Ethics of biomedical research in geriatrics

Mohamed Ali MEDDEB, Sarra BEN ABERRAHIM, Yomn NACEUR, Olfa BEKIR, Ons HMANDI
Moncef HAMDOUN, Mohamed ALLOUCHE

Department of Forensic Medicine – Charles Nicolle University Hospital – Tunis – Tunisia

Introduction

Elderly people are often excluded from clinical research and are treated with drugs that have only been tested in young adults. This is partly related to the difficulty of conducting geriatric clinical studies as well as the practical problems encountered at all stages of a clinical trial. From an ethical point of view, the decision-making ability and the free and informed consent of an elderly person require special attention in this case.

→ We aim in this work to study the practical problems encountered in clinical trials in geriatrics and the main ethical dilemmas that arise from them.

Discussion

- In industrialized countries, people aged over 60 years old represents about 15% of the population and would consume about one third of the prescribed drugs. Aging alone can change the way the body responds to drugs and this phenomenon is more amplified in elderly and ill patients. Nevertheless, older people are generally excluded from clinical research and are treated with drugs whose safety and optimal dosage are based on studies in young adults [1].
- The inclusion of older people in clinical studies is essential but not easy to put into practice and it is understandable that many studies exclude this population in view of the difficulties encountered when applying the research protocol.

- In fact, the recruitment of the elderly in a clinical study comes up against the patient's direct entourage, where the desire for protection is often expressed by the family. The elderly person is perceived as a fragile person who should not be disturbed, likely to develop side effects, who will not understand the information given about the study and will not be able to give free and informed consent. Some other issues raised seem to be related to the timing of the collection of information. Indeed, the morning is a busy period for hospitalized patients (toilet, care, exams, visits) while their attention is difficult to capture around meals.
- All of the reasons cited above represent only a small part of the problems encountered in biomedical research in geriatrics, where there is still debate about respect for ethical principles. Indeed, the dilemma between scientific validity and respect for ethical principles, namely autonomy, equity, benevolence and non-maleficence, comes to bear on another problem that arises, and even more amplified in the person elderly, which is the determination of the subject's ability to make a decision and the collection of free and informed consent.

- Now if we take the first part of the decision-making problem: Before any clinical study, we must first determine the ability of the patient to understand the study. He must be able to understand the purpose of the study, its implications, risks and benefits and especially his rights to withdraw at any time from the study. The way to determine this capacity for understanding has been widely debated but remains difficult in geriatric practice.

- The use of a cognitive function test, such as the MMSE, is a simple method of estimating cognitive abilities, but several authors report that these tests underestimate the prevalence of impairment of the decision-making capacity of the elderly subject. The opinion of the attending doctor may also be sought although it seems that he overestimates the ability of his patients to discern [2].

- Free consent on the other hand, implies that the person has decided to participate in the proposed study voluntarily, without outside pressure.
- Informed consent means that the one person enrolled into the study, has been properly informed of the purpose of the work, of its implications, and has been given the opportunity to ask questions and receive the requested answers.
- However, according to some studies, it appears that many seniors agree to participate in a study to please the doctor and the caregiver, others agree to participate because they think they will be better cared for if they agree, while others are afraid of being treated less well if they refuse [3].

- Can we really speak in those cases and in light of these findings, a free consent of the elderly? As a matter of fact, the signature of the consent form is also a problem in geriatrics because older people show a certain reluctance towards written documents, and in particular the need to sign a document [4].
- To remedy this, the consent form presented to seniors must be short and imperatively written in large print. It must be formulated in simple language, without a turn of complex sentences [5].
- Prior oral information makes it possible to present the study differently and leaves room for clarifications and open questions. The elderly must still be given time, if they wish, to reflect, to talk to their entourage and / or to the nursing staff if they wish.
- This often involves providing for a second interview, or even a meeting with the close entourage of the patient.

Conclusion

All phases of a clinical study in geriatrics are likely to pose specific problems: from the drafting of the protocol to the data collection, each step is to be prepared and conducted with care. Depriving older people of access to the most recent treatments is a translation of the non-respect of a fundamental ethical principle that is equity. However, it is essential and imperative that the team conducting biomedical research in geriatrics be more cautious in order to protect the rights of the patient..

References

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