

New Drugs in Oncology – A Challenge for Everyone

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Medical Oncology is the specialty that embraces benign or malignant tumors. The approach to an oncological patient is complex and implies multidisciplinary, that involves not only Medical Oncologists, but also Radioncologists, Surgeons, Imaging Specialists and Specialized Nurses, among others health professionals.

In recent years, there have been major advances in diagnosis and treatment of a vast majority of oncological diseases, with increase in overall survival, progression free survival, quality of life, and others endpoints used in oncological diseases.

As a physician, the main goal is to treat patients.

As Medical Oncologists, our ultimate goal is the treatment of the oncological patient, trying to increase overall survival, and other endpoints, with the least possible toxicity, while simultaneously, increasing the patient's quality of life.

However, nowadays, in Health, and particularly in Medical Oncology, it's inevitable to wonder about the cost of treatment. The increase of costs in Health is transversal and multifactorial, and as Medical Oncologists, we can't stop to question ourselves about why the costs of drugs are so high in Medical Oncology or if there are measures that could be implemented in order to reduce those same costs.

Considering the first question, that is, the high cost of drugs, we must mention some data: only 16 to 19% of clinically researched molecules obtain some degree of success and are approved for therapeutic use. The approval of a drug in Oncology is slow and extended, involving, among others, phase I, II and III studies, being the average of time between the beginning of clinical tests of a molecule and its hypothetical approval eight years. Most of oncological diseases are chronic, non "curable", so the

different drugs will work by a limited period of time (progression free interval) and the patient will, if fit and analytically compatible, most cases will be treated sequentially, with all, or most, of the therapeutic options.

Regarding the second question, it's an even more complex matter. In reality, the majority of current phase III clinical trials are designed to obtain results of efficacy and safety, in most cases an effectivity analysis cannot be performed.

Phase IV observational studies are the best kind of studies to evaluate effectivity, which increases delays in the evaluation of new molecules. How to perform this effectivity analysis even earlier and faster is something we consider fundamental in Oncology, and in this case, pharmacoeconomy may play a crucial role.

Pharmacoeconomy is the description and analysis of the cost of a new treatment/drug for the healthcare and the society. A pharmacoeconomical analysis considers the effects (consequences, results) and the costs; it actually is a comparative analysis of the alternatives, in terms of costs and consequences.

In a pharmacoeconomical analysis one must evaluate the clinical results, humanistic and economically (ECHO model). The clinical results are the medical events that occur as a result of intervention (increase survival, disease free survival, etc). The humanistic results integrate the patient's satisfaction and/or quality of life; result from treatment and are shown as patient's perception. The economical results are shown in terms of cost of treatment, global expense.

In a pharmacoeconomical analysis one must keep in mind the following concepts:

- **Cost-minimization analysis:** Looks only into the compared cost of treatment/drug, that is, cost per treated patient.

- **Cost-benefit analysis:** The costs are measured in physical units and are evaluated in monetary units; the benefit is measured in natural in health increase, clinical results, progression free interval; the results are shown as cost/effect.
- **Cost minimization:** Comparison between two types of treatment/drug, whose result is, presumably, similar.
- **Cost-benefit:** Evaluates the cost and the result of a treatment/drug.
- **Cost-efficacy:** Only one parameter of evaluation is consider and several types of treatments/drugs are compared in respect to that parameter.
- **Cost-utility:** Expresses all the effects of a specific drug until the patient's death.

Oncology is a very special area of Medicine in which, for instant, a four week improval in overall survival, or the increase in quality of life cannot be ignored. Maybe because of that, a quite significant percentage of current treatment guidelines of a huge part of oncological diseases enumerate a "list" of treatment options, but don't mention which of them have the best cost-effectivity.

That evaluation would be, in my opinion, quite pertinent, although, probably, it would not change the reality of clinical practice nowadays: most of the oncological diseases being chronic diseases in the majority of patients, the Oncologist, according to various factors such as comorbidities, clinical expertise with the different drugs, patient's will, among others, decides the timing in which treatment/drug is used, in a sequential manner.

Finding the balance that allows a rational management of resources without harming the oncologist's mission, to treat the patients in the best possible way, is a challenge that should be shared between the physician, the manager, the governmental entities, the pharmaceutical industry, and in my opinion, the patient himself [1-9].

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