

## **Letter to Editor. Polish text with information for the patient and the form of the informed consent for electroconvulsive treatment**

Contemporary medicine has departed from the model of old paternalist medicine, where the physician was the main and only person to decide about the patient's treatment, selecting the form and patterns of the applied therapy. Today the patient's active participation and decision-making is assumed at nearly all stages of illness.

The patient's appearance in a doctor's office is recognized as the patient's consent to the start of a diagnostic and/or therapeutic process unless the patient decides otherwise (e.g. asks for information pertaining a solution of a definite medical or para-medical problem). Invasiveness, possible occurrence of complications or side effects accompanying various diagnostic and therapeutic methods requires acquisition of a more definite rather than assumed consent expressed by the patient regarding the possible administration of a given method in his/her case. Furthermore, the patient may give his/her consent only if he/she receives comprehensive information concerning the offered form of diagnostics or therapy.

Acquisition of the patient's consent after giving him/her comprehensive information is called the Procedure of Informed Consent. This concept was first applied in 1957 in the USA in a court case of medical malpractice [1].

In pharmacotherapy the patient's consent to administration of a given drug is not usually obtained in writing. In this case assumed consent regarding the administered drug is recognized as sufficient. However, the element "consent" should not be neglected, and therefore the patient ought to be informed about the applied medicines. The patients may talk to the physician about their worries or doubts. He or she usually receives a detailed drug leaflet – informing the patient in detail about the therapeutic substance and various circumstances connected with its application. In some patients reading the leaflet may be inductive to developing excessive fear of taking the drug or to focusing on the possible side effects; other patients may find potential interactions or counter-indications which the physician might have overlooked. The existence of the former group of patients must not be used as an argument for selling medicines without drug leaflets or introduction of leaflets with highly limited information about the drug.

Usually the procedure of informed consent is applied in the situations connected with increased risk: in drug examinations, before invasive diagnostics, and before application of risky methods of therapy (e.g. surgical operations).

In psychiatry, the method that requires the procedure of obtaining the patient's informed consent after providing him/her with appropriate information is electroconvulsive therapy (ECT). In this case usually a general consent is obtained for the ECT procedures themselves, their application in general anesthesia and muscle relaxation with the use of definite anesthesiological procedures.

Among the first physicians appealing for application of informed consent in ECT in 1972 were the leaders of American electroconvulsive therapy, professors Fink and Abrams [2].

The necessity of obtaining a separate consent for electroconvulsive therapy was indicated by the American Psychiatric Association (APA) in their first recommendations of 1978 [3]. Later, in their second recommendations of 1990, APA emphasized the necessity of applying written form of informing the patient about various aspects of electroconvulsive therapy offered to him/her [4]. One of the first forms of written consent to ECT (one page) could be found in Fink's monograph of 1985 [5]. In the same year, the US National Institute of Mental Health published an extensive booklet consisting of several pages, comprehensively discussing the course of electroconvulsive therapy for the patient [6].

In Poland, the issue of informing the patient and obtaining his/her informed consent to ECT procedures was probably first discussed by Krzyżowski in 1991 [7].

Four years later we shared our own experience regarding various legal aspects emerging in the course of administration of ECT procedures [8]. Precisely ten years later, in another work [9] we indicated the absence of a Polish form of informing the patient about ECT and obtaining his/her informed consent. We emphasized that the conventional few sentences about ECT told the patient by his/her doctor cannot substitute complete written information. We also emphasized the necessity of developing a Polish form of informed consent in our monograph [10], at various scientific meetings like conferences and congresses [11], and in recent years also at the meetings of the Biological Psychiatry Section of the Polish Psychiatric Association.

Our long-lasting efforts have been successful. At the turn of 2015/2016, Prof. Piotr Gałecki – national consultant in the area of psychiatry – formed a team of experts who were supposed to develop a form of informed consent to electroconvulsive therapy. The working team included, among others, representatives of the Institute of Psychiatry and Neurology in Warsaw, Medical University of Lodz, and the President of the Biological Psychiatry Section of the Polish Psychiatric Association. Several remarks were also provided by the Patients' Rights Ombudsman, whose knowledge and involvement guaranteed that the results of the work would respect all the rights of patients with mental disorders qualified for electroconvulsive therapy.

Finally, the text of information for the patient and the form of informed consent were worked out (05.02.2016) and formally accepted by the Minister of Health, and, at the beginning of April 2016, sent to all psychiatric centers in our country (the text attached). For the time being the developed text will not be included in the inventory of medical documentation published in the Minister of Health regulation of November 9<sup>th</sup> 2015 regarding the kinds, range and templates of medical documentation and the

way of their processing [12]. Thus the Ministry has decided that the developed text can be modified and freely adjusted to the needs of particular users.

To sum up the detailed discussion of the developed text of information/consent it should be stated that it includes all regular components necessary for the patient to get acquainted with electroconvulsive therapy. The offer of a discussion with the attending physician of the problems that will emerge during or after reading the information is also important.

Some additional remarks will conclude the paper. Although history of ECT dates back to 19<sup>th</sup> century (or even further back), the first procedures that were commonly recognized as ECT were conducted by Cereletti and Bini in Italy in 1938, that is, in 20<sup>th</sup> century. It seems that some additional examinations mentioned in the text (eye fundus examination) or specialist consultations (neurological, ophthalmological) should be recognized as optional and not obligatory ones. In many cases they are not executed – either for financial reasons or due to lack of indications to perform them. Or, maybe, we should decide that in order to further improve the quality of health care the above mentioned examinations/consultations will be regularly executed.

According to APA recommendations [13] now we should not speak of contraindications to ECT procedures, but rather of circumstances increasing the risk of their application. This remark, however, is of lexical importance only. It is the attending physician who must assess the relation of potential benefits with the possible side effects, and make the final therapeutic decision.

It should be emphasized and appreciated that the project of developing the Polish text of information for the patient about the offered electroconvulsive therapy and the form of informed consent has been successfully completed.

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## **Information for the patient and form of informed consent to electroconvulsive therapy**

Copy for the patient/Copy for medical documentation (case history)

### **BASIC INFORMATION CONCERNING THE OFFERED THERAPY**

We suggest that you are administered electroconvulsive therapy that is recognized as an effective method of treatment of mental disorders.

#### **What is electroconvulsive therapy?**

Its history dates back to 19<sup>th</sup> century, when the first ECT procedure was executed. Since that time this therapy has been significantly modified by introduction of a short-time general anesthesia as well as muscle relaxation, which increase its safety, eliminating unpleasant sensations. Electroconvulsive therapy is recognized as a highly effective method of treatment of selected mental disorders.

#### **What does electroconvulsive therapy consist in and what is its course like?**

It consists in application of electric stimulation within the central nervous system evoking an epileptic seizure of short and controlled duration. The procedure is monitored with the use of equipment that allows for evaluation of its effectiveness. The time between application of anesthesia and the patient's waking up is about 15 minutes. Then life parameters – ECG, blood pressure, pulse rate, blood oxygenation – are monitored for about half an hour. After this time the patient is taken to the ward under care of medical personnel. The procedure is painless, due to muscle relaxation convulsions do not occur, the patient remains under constant care of an anesthesiologist, a psychiatrist and a nurse. We usually suggest execution of 8 to 15 procedures 2–3 times a week. For some patients we consider further procedures maintaining the achieved improvement. In the morning before application of ECT the patient must not eat anything.

#### **When is application of electroconvulsive therapy recommended?**

Electroconvulsive therapy is recommended in treatment of severe depression, some forms of psychotic disorders, other severe mental disorders and wherever the

accompanying somatic illnesses limit possible administration of medicines, or when pharmacotherapy proves not sufficiently effective. It is also administered to pregnant women, old persons and patients taking a large number of various drugs.

The decision about the start of ECT is made after obtaining the patient's informed consent and execution of appropriate medical examinations and consultations.

### **What is the effectiveness of electroconvulsive therapy?**

The effectiveness of the recommended electroconvulsive therapy depends mostly on the disorder the patient is suffering from, but usually it is assessed as high.

### **What examinations are performed before the patient is qualified for ECT?**

In each case the basic laboratory tests are performed, ECG and EEG are taken, eye fundus is examined and internist, neurological as well as ophthalmological consultations are performed. After examining the patient and getting acquainted with his/her medical records, an anesthesiologist makes the final decision about qualifying the patient for the therapy. This procedure allows for elimination of contraindications for administration of this therapy.

### **What are the contraindications for electroconvulsive therapy?**

Contraindications for administration of electroconvulsive therapy are few, but with some accompanying serious illnesses ECT should not be applied. These illnesses include: epilepsy and other severe brain disorders (e.g. brain inflammation, disorders with the increased intracranial pressure, the condition soon after cerebral stroke), severe heart diseases (up to six months after a cardiac infraction), significant hypertension, severe disorders of blood clotting or severe anemia, severe osteoporosis, aortic aneurysm, venous thrombosis or some ophthalmological disorders.

### **What side effects may occur during administration of ECT procedures?**

Like in any therapy, in electroconvulsive therapy there may also occur side effects. In about three out of four procedures no side effects are present. They may, however, occur in one in four procedures. The most frequently reported side effects include mild, temporary short-term memory disturbances, headaches and muscle pains. They are transitory symptoms that do not always occur. They do not require any special treatment since they usually disappear within 24 hours.

Few patients develop serious complications, which are possible to control. The risk of life-threatening complications is one in fifty thousand. It means that electroconvulsive therapy is among very safe therapeutic methods. Memory deterioration that is observed in some patients during and directly after the therapy usually disappears after a month and in rare cases after a few months. The fear that electroconvulsive therapy might cause permanent personality changes is unjustified.

During administration of an electroconvulsive procedure there may occur changes in blood pressure, irregularities in heartbeat and disturbed breathing. Their occurrence

rate is assessed as low; they usually manifest themselves in patients who already suffered from disorders or diseases of cardiovascular system or respiratory system. These symptoms often resolves spontaneously but they may also be controlled with standard therapeutic methods.