ABC of Methodology

This is a new Section of *Epidemiologia e Psichiatria Sociale*, that will regularly cover methodological aspects related to the design, conduct, reporting and interpretation of clinical and epidemiological studies. We hope that these articles will help develop a more critical attitude towards research findings published in the international literature and, additionally, will help promote the implementation of original research projects with higher standards in terms of design, conduct and reporting.

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What is a risk ratio?

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Previously in this journal, we discussed how to summarise the results of primary studies (Cipriani & Barbui, 2006). It is of interest to note, at this regard, that there are many ways of providing estimates for the relationship between two binary ("yes or no") variables. These ways have become increasingly popular in medical reports and nowadays clinicians need to clearly understand the meaning of these values in order to better inform daily clinical practice.

The risk (or absolute risk - AR) is the probability that an individual will experience a specified outcome during a specified period. The AR lies in the range from 0 to 1 and can be expressed as a percentage. In scientific literature, the word "risk" may either refer to adverse events (such as side effects) or desirable events (such as improvement of symptoms). If we have two comparisons, the ratio of the AR for each group is the relative risk (RR). In other words, the RR is the AR in the intervention group divided by the AR in the control group, that is the number of times more likely (RR greater than 1) or less likely (RR less than 1) an event is to happen in one group compared with another. The closer the RR is to 1, the smaller the difference in effect between the experimental intervention and the control intervention.

Conversely, the odds of an event are defined as the probability that an event will occur, expressed as a proportion of the probability that the event will not occur. The difference between AR and odds can be very clear if we use an example to explain the core difference between these two proportions (Bland & Altman, 2000). Let's imagine to have a die. All dice have 6 sides and thus there are 6 possible outcomes (namely, number 1, 2, 3, 4, 5, or 6). Let's throw the dice just once and a priori try to quantify the possibility to have one single side (say, number 4). The odds to produce number 4 is 1 (the "positive" event - that is, number 4) out of 5 (all the remaining "negative" events - that is, number 1, 2, 3, 5 or 6), that is 1/5. By contrast, the AR of producing number 4 is 1 (the "positive" event - again, number 4) out of 6 (overall the possibilities, including the desired event), that is 1/6. This example helps clarify that the AR is very close to the odds when events are rare (few events in the numerator and many people in the denominator); however, as event rates increase, the AR and odds can really diverge.

The odds ratio (OR) is the odds of an event happening in the experimental group expressed as a proportion of the odds of an event happening in the control group. OR has a very convenient interpretation in case control studies and is used to examine the effects of other variables on a relationship during logistic regression analyses (Bland & Altman, 2000).

RR and OR give an idea of the proportional reduction between the two comparison groups. There are two other ways of reporting results of primary studies. First, the relative risk reduction (RRR), which is the proportional reduction in risk between experimental and control participants in a trial. It's worth noting that it could be really misleading to consider only relative indices, without looking at absolute estimates of treatment effect. The absolute risk reduction (ARR) between the experimental

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and control groups is calculated by subtracting the AR in the experimental group from the AR in the control group.

Clinicians need absolute numbers to make sense of trial results (Streiner, 2005). ARR can vary a lot according to the hypothetical frequency of the outcome events, even if the RRR is the same. For instance, ARR is dramatically different when comparing the same RRR in high-risk patients (higher event rate) with low-risk patients (lower event rate) (see Figure).

ARR and RRR can be very useful when calculating one measure of treatment effectiveness, the number-needed-to-treat (NNT). NNT is the average number of people who need to be treated with a specific intervention for a given period of time to achieve one additional beneficial outcome (or to prevent one additional adverse outcome). NNT can be calculated as the reciprocal of the ARR (1/ARR) (see Figure). As people can not be treated as fractions, NNTs are usually rounded up to the largest absolute figure. This provides a conservative estimate of effect. NNTs should only be provided for significant effects because of the difficulty of interpreting the confidence intervals for non-significant results. NNTs are easy to interpret and can help clinicians make decisions about individual patients. However, NNTs can only be applied at a given level of baseline risk and the method of NNT may not apply to periods of time different to that studied in the original trials (Cook & Sackett, 1995).

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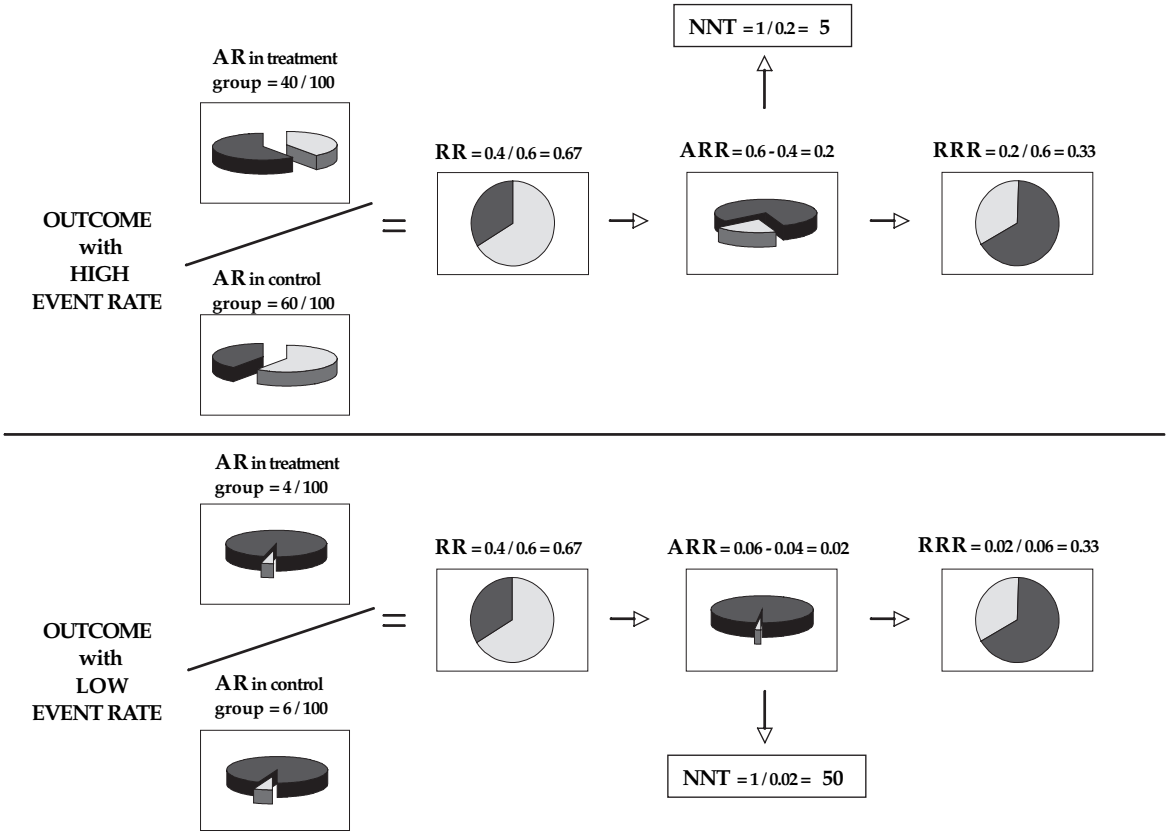

Figure – *AR: absolute risk; RR: relative risk; ARR: absolute risk reduction; RRR: relative risk reduction; NNT: number needed to treat (see text for details).*