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Informed consent in percutaneous coronary intervention

El consentimiento informado en el intervencionismo coronario percutáneo

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To the Editor:

The scientific and technical advances that have occurred in interventional cardiology in the last decades have allowed improving the quality of life and increasing survival of patients with cardiovascular disease. This, in turn, has created new ethical problems, which lead to a different assessment of moral behaviors in view of new technical and clinical possibilities[1].

New technologies involve risks for the physician and the patient from the technical, legal and moral perspectives, so it is necessary to establish an ethics to control the indication of percutaneous coronary intervention (PCI), and that it might be able to discern profits and losses, thereby ensuring the correct indications[2-4].

By use of PCI, the anatomy of the coronary arteries is assessed, as well as the presence of obstructive lesions in patients with known or suspected ischemic heart disease. Such a procedure is performed in fasting, conscious patients, lying on the angiography table. Local anesthesia is applied to the puncture site (groin, forearm or wrist) so the exploration might not be painful. Subsequently, catheters are inserted through the arteries to the heart, and once there, iodinated contrast medium is injected into the coronary vessels selectively. After obtaining angiographic images,the performing or not of percutaneous transluminal angioplasty is assessed, a procedure that involves balloon dilation or stent placement, or both, on the affected arterial site. Once completed, the catheters are removed, and the puncture site is compressed[5].

Among the various phenomena that influence the emergence of new ethical issues in medicine and its impact on PCI is patient autonomy, which requires, on the part of the specialist, providing adequate information of the procedures to be performed and their technical alternatives so that, on the basis of this, the patient can decide and consent[6].

Informed consent is a **process**, not an isolated event, of meetings and dialogues between the medical team and the patient, from the moment they see each other for the first time, where the physician provides **information** to the patient, so that he or she can make a responsible **decision**. Therefore, the concept is not limited to simply accept or refuse a certain treatment or intervention, but it focuses on reaching an agreement[7].

In general, the informed consent is considered a process with the following purposes[8]:

1. To respect the patient's rights and dignity.
2. To ensure and guarantee adequate information allowing the patient to participate in the decision-making processes that concerns him/her.
3. To support the professionals' actions enabling them to share the decision-making process with the patient and their family.
4. To determine the field of action within which medical action can lawfully develop.

The undoubted benefits that a proper process of Informed Consent provides for the patient are:

1. Therapeutic, since the correctly transmitted infor-

mation is a dynamic process that allows patients a greater acceptance of the proposed measures.
2. Helps to promote personal autonomy in decision-making.
3. Serves as the basis for dialogue about the disease process, and provides a higher quality in the professional-patient relationship.

The important thing is to make the Informed Consent an instrument for performing a most essential principle: the person is in effective control of his/her destiny, as befitting their infinite dignity, and that the information provided might be genuinely humanist[9].

In PCI practice the aspects explained must be taken into account, because in most cases, the physician-patient relationship is not properly exploited in the Informed Consent document, which should include comprehensive information on the details concerning the procedure, possible results, treatment options and their benefits and drawbacks[9].

Although the attending cardiologist who will indicate the PCI uses the written document as established, it is advisable to explain everything about the test, in order to clarify certain aspects such as:

- Importance of the procedure to be performed.
- The purposes intended and expected benefits.
- Side effects and possible complications.
- General dynamics of the study, which includes the aspects directly related to the procedure.
- Preparation for the test.
- Care and condition of the patient after the test, as well as prognosis, depending on the results.

The Informed Consent process is also important because it can be used to educate the patient about changes in habits and lifestyles, and the control of risk factors. To achieve this, the patient's hierarchy of values of and their motivations must be considered. In this way, a much higher level of participation and active support of the patient as a subject of their own health is achieved and even their inclusion to cardiovascular rehabilitation programs. Achieving that they might want to do, what they need to do in terms of their health, guarantees the commitment of the health team to promote styles and healthy lifestyles in patients[10].

Knowledge of the use of Informed Consent in the Hemodynamics Service, from the perception of the patient, allows synchronizing medical actions with patient's expectations, and promotes good psychological and biological preparation that will ensure higher quality results of PCI. Also, it is very useful to achieve good outcome and avoid immediate and late complications related to the intervention; all of which leads to a better quality of life for patients[11,12].

Their participation in solving the health problem is an issue that is benefited from the application of Informed Consent, and the conception of informed persuasion appears as conviction of the need to comply with medical recommendations by offering information[12].

This topic leads to reflection on the legal and moral responsibilities of the specialist, so it is extremely important for the cardiologist to set to optimal doctor-patient relationship where he/she can inform all aspects of the disease and the procedure to be performed[13].

Informed consent deserves the ethical importance it befits, rather than just understand it as a legal regulation[14]. In our country there have been several researches and reflections on its application, and there is a consensus on the value of its implementation in the health centers. However, difficulties in its implementation are reported, where aspects to be refined are needed:

- While the proposed treatment or procedure is explained in detail to the family and the patient, alternative methods and risks are rarely referred, let alone the option of not taking any treatment at all[12].
- Family members perceive, in each doctor-family interaction, a special drama and a sense of time pressure dominating the scene, and sometimes, the presentation of fundamental data on the quality of life expected for the patient is left to the last minute[11].
- On the other hand, there are some serious limitations in the context of communication between professionals and families because of the use of technical language, which causes a misunderstanding or changes of opinions among family members [15].

It is important to point out that informed consent is a key aspect in medicine and demonstrates a greater perception that health problems are more human than technical, which justifies the introduction of specific ethical and legal criteria when evaluating the quality

and competence of health care. Providing information and obtaining consent of the person, are part of all interventions in the health context, and are another duty of all professionals, along with the proper provision of services.

In PCI practice, informed consent should remain subject to a process of refinement, where the written document should not have priority over the right information that should be offered to the patient.

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