between the varenicline and placebo groups. A number needed to harm of 100 would therefore have been obtained regardless of the absolute risks for the two treatment groups, as long as the absolute risk difference between them was 0.01. The number needed to harm should therefore be presented alongside other measures of risk, including the absolute risks of the adverse event of headaches for both the varenicline and placebo groups.

1 Sedgwick P. Number needed to treat II. *BMJ* 2011;342:d2664.
2 Fagerstrom K, Gilljam H, Metcalfe M, Tonstad S, Messig M. Stopping smokeless tobacco with varenicline: randomised double blind placebo controlled trial. *BMJ* 2010;341:c6549.
3 Sedgwick P. Number needed to treat I. *BMJ* 2011;342:d2463.

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