

Patient, doctor, disease, and informed consent

Il paziente, il medico, la malattia e il consenso informato

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Lung cancer is the 10th ranking cause of death in the world: its incidence has reached a steady state in the male gender while it is still increasing in females. Even if data are now available on lung cancer screening with low-dose spiral computerized tomography (CT), still today the diagnosis is often late, due to underestimation and late appearance of specific symptoms. Hence, in the great majority of cases (stages IIIB and IV) the only possible option is a definitive chemotherapy with a platin doublet, alone or with bevacizumab, or other target drugs. Unfortunately, the results are not satisfying, either for overall survival or for progression free survival.

So, performing new clinical trials is essential.

Taking into account the prognosis of locally advanced or metastatic lung cancer, the utility of chemotherapy is discussed more often with the patient's relatives than with the patient him/herself. But survival and quality of life (QoL) are significantly better in patients treated with chemotherapy than in those who receive the best supportive care but not chemotherapy.

In this respect it has been demonstrated that the patient is more agreeable to chemotherapy than are the relatives and even the doctor, if the expected results are in terms of survival or quality of life [1]:

- 57% of patients opt for chemotherapy if the one-year-survival is at least 10%
- 68% of patients opt for chemotherapy if the QoL is ameliorated
- the majority of patients opt for chemotherapy if a median survival of at least 4.5 months is expected.

So, a real informed consent is of paramount importance in order to obtain the patient's cooperation

for the therapeutic plan. The informed participation of the patient – in the sense of understanding the disease, its therapy and the interaction between the two – is necessary for the patient to be able to deal with a critical period of his/her life. This task is even more important in the case of enrolment in clinical trials.

The study by Zaric et al. in this issue [2] carried out a survey on the perception of lung cancer patients undergoing experimental treatments. The authors argue that "the patients participating in clinical trials contribute not only to their own and future patients' treatment benefits, but also to the benefits of medicine and the science itself" and they ask the question: "physicians are aware of this fact, but are the patients aware of the same fact, too?".

In this respect, 59 patients with advanced lung cancer, previously treated and enrolled in a clinical therapeutic trial, filled in a questionnaire with 20 items. The patients were asked about their knowledge of their own disease (type, stage) and the kind of therapy (previously and currently received), about the information received on the trial results, and about the utility of the experimental trial itself and the quality of treatment.

All the patients were familiar with the nature of their disease, and the majority of them knew their lung cancer stage. A significant number of patients knew what kind of chemotherapy they received.

Almost all patients knew that they were participating in a clinical trial and they believed that the chemotherapy given in the clinical trial would give them a better chance for survival.

The fact that 8.5% of the patients (more often the less educated ones) did not read the entire informed consent form (ICF) is an alarming finding, because

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the ICFs provide more detailed information about the trial than an investigator can give during the interview with a patient. This suggests that doctors should pay more attention when they provide information to less educated patients. Giving clear information, maintaining the patient's hope for the future, permits to obtain the confidence and the collaboration of the patient.

Some practical suggestions for physicians that can be derived are:

- When informing the patient take into account their educational level and do not use only the informed consent, in particular in the presence of less educated patients.
- Do not hide from the patients their real condition.
- Do not inform only the relatives, but make sure also the patients are informed.

The results of the study by Zaric et al. strengthen the fact that an honest attitude ameliorates the relationship between patients and doctor, providing the patient with the knowledge to understand their disease, its actual state, the type and purpose of the treatment, and helping them to cope with a very difficult period of their life.

References

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