Informed Consent in Japan

Since about thirty five years ago when the Declaration of Helsinki (1) was adopted by the 18th World Medical Assembly in Helsinki, Finland, in 1964 in order to protect patient’s rights and to establish the proper reciprocal reliability between patients and physicians, the concept of Informed Consent (2) has been innovated and maintained as a moral law in medicine. The most important or the essential factor of informed consent is the patient’s autonomy in deciding acceptance of a certain diagnostic procedure or treatment. However, in the oriental countries including Japan and other Asian countries, or in even some European countries, informed consent in the strict sense is not fully understood, nor practiced in the actual medical field in a written explanation and agreement. In Japan, in the final decade of the 20th century during which time significant numbers of medical unethical scandals became manifest and patients themselves became aware of a sense of victimizations and the need for protection of their rights, a written form of informed consent has been legally required in the field of clinical medicine as well as in biomedical research.

In this context in the Japanese medical field, it is interesting that Narumi and his colleagues (3) attempted to investigate the degree of the patient’s understanding of their disease, and diagnostic or treatment procedures and also the significance of informed consent for a medical procedure such as coronary arteriography which is necessary for the optimal treatment but might have some life threatening risks. Although the survey population in Narumi’s paper is limited to a certain area of a local city in Japan, the results are interesting and suggestive in that the higher educated had the better understanding about informed consent and the more autonomy in the decision of acceptance of important medical procedures. As a whole, only about 20% of all patients studied in the questionnaire made a decision by autonomy and more than half of coronary angiography candidates needed family assistance.

Judging from the results of his investigation, informed consent is not always effective in supporting the patient’s right to know about the details of his disease and the pertinent diagnostic or treatment procedures, and sometimes it even gives patients unnecessary anxiety (negative effect) by letting them know the possible risks of the procedures or the nature of their disease. Most Japanese patients are not yet familiar with a concept such as human rights or informed consent. Generally speaking, in modern Japanese society, informed consent has become rather effective as a written evidence in protecting the physician’s justice. In Japan, a country which is strongly influenced by the U.S. and Europe, the time is drawing near when any medical procedures must be conducted under a written contract between physicians and patients. Accordingly, patients as contractors on one side have to decide by their autonomy (or their own responsibility) whether they should accept a certain medical procedure or not. Nevertheless, Japanese average patients as described in Narumi’s paper, informed consent can not yet easily be digested and accepted at the present time.

Many more years will be needed in Japan before the time when informed consent becomes properly understood and effective in protecting the rights of both patients and physicians.

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References