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Perspective

Drug Efficacy and Adverse Effects

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DESCRIPTION

• Efficacy is the ability to produce an effect (e.g. lowering blood pressure). Efficacy can only be an accurately assessed ideal condition (i.e., if the patient is selected using appropriate criteria and adheres to the dosing regimen strictly). Therefore, efficacy is measured under expert supervision in the group of patients most likely to respond to the drug, such as in controlled clinical trials.

• Effectiveness differs from efficacy in that it takes into account how well the drug actually works.

In many cases, drugs that are effective in clinical trials are not very effective in actual use. For example, drugs may be very effective in lowering blood pressure, but they are inadequate because they cause so many side effects that patients stop taking them. If the clinician inadvertently prescribes the drug (e.g., a fibrinolytic drug given to a patient with suspected ischemic stroke, but no intracranial hemorrhage detected), the efficacy is less than effective. There is a possibility. Therefore, efficacy tends to be less than efficacy. Patient-centric results should be used, rather than surrogate or tentative results, to assess efficacy and efficacy.

Patient-centric results

Patient-centric results affect patients' well-being. These include one or more of the following:

- Extension of life
- Improvement of function (e.g. prevention of disability)
- Relief of symptoms

Surrogate result

Surrogate or intermediate results are related to those that do not directly affect the well-being of the patient. These are characteristics such as physiological parameters (such as blood pressure) and test results (such as glucose and cholesterol levels, tumor size on CT scans) that are often thought to predict actual patient-centric results. For example, clinicians usually believe that lowering blood pressure can prevent patient-oriented consequences of uncontrolled hypertension (for example, death from myocardial infarction or stroke). However, perhaps because of its fatal side effects, the drug can lower blood pressure but not mortality. Even if the surrogate is simply a marker of the disease (e.g. HbA1C) and not the cause of the disease (e.g., hypertension), interventions can lower the marker by means that do not affect the underlying disease. Therefore, surrogate results are less desirable measure of efficacy than patient-centric results. Surrogate results, on the other hand, can be much more practical, for example, when a patient-centric, results appear after a long period of time (e.g., renal failure secondary to uncontrolled hypertension), or in rare cases. I have. In such cases, clinical trials need to be conducted on a very large scale and over a long period of time, unless surrogate results (such as lower blood pressure) are used. In addition, death and disability, which are the primary patient-centric endpoints, are bisected (i.e. yes / no), but surrogate results are often continuous numerical variables (e.g., blood pressure, blood glucose). In contrast to the dichotomy results, numerical variables can indicate the magnitude of the effect. Therefore, surrogate results often provide far more analytical data than patient-centric, results, allowing clinical trials to be conducted in far fewer patients. However, surrogate results should ideally be clearly correlated with patient-centric results. There are many studies in which such a correlation seemed reasonable, but did not actually exist. For example, treatment of certain postmenopausal women with estrogen and progesterone yielded a more favorable lipid profile, but failed to achieve the assumed corresponding reduction in myocardial infarction or cardiac death. Similarly, lowering blood glucose levels in ICU diabetics to near normal level results in higher mortality and morbidity (perhaps by causing episodes of hypoglycemia) than lowering blood glucose levels to slightly higher levels. Some oral hypoglycemic agents lower blood sugar levels, including HbA1C levels, but do not reduce the risk of heart events. Some antihypertensive drugs lower blood pressure, but do not reduce the risk of stroke.

Adverse effects

Similarly, clinically relevant adverse effects are patient-oriented endpoints. Here is an example

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- Death
- Hindrance
- Mild pain

Surrogate adverse effects (e.g., changes in serum marker levels) are commonly used, but should ideally correlate with patient-specific side effects, as well as the consequences of surrogate efficacy. Clinical trials carefully designed to prove efficacy have a hard time identifying side effects, even if the time it takes to develop side effects is longer than the time it takes to generate benefits, or even if the side effects are rare. There is a possibility. For example, Cyclooxygenase 2 (COX2) inhibitors quickly relieve pain and can be shown to be effective in relatively short studies. However, the increased incidence of myocardial infarction caused by some COX2 inhibitors occurred over a long period of time and was not apparent in shorter, smaller studies. Because of this, and because clinical trials may exclude certain subgroups and high-risk patients, side effects are not fully known until the drug has been in extensive clinical use for years. There is a possibility. The side effects of many drugs are dose-dependent.

Balancing drug benefits and adverse effects

Whether a drug is indicated depends on weighing its benefits and harms. In making such decisions, clinicians often consider some subjective factors such as personal experience, anecdotes, peer habits, and expert opinion.

Therapeutic index

The goal of drug development is to make a big difference between the effective amount and the amount that causes side effects. The big difference is called the wide treatment index, treatment ratio, or treatment window. If the therapeutic index is low (e.g.<2), factors that are not normally clinically important (e.g. food-drug interactions, minor dosing errors) can have adverse clinical effects. Warfarin, for example, has a narrow therapeutic index and interacts with many drugs and foods. The inadequate anticoagulant therapy increases the risk of complications resulting from the disease treated with anticoagulant therapy (e.g., increased risk of stroke in atrial fibrillation). Excessive anticoagulant therapy, on the other hand, increases the risk of bleeding.