Observational Studies

Observational studies differ from clinical trials in that the investigator does not assign treatments to subjects, but merely collects data.  The main types of observational studies in medicine are cohort studies and case-control studies.

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In cohort studies, data are collected on patients for a period of time. These studies can be retrospective or prospective. Two groups of patients are followed: patients who had some type of exposure, and patients who were not exposed. Investigators follow these groups to see how many people develop a specific outcome. (For example, you could follow smokers and non-smokers and see how many developed lung cancer).

Because the data is usually collected over a specific time range, an absolute risk of an outcome can be calculated, as well as an incidence. In the following table, the absolute risk of the outcome in the exposed group is 20/100 and 10/100 in the unexposed group.  To determine the relative risk, the risk in the exposed group is compared to the risk in the unexposed group to calculate a relative risk. The relative risk is 20/100 divided by 10/100 or 2.0.

|  | Outcome + | Outcome – | Total |
|---|---|---|---|
| Exposed | 20 | 80 | 100 |
| Unexposed | 10 | 90 | 100 |

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Case-control studies compare cases (those with a disease) to controls (those without the disease).  The controls are usually matched to the cases on a few factors (typically age and gender).  Investigators then look back to compare the number of individuals in each group who had an exposure of interest.  For example, when toxic shock syndrome was first investigated, investigators looked at cases (patients who developed TSS) and controls (patients who didn't). It was determined that people who developed TSS (cases) were more likely to have the exposure of having used superabsorbent tampons.

The odds ratio (OR) is the chance of a case having had an exposure compared to not having had an exposure. In the table below, the odds of exposure for cases is 30/12.  The odds of exposure for controls is 30/84.  Finally, compare these two odds: (30/12)/(30/84).  This gives you and odds ratio of 7.0.

|  | Cases | Controls |
|---|---|---|
| Exposed | 30 | 30 |
| Unexposed | 12 | 84 |

Odds ratios are used in case control studies, because relative risks (and incidence) cannot be determined.  Odds ratios are more commonly seen in logistic regression, a topic which we be covered later.