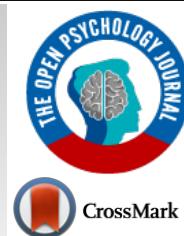




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REVIEW ARTICLE

Psychological and Medico-Legal Perspectives on Electroconvulsive Therapy and Patient-Centered Care: A Short Review of Cross-Cutting Issues

Valeria Tullio^{1,2}, Stefania Zerbo², Antonietta Lanzarone², Salvatore Procaccianti² and Antonina Argo^{2,*}

¹Department of Psychology, Educational Science and Human Movement, University of Palermo, Palermo, Italy.

²Department of Health Promotion, Mother and Child Care, Internal Medicine, and Medical Specialties (PROMISE) – Medico Legal Section, University of Palermo, Palermo, Italy.

Abstract: Electroconvulsive therapy is a treatment that, since its first administration, has been a major topic for debate within the scientific world. In recent years, the debate has become increasingly focused on the short- and/or long-term efficacy of electroconvulsive therapy, its appropriateness in clinical settings, its mechanism of action, the impact evaluation of transient and/or persistent adverse effects, and the drafting of international guidelines, etc.

From the authors' point of view, these themes are inevitably crossed by three other fundamental issues of significant psychological, relational, ethical, and medico-legal impact. Still, they are less studied than purely biomedical issues in recent times. Therefore, the aim of this article is to focus on the following cross-cutting issues: the therapist-patient relationship, the patient's perspective, the attitude on electroconvulsive therapy, and informed consent.

This short review refers to the international literature on ECT published since 2000. Analyses of the three previously listed topics are, in part, made within the context of Italian medical settings.

Keywords: Electroconvulsive therapy, Psychological perspective, Medico-legal perspective, Patient's perspective, Therapist-patient relationship, Patient-centered care model.

Article History

Received: March 20, 2020

Revised: May 28, 2020

Accepted: June 10, 2020

1. INTRODUCTION

In 1938, Ugo Cerletti and Luigi Bini first treated patients affected by schizophrenia with the application of electricity. Some years later, Clemente Catalano-Nobili and Giannetto Cerquetelli considered the possibility that Electroconvulsive Therapy (ECT) could be a therapeutic option for some mental disorders. An ECT session consists of applying an electrical current to the scalp (by the bitemporal or unilateral placement of electrodes) in order to provoke a generalized epileptic seizure that induces relief of symptoms caused by severe depression and other mental diseases. It is worth noting that the true mechanism of action remains elusive [1, 2]; however, it is assumed that ECT influences the biochemical abnormalities related to various mental disorders, such as blood levels of carbamylated erythropoietin and homovanillic acid and Brain-Derived Neurotrophic Factor (BDNF) in refractory depressed patients [3, 4]. Additionally, it appears that this action is carried out with modulation of neurotransmitters [5], specifically monoamine metabolites [6] and brain plasticity [7].

From the beginning, ECT has gained significant attention within the scientific community, divided into supporters and opposers. The radically contrasting positions of researchers and the general population's myths and misunderstandings regarding ECT have hindered a reflection on the use of this treatment and the *humanization of the care* process. The concept of humanization refers to *taking care of the person*; that is, considering the patient not only as someone receiving medical care, but also as a unique individual with feelings, knowledge, and personal beliefs, all of which require attention and thoughtful consideration when evaluating their health. Humanization of care, therefore, means bringing the patient's physical, psychological, and social entirety back to the center of medical action [8]. In this perspective, the therapeutic alliance, the patient's perspective on treatment, and the informed consent are highly relevant.

2. USE AND PRACTICE: AN OVERVIEW

The rates of use, practice, and ECT parameters vary markedly throughout continents and countries. Therefore, the lack of homogeneity makes it difficult to obtain and analyze data at a global level. Although many different guidelines

* Address correspondence to Department of Health Promotion, Mother and Child Care, Internal Medicine, and Medical Specialties (PROMISE) – Medico Legal Section, University of Palermo, Palermo, Italy, E-mail: antonella.argo@unipa.it

describe the theory and practice of ECT, there are no uniform practices worldwide [9 - 12]. Many articles have explored contemporary utilization and practice of ECT throughout the world. There is a large variation in ECT utilization and practice worldwide [12 - 39]; this raises some clinical and ethical issues which will be mentioned in the following paragraphs. Modified ECT [M-ECT] is administered in most countries. Unmodified ECT [UM-ECT] (in some cases with anesthesia, but without the use of muscle relaxants) is still in use in Asia, Africa, Latin America, and even in Europe (e.g., Ukraine, Russia, Turkey) [12, 14, 24]; bilateral electrode placement is more common than unilateral electrode placement [12, 15 - 17]. Different countries identify different diagnostic indications for ECT (psychiatric disorder during pregnancy, schizophrenia spectrum disorders, mood disorders, catatonia, suicidal risk, but also personality disorders, PTSD, cognitive and neurological diseases, autism, anorexia, etc.) [12, 13, 19]. In Western countries (Europe, USA, Australia, and New Zealand), ECT is mainly administered to elderly and female patients (in some places, the female proportion is much higher), while in those areas of the world where UM-ECT is administered, it is predominantly prescribed to younger and male patients. In some countries, ECT is administered to children and adolescents [15, 20, 32, 33]. ECT is administered worldwide, even when informed consent is not obtained from the patient [12, 26, 38]. There is also a great variability between different countries regarding the procedures relating to the acquisition of informed consent [12, 13, 15, 23]. In most countries, written consent is required, while in some countries, the patient's consent is merely verbal [15]. Patient consent is often required for each ECT session (e.g., Italy, Ireland, Latvia), and sometimes accompanied by another specific "form" for anesthesia procedure; other times the patient signs a single "consent form" which also includes the acceptance of anesthesia and any maintenance therapy [12, 15, 30, 31, 39]. In many countries, ECT is frequently used as the first-line acute treatment (e.g., Saudi Arabia) [12, 24] and not only as a last resort for medication-resistant conditions (e.g., Italy) [10, 30, 31]. In some countries, psychiatrists who have no formal training in ECT [34] or medical professionals other than psychiatrists (geriatricians and nurses) administer ECT [12, 13, 15]. Several countries lack national guidelines (e.g., New Zealand) [38], and sometimes national guidelines are not updated to reflect recent scientific literature [39]. In some cases, there is no continuous training of operators. In some countries (e.g., Italy) [31], ECT can be administered only in certified psychiatric facilities (e.g., with anesthesia division) but, around the world, the ECT infrastructures are not always standardized and in some cases, ECT is conducted in spaces, such as recovery rooms, and even patients' hospital rooms [20]. Although not all studies agree on this, the overall usage trend of ECT seems to be decreasing; yet, in the countries where it is administered, ECT use in ambulatory settings is increasing [12, 13, 22].

3. PSYCHOLOGICAL, MEDICO-LEGAL, AND ETHICAL ISSUES

Quality healthcare practice is reliant on the adherence of the following factors: the therapist's professional, ethical, and

legal competences to provide adequate care to the patient; the patient's right to be adequately informed about the treatment and his right to receive or refuse the treatment; legislative/governmental directives; and the ethical codes and practice guidelines of professional organizations [40]. These factors are closely interconnected, and in the context of mental health, the therapeutic alliance, the respect of the patient's comprehension of, and willingness to accept the treatment plan assume relevant importance.

This becomes even more true when a treatment, such as ECT, is perceived to be highly distressing by patients.

3.1. The 'Meaning' of Disease and the Therapeutic Relationship

A key factor in the treatment pathway is the possibility for patients to make sense of their suffering. In this regard, the therapist-patient relationship, the therapist's ability/disposition to listen, and his theoretical reference model take on a central role.

As underlined by the American Psychiatric Association [41]: "The physician-patient relationship is the cornerstone of psychiatric practice, and its goal is to promote patient health and well-being, embodying the key ethical considerations of respect for persons, fairness, and beneficence. Patients often lack medical expertise and sometimes struggle with symptoms that adversely affect their autonomous decision-making. The psychiatrist is responsible for rendering medical care in the patient's best interest while respecting the patient's goals and autonomy. The physician-patient relationship is a collaborative endeavor between two autonomous individuals who establish a professional relationship for the benefit of the patient (p. 2)." In the first half of the 1900s, both Jung [42] and Balint [43] affirmed that the therapists themselves are a healing factor (the *drug-doctor*) and that, as such, they can also cause *side effects*. According to the author, the emotional components and the attitude towards the disease or its meaning are both factors that guide the relationship between the clinician and the patient and that affect the outcome of the therapy. Therefore, they must be carefully considered [44, 45].

The treatment plan and clinical interview procedures are determined by the therapist's theoretical reference model. The *disease-centered model* considers disease in purely biological terms; during the interview, the therapist considers, with particular attention, the elements that reconnect to the hypothesis of a biological problem/damage, while less importance is given to the patient's point of view regarding their own disease.

The organic view of mental disorders emphasizes pharmacological treatment to target presumed biological abnormalities [46] and prefer an approach that is nosographically [47] oriented to diagnosis.

The risk is "jailing" the patient within the diagnostic response, making him impotent with respect to the disease (he can only wait for the psychiatrist to find the most suitable therapy and for this to take effect), or neglecting important factors for the treatment process, such as the patient's interpersonal relationship and cultural context. The *patient-*

centered model seeks to combine the purpose of the disease treatment with the attention to the experiential side of the disease (the patient's sense of disease, his/her expectations, desires, needs) [48, 49]. In this perspective, the therapist tries to establish a therapeutic alliance [50] that allows the patient's requests to be harmonized in compliance with clinical protocols [51].

Concerning the ECT, the scientific perspective focused on the cognitive components of mental pathology and on the biological basis of behavior that considers the patient's suffering in an exclusively negative way, views ECT as a rapid method to pull out the patient from the criticality dimension, and to reestablish the possibility of explicit communication between patient and therapist. In this perspective, the explanatory hypotheses of mental disease consider the fundamental role played by errors and distortions in the processing of information, and by the rigidity of nonrealistic cognitive schemas formed during childhood which, associated with genetic, neurobiological, and environmental factors, interact in the development and maintenance of symptoms [52]. Therefore, according to this approach, the remission of the most severe symptoms obtained through ECT can allow therapists to help patients learn the necessary skills they can take advantage of in everyday life once treatment concludes [53].

Alternately, psychiatrists and psychologists who adopt psychodynamic and phenomenological approaches, which are more concentrated on the inter-, intra- and trans-psychic dimensions of mental disorders and its' significance in patient's life, emphasize the risk that this treatment moves the patient away from the awareness of being a subject and not the object of therapy [54 - 57]. They believe that the use of ECT can make it difficult for patients to look inside themselves, to confront themselves, recognize their internal resources, and adequately accomplish the therapeutic pathway necessary to integrate the experiences related to the disease in their *life history*. Around the world, many psychiatrists in the past and still are nowadays opposed to the use of ECT. Notably, in the 1960s, the greatest critics against ECT were the Antipsychiatry Movement exponents (Laing, Szasz, Cooper, Foucault and Basaglia). Despite some extremism [58], the antipsychiatry movement has generated demand for guidelines, which outline the provision of psychiatric services (including ECT guidelines) and to renew the traditional psychiatric approach, which is to promote the rights of the mentally ill, the recognition of the patient as "individual," and put the doctor-patient relationship at the center of the treatment process.

A good therapist-patient relationship takes the time to develop and strengthen the patient's internal resources that the patient can draw upon to face their disease and adhere to their treatments [51].

As also evidenced by the Italian National Bioethics Committee [35], there is a risk that some psychiatrists prefer to resort to ECT, instead of other methods, since they are unable to accept the suffering of the patient themselves. In this regard, the American Psychiatric Association [41], in the Commentary on Ethics in Practice (2015), underlines that for ethical practice of psychiatry, the therapists' ability to reflect on their role, on

the reasons that push them to make a certain therapeutic decision, and about their potentials *blind spots*, is relevant.

In the perspective of analytical psychology, these blind spots can be traced back to the themes of the *shadow*, as theorized by Jung [59], and to the *wound of the therapist*, mentioned by Guggenbühl-Craig [60]. According to these authors, the impossibility for therapists to recognize their own difficulty in accepting their suffering and that of patients (the blind spots), could activate highly collusive dynamics, based on unconscious projection and identification mechanisms [43]. Indeed, colluding the patient's fear with their own illness and difficulty in dealing with a long and painful process essential to understanding the meaning and nature of that suffering might cause psychiatrists to resort to ECT, which would seemingly provide a quick solution to the psychic pain of the patient.

Therefore, instead of collaborating with the patient, helping them in the long and painful process of dealing with their suffering, of accompanying them for all the necessary time (the *kairos* time, the *needed time*, a time that cannot be predetermined but only lived), these care professionals, frightened by their own suffering (and by that of the patient) prefer to focus on the crisis event and not on the process, adopting a technical solution (ECT), apparently controllable and defined over time (the *chronos* time, the predictable and quantifiable time).

The literature demonstrates a correlation between the therapeutic relationship and improved outcomes, and its potential is an acknowledged prognostic indicator [41, 44]. The characteristics of the psychiatric patient, the peculiar forms of the time and the listening, and the goals and purposes of the therapeutic process itself make the therapist-patient relationship, in mental health, *unique*. This particular relationship is a clinical tool that gives the clinician a potential instrument to create a bonding with patients with severe mental illnesses and help them to manage it while optimizing their strengths [61 - 63].

Undoubtedly, this requires a paradigm shift. The *kairos* time does not only concern the patient but also a therapist and, as mentioned, includes but does not coincide with the time dedicated to the single session; it concerns the wider mental space/time the therapist dedicates to the relationship with the patient. The anamnestic collection phase is, for example, an essential moment for building a good relationship. As some authors suggest, adequate training of psychiatrists, nurses, and others health professionals on the most suitable way to communicate with different patients (e.g., "open" or "closed" questions, complete or incomplete sentences) and with their family members, the focalization on the patient's concerns, positive regard, and personal respect, appropriate involvement of patients in decision making, genuineness with a personal touch, are factors that can favor a good therapeutic alliance and enhance adherence to the treatment [64 - 67].

Trust, empathy, communication, listening, and sharing of information have been identified in the literature as factors that exist in a positive therapist-patient relationship.

Particularly, empathy is considered an essential factor that can help the clinician (and the patient) in making a correct

diagnosis in a context, such as that of mental health, where it is not easy to obtain information from the patient regarding their state of health [68]. All of this is probably overlooked in all cases in which the ECT is used as first-line treatment and not as a last resort for medication-resistant conditions.

Another relevant issue is the evaluation by therapists of ethical aspects of treatment and implementation of appropriate safeguards to patients in ethically complex situations [41]. It is essential, in fact, to guarantee to the patient the right to be recognized in their specificity and identity, to receive treatments consistent with their particular health condition, to receive care without altering, more than necessary, awareness of themselves, their life habits and expectations for the future [69]. It is important to mention here that the post-ECT session memory loss is a question that concerns, crosswise, the issues of the therapist-patient relationship, the patient's rights, and the informed consent value.

According to Seniuk [70], in the current model of informed consent for ECT, the loss of memory (side effects) is presented as predictable and reasonable results that could be expected from a direct brain intervention. The opinion of this author is that the model of informed consent for ECT reflects a *brain-related* view of therapy (and its side effects) by health professionals. However, from the perspective of the patient's experience, the post-procedure experience of retrograde amnesia is not simply a limitation of the function that is isolated in a dimension of a person's life. Rather, it is an experience that inevitably influences the patient's sense of self. In fact, the use of ECT induces a loss of memory (anterograde and retrograde amnesia) [71] that involves removing part of the patient for the therapy itself. Moreover, therapists who adopt psychodynamic and phenomenological approaches point out how the loss of memory suffered by these patients does not facilitate patient-clinician compliance because it hinders the patient recognition of the disease.

Memory impairment varies based on factors such as electrode placement, stimulus waveform, site of seizure initiation, anesthesia, and pattern of activation [72, 73]. Anterograde amnesia (the decreased ability to retain newly acquired information) often resolves within a few weeks after ECT sessions. Retrograde amnesia recovers more slowly than anterograde amnesia and seems to remain permanent about 28% to 55% [74, 75]. Retrograde amnesia is the most anxiety-inducing cognitive effect of ECT [73] because it impairs the recollection of the past (some patients report retrograde amnesia) that extends back for years [73]. Therefore, the loss of the basis of individual identity and biographic continuity (*i.e.* the loss of memory) can lead to severe consequences on mental health, daily functioning, and quality of life [76]. Bilateral ECT, the most common electrode placement, causes more retrograde amnesia than right unilateral [77].

On the human necessity of narrating one's own life story as an expression of the feeling of continuity in time and space, and therefore, of the link between memory and identity, Sacks [78] writes: "we have, each of us, a life-story, an inner narrative, whose continuity, whose sense, is our identities. Biologically, physiologically, we are not so different from each other; historically, as narratives, we are each of us unique. To

be ourselves we must have ourselves-possess, if need repossess, our life-stories. We must 'recollect' ourselves, recollect the inner drama, the narrative, of ourselves. Man needs such a narrative, a continuous inner narrative, to maintain their identity, his self" (p. 89).

In this regard, some authors [79, 80] expressed their concern about the risk of a distorted use of ECT that would remind the so-called *annihilation method* devised by Bini in 1947 [81]. Bini identified, in the memory loss (therefore in cancellation of a component of a patient's personality), the main therapeutic mechanism of ECT, starting from the assumption that for these patients *to forget is to heal* [82].

3.2. Experiences of Patients

In the *patient-centered care* orientation, the patient's perspective and attitude on therapy are not only considered essential elements for effective treatment, but also they are essential for scientific, clinical, and ethical reflection on the means used to achieve the expected outcomes [83].

Therefore, it is essential to consider the patient's point of view on the treatment, on the therapeutic plan, on the relationship with the therapist, on the thoroughness of information received regarding the treatment and the incidence of side effects on their lives, on the support received from the health care personnel, and on the respect for their choice to undergo treatment or not, before implementing ECT, both in research and practice.

Most research conducted on ECT is quantitative, mainly focused on verifying the efficacy of the treatment through the use of biomedical parameters, on issues related to the improvement of the technique (*e.g.* placement of electrodes, anesthesia *etc.*) and clinical applicability (*e.g.* clinical conditions, procedures, standards for the application *etc.*). There is a less qualitative research that has considered the patients' subjective perceptions of ECT, despite the fact that a qualitative approach in which patients are able to freely narrate their experiences and emotions might bring several benefits to research [84]. Based on the existing literature, researcher and patient opinions on ECT fall into one of the two categories: those who support ECT, typically those who have received or administered treatment positively and perceived that they benefited from it [85 - 87], and those who opposed, typically those who had negative experiences receiving or administering treatment, or felt that there was an insufficient benefit and/or have suffered severe adverse effects [88]. Few people are ambivalent about ECT [89].

In regard to patient perception of the benefits of ECT, some authors have highlighted that research sponsored by patient advocacy groups have reported lower rates of perceived benefit, compared to studies conducted by clinical teams. According to these authors, this discrepancy in reporting is attributable to the fact that the methodology used in the studies, conducted by clinical teams to obtain the opinions of the patients (*i.e.* number of items, the complexity of the interview, interview setting and interviewer status), excessively influences the reporting of the perceived benefit and willingness to repeat the treatment (maintenance treatment) [88, 90 - 93]. Certainly, independent interviewers who do not have any

influence regarding the patient's condition or treatment may obtain more valid data than a current or past treating therapist [84]. Moreover, further research shows that high perceived benefit rates are more frequent in studies conducted immediately after treatment, while low perceived benefit rates are more frequent in research conducted many months after the treatment [88, 94]. The more negative perception of ECT experience long after the treatment as compared with the perception observed just after the treatment may be related to high rates of relapse of mental disease months to years following ECT and to long-term side effects of ECT (*e.g.*, the memory loss) perceived as highly disturbing by patients. Furthermore, a long time after the end of the therapy, both the inevitable "dependency condition" of the patient towards the therapists and the pressure of the therapists' expectations decrease.

Studies examining perceived benefits of ECT and memory loss, following ECT among patients show contradictory results in that they are strongly biased by methods, expectations, and perspectives of researchers (*e.g.*, qualitative or quantitative research design, use of structured questionnaire or interview, approach centered to the disease or patient) [74, 95].

Regardless of the debate about the methodology with which the studies were carried out, both positive and negative patient experiences with ECT must be considered in a way that is more complex than simply an evaluation of treatment efficacy. Many patients reported feeling pleasant emotions soon after treatment related to a positive global impact on the sense of self. Also, sharing with others, caring and compassionate interactions with staff, family support, and rapid mental health improvements are described by patients as positive aspects of their ECT experience. Conversely, side effects that include fear, stigma, feelings of shame and humiliation, worthlessness and helplessness, sense of having been abused and assaulted, and other aspects of the procedure itself are described by patients as negative aspects of their experience. Sadly, just a few of these patients feel capable of telling their health professionals about the strength of these negative feelings [96, 97]. In addition, some studies have shown that often, in marked contrast to the patients, the relatives and the clinicians were more satisfied with ECT. It seems clear that what clinicians and patients' relatives assume to be *satisfying* does not match with patients' perceptions [74, 86, 93].

In this regard, as suggested by Koopowitz *et al.* [84], to be able to assume that patients are satisfied with ECT, or are not subjectively troubled by persistent memory loss, it would be of great importance to explore in-depth what the subjective experience of memory loss and cognitive decline means to the patient's sense of self.

There are a number of articles that underline, in particular, the fear of ECT as an important theme. Most patients experienced strong fear before and/or at the time of the ECT session. Fear of the procedure itself, fear of dying, fear of a personality change, fear of brain damage are the themes reported by patients frequently. Often this fear decreases significantly or completely ceases after the first treatment [84, 97]. However, according to Obbels *et al.* and Fox [98, 99], a

significant proportion of patients experience *ECT-related anxiety* to such an extent that they will refuse or discontinue the treatment (also despite prior successful courses of ECT). The patients' explanations for their fear are so grossly disproportionate to the intensity of the fear, that they suggest unconscious aversive conditioning to ECT, a kind of post-traumatic stress reaction [100, 101]. Because, as said previously, for the patients who do not feel capable of communicating their fears regarding ECT, a good therapist-patient relationship may be of great reassurance. Although recent research [102] (with the limit of administering a questionnaire in which is possible to answer only "true" or "false") reported a high degree of patients satisfaction and no significant differences between M-ECT and UM-ECT, while another previous study [17] highlighted that UM-ECT is associated with an increased risk of pre-treatment anxiety.

Scholars have also investigated the patients' perception of informed consent and respect for the freedom to undergo or not to undergo therapy [101, 103 - 107]. Researchers suggest that patients are frequently unsatisfied about these issues [104, 105, 108, 109]. Several articles emphasize the patient perception of insufficient or inadequate information on the risks and adverse effects of therapy [104, 105, 108]. Particularly, patients undergoing UM-ECT complain of deficiencies in the information provided about and consent toward the procedure [14].

The question of informed consent is also related to memory and cognitive decline after an ECT session. Sometimes, patients do not recall having had the procedure explained to them, and in some instances, do not recall giving informed consent [75].

Furthermore, studies have indicated that some patients decide to undergo treatment based on mistaken beliefs that their illness has lasted too long, that they have not any other choice or that ECT can erase their distressing memories. Sometimes patients consider ECT as a desperate last resort [84, 86, 104, 110, 111].

On the issue of the freedom to choose whether or not to undergo ECT, in many cases (about one-third undergoing ECT), patients reported feeling coerced by therapists to have the treatment [86, 96, 104, 111]. In this regard, Burstow [80], Clarke, Barns and Ross [112] put in evidence that women have a greater perception of coercion in ECT treatment than men; particularly ECT is experienced by these women like abuse or punishment which they cannot oppose [84, 92, 96, 104, 112]. The attitude toward these patients regarding ECT is based on resignation and acquiescence towards therapists [105, 112, 113]. The ethical question is whether, in all these cases, the patient's choice can still be considered as freely and competently made, or coerced.

Regarding the attitudes toward ECT among participants who received treatments involuntarily or do not remember having given consent and those who received the treatments voluntarily, research reports conflicting results. Some studies affirm that there are no difference between the two groups in their perception (positive) of benefits of the ECT [114]; others report low compliance to cure process (*e.g.*, maintenance

treatment), ambivalent feelings and perception of ECT as an illegal treatment in patients who received treatments involuntarily [89, 103, 104].

The principles of Autonomy, Beneficence, Non-Maleficence, and Justice (fairness in the application of medical treatment), which are the founding principles of medical ethics, aim to preserve the ethical values in the performance of the profession. They underline the importance of respect for a patient's dignity, needs, and personality [40].

The principles of Beneficence and Non-Maleficence refer to some ethical and clinical objections related to the use of the UM-ECT, the administration of ECT on children and adolescents, and the administration of ECT by non-specialists or therapists without continuous training. Regarding UM-ECT (mainly used in developing areas for its low cost, and the need for simple and cheap equipment) [14, 22, 115], concerns are related to the greater number and severity of physical and psychological "damages" suffered by these patients (e.g., spinal fracture, musculoskeletal complications, risk of loosened or broken teeth) [17], compared those that were treated with M-ECT. In terms of the use of ECT on children and adolescents, concerns are related to the fact that the brain's structure and the personality of these subjects are still developing. Therefore, it is difficult to predict the long-term consequences of this experience on the physical and mental health of young patients [32, 33]. Regarding the administration of ECT by non-specialists and/or those who lack continuous training of the health professionals, ethical and clinical objections refer, obviously, to the risks for patient's health. In fact, unskilled operators may not be able to adequately manage the emergencies; the procedures may not be applied correctly; finally, the lack of continuous training can lead to the application of obsolete procedures by operators and, consequently, can expose the patient to avoidable risks and suffering.

Clinicians must always make sure not to damage the patient, to always act in the best interest of the patient, and, last but not least, to respect the patient's autonomy.

Professionals who work in the field of mental health know how difficult it is to manage the *dependency* condition that psychiatric patients often have towards their therapist. One of the aims of *patient-centered* therapeutic pathways is to transform the relationship of dependence into a relationship of trust, which is essential for establishing a good therapeutic alliance [116]. The patient's ability to trust is the result of a long process that must be grounded on the certainty that the therapist will treat them with respect, which will not damage them. This also applies to patients who are severely ill. The clinician must establish an adequate relationship with the patient in order to make them the *subject* of their treatment rather than an *object* by promoting the patient's ability to take responsibility for their mental healthcare. This does not imply that the therapist must renounce the decision-making role since the therapist has the responsibility to protect the patient's health and well-being. It is a matter of abandoning a "paternalistic approach" to psychiatry [40], recognizing and enhancing the patient's "competences" regarding his illness and his way of managing it.

3.3. The Informed Consent

In compliance with the ethical principle of patient Autonomy, as for any therapeutic plan, the legal framework provides for ECT the mandatory informed consent of the patient or his legal representative [117]. The patient's signature of ECT form could be a sign of acceptance without true awareness of risks/benefits balance, and special caution must be taken when obtaining informed consent, which is not a mere list of potential damages and advantages [118]. It is important that the informed consent is considered a "process of sharing" between the therapist-patient and/or his family members.

The knowledge and the conscious acceptance by the patient is, therefore, the foundation of the legitimacy of the treatment and it is provided, in Italy, by the Law 219/2017 (Informed Consent and Advanced Directives) [119] and doctrine.

The Italian National Bioethics Committee [120] has taken a stance on the topic of mental health; ECT has not been condemned, but it has been recommended that it should be used sparingly. The Committee, despite being aware of the great difficulties in acquiring informed consent from the psychiatric patient and those who legally represent him, still recall the inalienable ethical rights of the patient to provide such consent. The opportunity to inform the psychiatric patient is a sign of recognition of the dignity of a person. The Latin root of the consensus shows a semantics, which indicates the convergence of feelings, ideas and thoughts in the direction of a common solution to the problem peacefully together and personally [121]. This appears to be of particular relevance, especially in the case of treatments that, like ECT, may have severe adverse effects such as memory loss, altered executive functions, cognitive disorders, and in rare cases, death [122 - 128]. In the case of post-treatment memory loss, for example, a video on the process of explication risks/benefits and of patient signature of informed consent may reassure him that the treatment was not carried out against his will.

As emphasized by Roberts [129], the value of autonomy is that healthcare providers should be bound to the individual's values and desires regarding healthcare interventions, allowing individuals to live their own lives in accordance with their own values. To respect the fundamental principle of decision-making, autonomy and professional integrity should prevent the risk of coercion, deception or manipulation [130].

The approach based on the principle of autonomy decision-making falters, however, when this principle was presented to psychiatric patients who traditionally are considered partially or totally not autonomous, due to their disease, they did not have the real ability to express a consensus.

The spread of the "patient-centered model" has allowed the development of some intervention practices aimed at patients with severe mental disorders. Some patients subjected to ECT suffer from severe mental disease, they are apparently unable to cooperate in an ordinary course of therapy, and are considered as "beyond psychotherapeutic reach," or "out of contact." Psychiatric diagnoses for these patients are often psychosis, schizophrenia, severe dementia, or mental retardation [131]. The patients with these diagnoses are considered

unable to express their acceptance or refusal to therapy, and therefore, the treatment is administered without their consent, though some interventions may help. The “Pre-Therapy” [132], for example, defines “pre-expressive functioning” the bizarre and incomprehensible symptomatic behaviors. In this perspective, these behaviors demonstrate the possibility of development and expression, resulting in growth from “pre-expressive” to “expressive” behavior, by specific techniques. The goal of pre-therapy is to improve the capacity of “out of contact patients” for being in contact with others, and potentially to contribute to their becoming so well-functioning that they can participate in an ordinary course of therapy or express their consent to a therapeutic plan [131].

From the medico-legal perspective, the right of a patient to express choice does not exist without the recognized ability to understand information about the treatment and its possible outcomes. This could create a conflict with the ability to exercise other rights, namely the right to be involved in care with respect to the possible advantages and disadvantages of the proposed treatment program. More frequently, this conflict can not be resolved with a deeper discussion on the concept of decision-making autonomy, but rather by considering the patient a person unable of self-determination (*i.e.* incompetent patient). Some authors have emphasized the usefulness of introducing the concepts of *partial ability* and *intermittent ability* with which it implements an attempt to avoid expressing the artificial dichotomy between *able* and *incompetent*. The assumption of the inability of discernment, in whole or in part, should not be an appropriate justification for the psychiatrist; the healthcare professional should always examine each case with caution to determine how and when to provide information suitable for the individual patient in reference to its situation and its social context [133 - 136].

In fact, informed consent is an ethical principle in a complete sense of the term, since it is closely related to the bioethical principle of autonomy. It cannot and should not be only an instrument of defensive medicine, only intended to protect the healthcare professionals. Consequently, it should dismiss the use of term, purely legal and formal, and confer to it moral merit. The main feature of autonomy, also in the physician-patient relationship, is morals, not only legal.

The exception of patient consent, in the application of above mentioned principle, is indicated, for example, in the case of pernicious catatonia, in which the duty of therapy is governed by the so called *state of necessity*: within this assertion that in the case of risk of death or serious injury to any third party concerned, the specialist is required to implement all the measures available to save lives or prevent damage and, just in provided cases, by specific, special rules (in Italy the Law number 180/1978 [137] on psychiatric health care system), to allow people physical coercion.

4. DISCUSSION

In almost 75 years of history, ECT has continued to be developed through technical innovation and quality assurance measures. Nowadays, psychiatry is increasingly committed to protecting the patients, their well-being, and their decision-making autonomy regarding the treatment process.

To *cure* (linked to a conception of clinical intervention in which the biological side prevails) is needed to *care* (linked to a holistic conception of the person, made up of organic, psychological and relational needs and emotional). For many years, the *paternalistic* approach to mental healthcare has been the main orientation of professionals. According to this perspective, it was the task of mental health professionals to make all of the therapeutic decisions with little or no input from the patient. In recent years, this orientation has been replaced by the *patient-centered* care approach that aims to personalize care according to professional’s judgments and individual patients’ needs, values, and experiences. In this perspective, the importance of the clinician’s ability to establish a relationship with the patient based on participation and trust, and the informed consent assumes new relevance. The patient’s decision (or that of their legal guardian) to undergo or continue ECT may be influenced by the way the therapist communicates information and by the therapist’s approach to the patient’s disease or care.

A good therapist-patient relationship is, above all, built on emotional aspects, not only on information communication. Therefore, listening, understanding, and explaining are the essential abilities of a clinician, which can favor a partnership aimed at improving patient health. In this regard, informed consent is a tool which, on one hand, allows the patient (and his/her family) to analyze the risk/benefit ratio in-depth, promoting adequate medical decisions that maintain both respects for the patients’ autonomy and the principle of beneficence [97], and on the other hand, strengthens the therapist-patient relationship. Besides, trust between clinician and patient positively affects the patient experience, which then increases treatment compliance, patient satisfaction, and perceived efficacy of care and may reduce the likelihood that patients sue over medical mistakes [68].

CONCLUSION

There is still controversy regarding the use of ECT as a treatment method. The aim of this review was to focus the attention on the therapist-patient relationship, the patient’s perspective and attitude on ECT, and the informed consent. These issues, of significant psychological, relational, ethical, and medico-legal impact (particularly the risk-benefit evaluation of ECT), have been addressed from the “patient-centered” perspective.

The importance of the paradigm shift from a disease-centered approach to a patient-centered approach when treating patients was highlighted in this paper. In fact, the patient-centered orientation favors, by qualitative approaches, an in-depth assessment of the patient’s experience treatment and the psychological and social factors that might favor or hinder the patient adherence to therapy. The qualitative assessment, most suitable to deepen knowledge of multidimensional and abstract concepts like the therapist-patient relationship, can help clinicians to improve the therapeutic alliance, reduce the risk of refusal treatment or drop-out among patients, and provide reflection elements for researchers and policy makers.

LIST OF ABBREVIATIONS

- ECT** = Electroconvulsive Therapy
M-ECT = Modified Electroconvulsive Therapy
UM-ECT = Unmodified Electroconvulsive Therapy

CONSENT FOR PUBLICATION

Not Applicable.

FUNDING

None.

CONFLICT OF INTEREST

The authors declare no conflicts of interest. All authors have made substantial intellectual contributions to the work and approved it for publication.

ACKNOWLEDGEMENTS

Declared none.

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