

Communicating Risks Clearly: Absolute Risk and Number Needed to Treat

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Researchers have an obligation to present risks as fairly and clearly as possible for their readers. However, they typically favor the most obscure presentation: relative risks [1]. Relative risks can be misleading, because a dramatic reduction in relative risk may correspond to only a small drop in absolute risk. For example, if a treatment cuts the risk of disease from 2% to 1%, then the relative reduction in risk is 50% (relative risk = 0.50), but the absolute reduction is only 1%. This article highlights the importance of reporting absolute risks and the related statistic, number needed to treat (or harm).

CASE STUDY: THE WOMEN'S HEALTH INITIATIVE

Postmenopausal hormones were once hailed as the proverbial “Fountain of Youth” for women. However, this perception changed in 2002 when the Women’s Health Initiative (WHI) trial [2] was abruptly halted because it had become clear that hormones were doing more harm than good. In this large, randomized, double-blind study, hormones significantly increased the risks of breast cancer and heart disease compared with placebo. The latter finding was particularly surprising because most researchers had previously believed that hormones decreased heart disease risk.

When the results of the WHI were released, 14 million women in the United States who were postmenopausal, including one-third of all women 50-74 years old, were on hormone therapy; 6 million were taking oral estrogen and progestin (the specific therapy tested in the trial) [3,4]. Thus, the impact of the trial results would be widespread. Those researchers who released the results had to think carefully about how to drop their “bombshell” on the public. In a praiseworthy example of the judicious use of statistics, the researchers used absolute risks and whole numbers to convey risk to the medical community, media, and public.

Prevalence: the proportion of subjects who have a particular outcome at a given time point; includes both old and new cases.

ABSOLUTE VERSUS RELATIVE RISKS

Absolute risks may be expressed as a prevalence, cumulative risk, or incidence rate, depending on the study design. Relative risks are formed by dividing the absolute risk of an outcome in a treated or exposed group by the absolute risk in a control (reference) group. Confounder-adjusted relative risks may also be calculated by using logistic regression or Cox regression. Relative risks lower than 1.0 indicate a decreased risk (protective effect); and relative risks higher than 1.0 indicate an increased risk.

Cumulative risk: the proportion of subjects who develop a particular outcome during a longitudinal study.

In the WHI, risks were presented as incidence rates. An incidence rate is the number of events divided by the total number of “person-years.” For example, in the hormone group, researchers followed 8506 women for an average of 5.18 years and a total of 44,061 women-years; 166 of them developed invasive breast cancer, which yielded an incidence rate of $166/44,061 = 0.0038$ cases per woman-year, or 38 cases per 10,000 women-years. In the placebo group, there were 124 cases of breast cancer in 41,320 women-years, which yielded

Incidence rate: The rate at which new outcomes occur in a longitudinal study, expressed as the number of new cases per person-year.

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Table 1. Heart attacks, breast cancer, colorectal cancer, and hip fracture outcomes in the estrogen plus progestin group versus the placebo group in the Women's Health Initiative, * expressed in terms of absolute risks (rates and rate differences) and relative risks (hazard ratios)

	Rate in Hormone Group, per 10,000 Women-Years	Rate in Placebo Group, per 10,000 Women-Years	Rate Difference, Events per 10,000 Women-Years	Relative Risk (hazard ratio) [†]	Relative Risk Interpretation
Heart attack	37	30	7 additional	1.29	29% increase in risk
Invasive breast cancer	38	30	8 additional	1.26	26% increase in risk
Hip fracture	10	15	5 fewer	0.66	34% decrease in risk
Colorectal cancer	10	16	6 fewer	0.63	37% decrease in risk

*From Ref. 2.

[†]The hazard ratios (relative risks) reported in the articles have been adjusted for factors such as clinical center and thus give slightly different results than are obtained by dividing the absolute rates in the 2 groups.

an incidence rate of 0.0030, or 30 per 10,000 women-years. Thus, in absolute terms, the increase in risk for the hormone group was 0.08%, or 8 cases per 10,000 women-years.

Dividing these 2 absolute risks (0.0038/0.0030) gives a relative risk of 1.27, which can be interpreted as a 27% increase in risk. The relative risk reported in the article is actually slightly different, 1.26, because the researchers used the Cox regression to adjust for factors, for example, the clinical site. The absolute and relative risk numbers for heart attacks, breast cancer, colorectal cancer, and hip fracture in the WHI are given in Table 1.

Although they are based on the same numbers, the absolute and relative risks convey quite different pictures. Risk increases of 29% (for heart attacks) and 26% (for breast cancer) sound large and alarming. However, in fact, a woman's annual risk of a heart attack increases by only 7 of 10,000 (0.07%, a tiny fraction of a percent) and her risk of breast cancer increases by only 8 of 10,000 (0.08%). Thus, the risk of hormones to any individual woman is actually quite small.

The researchers could have chosen to highlight the more dramatic relative risks. However, this would have been needlessly frightening for the millions of women on hormones. Instead, the researchers prudently emphasized the absolute risks, citing them in the abstract of the article and in their communications with the media [4]. Not only did they include the absolute risks (eg, 0.0038 and 0.003), they translated these percentages into easy-to-understand whole numbers: 38 of 10,000 and 30 of 10,000. As a result, the press reported the absolute risks more often than they reported the relative risks [4].

Table 2. Number needed to treat and number needed to harm for heart attacks, breast cancer, colorectal cancer, and hip fracture

	Absolute Rate Difference, events per 10,000 Women-Years	Number Needed to Harm	Number Needed to Treat
Heart attack	7 additional	1429	–
Invasive breast cancer	8 additional	1250	–
Hip fracture	5 fewer	–	2000
Colorectal cancer	6 fewer	–	1667

Researchers (and journalists) got another thing right: they not only highlighted the harmful effects of hormones but also their beneficial effects. Hormones protected against several diseases, including hip fracture and colorectal cancer. The risks of estrogen plus progestin outweigh the benefits simply because heart disease and breast cancer happen to be more common than colorectal cancer and hip fracture. Again, only the absolute risks reveal this overall balance; the relative risks convey no information about the relative frequency of different diseases.

NUMBER NEEDED TO TREAT OR HARM

A statistic that is directly related to the absolute risk but that offers a slightly different perspective is the number needed to treat (or to harm). The number needed to treat tells us how many persons would have to be given a beneficial intervention to prevent 1 case of disease; and the number needed to harm tells us how many people would have to be given a harmful intervention to cause 1 excess case of disease. The number needed to treat (or harm) is equal to the inverse of the absolute risk difference. For example, treating 10,000 women with estrogen plus progestin for 1 year yields 8 excess cases of breast cancer. So, one would need to treat $10,000/8 = 1250$ women for 1 year to cause a single excess case. The numbers needed to treat (or harm) for heart attacks, breast cancer, colorectal cancer, and hip fracture are shown in Table 2. Similar to the absolute risk, the number needed to treat (or harm) helps people to understand both the individual and societal impacts of a given intervention. For example, it tells us that, of 1250 women who take hormones for 1 year, 1 woman will get breast cancer due to her use of hormones.

Although the risks to a given woman are small, the overall public health impact of hormone therapy was still large because so many women were taking hormone therapy before the WHI results were released. With 6 million women taking oral estrogen plus progestin, in the United States, this translates to 4800 excess cases of invasive breast cancer per year. An additional 8 million women were on other types of hormone therapy, some of which also likely increase breast cancer risk; thus, the number of excess breast cancer cases

likely was larger. In fact, the impact of hormones was so dramatic from a societal perspective that, when hormone use dropped precipitously after the results of the WHI, there was a measurable decrease in breast cancer rates in the United States [5,6].

CONCLUSIONS

Absolute and relative risks convey very different pictures of the effect of an intervention or exposure. Readers and researchers should pay more attention to absolute risks and the related statistic, the number needed to treat (or to harm). Absolute risks are more informative and straightforward than relative risks; they are also useful for assessing the overall harms and benefits of an intervention as well as the societal impacts. Expressing absolute risks in terms of whole numbers (rather than as decimals or percentages) improves interpretability.

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