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SOMMARIO
SUMMARY

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An end randomization

All the most prestigious research in medicine and surgery around the world is nowadays conducted by means of prospective, randomized studies. That means that two groups of patients are established for comparison of similar age, sex, disease stage, and so forth; they are then treated with either therapeutic protocol A or B.

The patients are assigned to group A or B at random, that is through drawing lots. If the results of the study show the superiority of one of the two therapeutic protocols, A or B, the less effective protocol is immediately abandoned. Up to that point, the two protocols are considered equivalent and assigning patients **in this manner** is considered ethical.

In 2001, I myself was a candidate for randomization into group A or B, after being operated on for retroperitoneal non-Hodgkin lymphoma stage IV. The treatment was **chemotherapy and immunotherapy, i.e.:**

Group A = C.I.O.P. + MabThera;

Group B = FN + MabThera.

However, I refused randomization and asked to be put into group B as I preferred that treatment protocol. My choice was allowed since individual preference does not affect the results of the study; only the total number of patients is of importance and this number must be the same for the two groups.

In brief, the lottery aspect of selecting patients for the groups could be replaced by the free choice of the patient. In this way, the patient would not feel like a guinea pig and would take part in the clinical experiment with greater enthusiasm.

As there is no proof of the superiority of either treatment at the start of the trial, the choice of the patient is "random" and the process of randomization is respected with regard to the scientific validity of the study.

Thanks to my experience as a physician, scientist and patient, I can affirm that the adoption of the free choice method and the abandonment of asssigning patients by number is indispensible and cannot be delayed in clinical trials of therapeutic protocols. Free choice respects the dignity of the patient as a human being and, at the same time, guarantees the scientific rigor of clinical studies.

The method of free choice I am proposing should not be confused with free choice of therapy, as recently seen in the case of the "Di Bella" therapy or other alternative therapies for the treatment of tumors. In fact, the two therapeutic protocols being compared in trials are both held to be effective by the scientific evidence available and by the most important international therapeutic centers; so much so that prospective, randomized trials are deemed necessary to demonstrate the superiority of one over the other.

It is only the assignment of individual patients to one or the other therapeutic group that is called into question. Currently, drawing lots is the criterion used throughout the world today, whereas I propose, from my own experience, the criterion of free choice, out of respect for the individual and to ensure the necessary scientific rigor.

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