

RGH Pharmacy E-Bulletin

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A joint initiative of the Patient Services Section and the Drug and Therapeutics Information Service of the Pharmacy Department, Repatriation General Hospital, Daw Park, South Australia. The RGH Pharmacy E-Bulletin is distributed in electronic format on a weekly basis, and aims to present concise, factual information on issues of current interest in therapeutics, drug safety and cost-effective use of medications.

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Practical clinical biostatistics –assessing risk

Clinicians need to have a grasp of the basic concepts of practical biostatistics to enable them to interpret the findings of research and apply this interpretation in the clinical practice.

Scenario

A study investigating the efficacy and safety of an antiplatelet agent reports the risk of a vascular event in the placebo group was 11.4% compared to 9.3% in the treatment group, measured over one year. In the placebo group 2.7% of subjects suffered a major bleed, compared to 3.7% in the antiplatelet group. Meanwhile, an advertisement states there was nearly a 20% reduction in risk of vascular events with the antiplatelet compared to placebo. What do these numbers actually mean?

Relative and Absolute Risk Ratio

Relative risk (RR) is the ratio of the rate of an event in a treatment group compared to the control group

In this case, the rate of a vascular event amongst those receiving placebo (9.3%) / rate of a vascular event amongst those receiving active treatment (11.4%) = 0.82.

The relative risk reduction (RRR) = $1 - RR = 0.18$ or 18%.

The absolute risk reduction (ARR) = absolute risk (AR) of an event in control group minus AR in treatment group: in this case, 11.4% - 9.3% = an absolute risk reduction of 2.1%

Number Needed to Treat vs. Number Needed to Harm

As it relates to the example provided, the number needed to treat (NNT) represents the number of patients that need to be treated with the antiplatelet drug to prevent a vascular event in one of these patients. NNT is the reciprocal of the ARR and must include a time period i.e. $NNT = 1/0.021 = 48$. This means that 48 patients would need to be treated with the antiplatelet drug rather than placebo for one year to avoid a vascular event in one patient. It is not possible to predict the patient for whom this benefit will occur.

Conversely, AR increase of a major bleed with the antiplatelet was 1% (3.7% - 2.7%), representing a number needed to harm (NNH) of 100 patients treated with the antiplatelet compared to placebo for one year for one extra major bleed.

When cited, RR values are accompanied by 95% confidence intervals (CI). The 95% CI indicates that if the experiment is repeated many times, at least 95% of the CI would include the true population mean. If the CI includes 1.0 there is no statistical difference between the treatment and control group.

An understanding of biostatistics is important for application of evidence to the clinical setting. Typically RRR are reported, particularly in promotional material, as they tend to be larger and potentially more impressive than ARR. However, the benefit of therapy for any given individual will depend on the individual's baseline AR. For example, if baseline risk of a vascular event is 1% and RRR is 18% with antiplatelet therapy, the ARR will be reduced from 1% to 0.82%, equating to an ARR of 0.18% and a NNT of 556 to avoid one extra vascular event over one year. This may not be deemed clinically significant, regardless of the 95% CI.

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FOR FURTHER INFORMATION – CONTACT THE PHARMACY DEPARTMENT ON 82751763 or email: chris.alderman@rgh.sa.gov.au
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