



Research Paper: The Quality of Informed Consent Obtaining Before Electroconvulsive Therapy: A Report From a Referral, Academic Hospital



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ABSTRACT

Background: In patients undergoing Electroconvulsive Therapy (ECT), obtaining written Informed Consent (IC) must be the standard measure before the procedure. The patient must be informed about the risks and benefits of the treatment and alternatives.

Objectives: We aimed to investigate the quality of IC obtaining before the ECT course in an academic hospital in the North of Iran.

Materials & Methods: This study was conducted at an academic center in the north of Iran during 2018-2019. Firstly the patients' mental capacity was assessed, and if it was not adequate for giving informed consent, a patient's relative was interviewed. The collected data were analyzed by SPSS V. 22. The Kolmogorov-Smirnov test was used to evaluate the normality assumption. To compare the mean scores in subgroups, we applied t-test.

Results: A total of 259 people enrolled in the survey and were interviewed. Schizophrenia was the main cause of receiving ECT. The Mean±SD score of receiving information was 8.22±3.68 (0-16), understandability of IC 3.03±1.76 (0-6), patients' voluntary acceptance of the treatment 1.38±0.68 (0-4) and physician-patient relationship 6.11±2.16 (0-12). The total Mean±SD score was 18.05±3.16 (0-38).

Conclusion: IC process was not optimal in our center; however, great trust in the physicians was noticeable. The physician-patient relationship had the highest score while the intentional obtaining of informed consent achieved the lowest.

Keywords: Electroconvulsive therapy; Informed consent; Inpatients

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Highlights

- Informed consent obtaining process before electroconvulsive therapy was not an appropriate course in an academic hospital in the North of Iran.
- Physician-Patient relationship item got the highest score in informed consent obtaining while receiving the voluntary informed consent achieved the lowest.

Introduction

Since the 1950s, the idea of obtaining Informed Consent (IC) as an ethical-legal process has appeared in the literature [1]. The importance of patients' right to be informed about their planned therapeutic interventions has been under scrutiny worldwide [2].

The IC process includes exact explanations via an interaction between patient and medical team, patient's decision making about accepting the procedure, and finally documentation [3, 4]. The idea of obtaining IC is to provide a clear understanding of all the potential risks, benefits of the treatment modality, and the other available options [2, 5]. In addition to ethical aspect, thanks to the huge available information via the internet, patients' attitude has revolutionized, and general public awareness has been significantly increased [6]. Patients often do not accept being passive in their management's process [7, 8]. According to law, planning the treatment without an IC is considered negligence for both anesthesiologist and psychiatrist. Therefore, in addition to wasting doctors' time and energy, compensation might be demanded [7].

Furthermore, well obtaining IC improves the patient-doctor relationship. Overall, regarding the importance of IC, Electroconvulsive Therapy (ECT) patients are not excluded [1]. However, these conditions are challenging. Despite the absolute need for the treatment, due to the lack of mental capacity, the patient might not have enough authority to give IC, and a relative should decide for the patient. So psychiatrists must choose in complex legal conditions between the required permission and patients' health care. This paper investigated the quality of IC obtaining before the ECT course in Shafa Hospital, a referral and academic center in the North of Iran.

Materials and Methods

After approval of the Research Ethics Committee of Guilan University of Medical Sciences this study was conducted at Shafa Hospital, an academic and tertiary

center admitting all types of elective and emergency psychiatric cases during 2018-2019. Firstly the patients' mental capacity was assessed by a responsible resident of psychiatry. If the patient did not have adequate ability and insight for giving IC, a relative who could legally decide on her/his conditions would be involved in realizing how they were disclosed and received the required information. After that, a questionnaire containing 19 items was filled via a face-to-face interview. The questionnaire had 4 sections of physician-patient relationships with 6 questions, how patients received information with 8 questions, patients' voluntary consent with 2 questions, and 3 questions for understandability of IC. Each question could be scored between 0 and 2. So that the answers of "Yes" and "to some extent" scored 2 and 1, respectively, while the answers of "No", "I cannot remember", and "I don't know" scored 0. The mentioned questionnaire was taken from Sheikh Taheri's paper which its content validity was confirmed by 10 members of the Anesthesiology and Psychiatrists department [9]. It should be noted that none of our cases had enough eligibility for this purpose.

Statistical analysis

The Kolmogorov Smirnov test was used to evaluate the normality assumption. To compare the mean scores in subgroups, we applied t-test in SPSS V. 22.

Results

A total of 259 people were interviewed. After a brief evaluation, we decided not to enroll the patients to clarify the quality of the IC obtaining process. The Mean±SD age of our patients was 43.48±13.58 years, 164 (63.3%) were male, 46 (17.8%) were graduated, 122 (47.1%) had a diploma, and 91 (35.1%) were under diploma. Psychosis with 154 cases (63%) was the leading cause of receiving ECT, followed by bipolar disorders with 91 cases (35.1%) and major depression with 10 cases (3.9%). All questions of the four evaluated areas and the answers are presented in Table 1.

Table 1. The questions and answers in different areas of questionnaire

| Questions | No. (%) | | | | |
|--|--|------------|------------|-----------------|-----------|
| | Yes | Partly | No | Cannot Remember | |
| Questions about providing adequate information | 1-Has anyone provided you with information about your illness? | 88 (34) | 136 (52.5) | 35 (13.5) | 0 (0) |
| | 2-Has anyone provided you with information about the procedure of treatment? | 63 (24.3) | 127 (49) | 65 (25.1) | 4 (1.5) |
| | 3-Has anyone provided you with information about the risks and benefits? | 96 (37.1) | 99 (38.2) | 52 (20.1) | 12 (4.6) |
| | 4-Has anyone provided you with information about the reason for choosing this treatment? | 64 (24.7) | 58 (22.4) | 125 (48.3) | 11 (4.6) |
| | 5-Have you been informed about the other treatment options? | 25 (9.7) | 39 (15.1) | 183 (70.7) | 12 (4.6) |
| | 6-Have you been informed about the length of hospital stay? | 86 (33.2) | 114 (44) | 43 (16.6) | 16 (6.1) |
| | 7-Have you been informed about the way of follow-up? | 203 (78.4) | 43 (16.6) | 13 (5) | 0 (0) |
| | 8-Have you been informed about the costs? | 4 (1.5) | 4 (1.5) | 243 (93.8) | 8 (3.1) |
| Questions about the tangibility of the IC | 1-Is the explanations for IC content adequate? | 37 (14.3) | 150 (57.9) | 25 (9.7) | 47 (18.2) |
| | 2- Are the content of the IC comprehensible? | 32 (12.4) | 160 (61.8) | 16 (6.2) | 51 (19.6) |
| | 3- Have you been aware of the refuse rights? | 134 (51.7) | 69 (26.6) | 17 (6.6) | 39 (15.1) |
| Questions about the voluntary IC | 1- Have you given a choice to select other treatment options? | 27 (10.4) | 35 (13.5) | 142 (54.8) | 55 (21.3) |
| | 2- Have you been informed of the pros and cons of the other options? | 10 (3.9) | 13 (5) | 177 (68.3) | 59 (22.8) |
| Questions About the Patient-Physician Relationship | 1-Do you have trust in your doctor? | 234 (90.3) | 21 (8.1) | 4 (1.5) | 0 (0) |
| | 2- Have you given enough time to think over the questions? | 68 (26.3) | 145 (56) | 37 (14.3) | 9 (3.4) |
| | 3- Can you easily contact your physician? | 26 (10) | 119 (45.9) | 114 (44) | 0 (0) |
| | 4- Have you received the informative answers to your questions? | 31 (12) | 113 (43.6) | 111 (42.9) | 4 (1.5) |
| | 5-Does your doctor devote enough time to clarify the IC? | 8 (3.1) | 153 (59.1) | 82 (31.7) | 16 (6.1) |
| | 6-Are the explanations comprehensive? | 40 (15.4) | 219 (86.6) | 0 (0) | 0 (0) |

The Mean±SD score of receiving information was 8.22±3.68 (0-16), understandability of IC 3.03±1.76 (0-6), patients' voluntary acceptance of the treatment, 1.38±0.68 (0-4) and physician-patient relationship 6.11±2.16 (0-12). Totally the Mean±SD score was 18.05±3.16 (0-38). The scores for each section and item are presented in [Table 2](#).

Discussion

In modern clinical practice, IC is routinely obtained before any treatment intervention [5, 10-12]. Studies indicate that a low level of awareness regarding the treatment process predisposes medico-legal cases and claims

against physicians. In many cases, when treatment outcomes are less than expected, the patients do not sue doctors for financial gain, but their anger is only because they have not received any explanation from their physicians [10]. Unfortunately, studies have indicated that the quality of obtaining IC in current clinical practice is so far from optimal [13]. The majority of available literature has discussed the issue in other conditions rather than ECT [9, 14]. In some conditions like ECT, there is not a general agreement [15]. ECT has been considered the last option in medically-resistant and emergency cases with at least adverse effects [16-18]. So respecting patients' autonomy while ECT could be lifesaving makes a challenging issue [19]. Like the previous studies, we

Table 2. The acquired scores in 4 different areas

| The Field of Questions | Number of Questions | Acquiring Scores Range | Mean±SD |
|---|---------------------|------------------------|------------|
| Providing adequate information to the patients | 8 | 0-16 | 8.22±3.68 |
| Understandability of the IC | 3 | 0-6 | 3.03±1.76 |
| Patients' voluntary desire in accepting the treatment | 2 | 0-4 | 1.38±0.68 |
| Physician-Patients' relationship | 6 | 0-12 | 6.11±2.16 |
| The whole questionnaire | 19 | 0-38 | 18.05±3.16 |

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found that the IC obtaining process was not appropriate in our hospital. None of our cases had enough capacity to give the IC, and consequently, a relative was interviewed. In line with present study, Kaufmann et al., in an empirical study in which 32 psychiatrists were involved, evaluated the mental capacity of their patients to consent or refuse ECT treatment. They reported that these cases were rarely reliable for decision-making about their treatment option. They had an agreement that a relative or medical team must make the final decision [20]. However, a few studies believe that in these conditions, a team discussion and decision might be preferred. In Duxbury et al. study, some patients declare that ECT administration should be wholly decided by clinicians, and there is no need to involve non-medics [21]. Unlike this opinion, some other studies indicate that patients' right to choose ECT must be seriously respected. The issue remains challenging with unanswered questions such as how much information the patient should receive.

Furthermore, patients' requests for information significantly vary according to their educational level, culture, and beliefs [12]. Studies state that cultural characteristics and clinicians' attitude toward the required level of information to the patients affects the IC process [9]. Some researchers have reported that 60%-70% of patients do not read the IC statement before signing it [22]. In contrast, other states that truly informed patients felt less anxiety and were more satisfied compared to the non-informed group. It was also found that extended written before treatment makes patients and their relatives more prepared to face unwanted complications [23]. Unlike Lavelle- Jones, Howlader et al. showed that 89% of individuals in their survey preferred to receive detailed information before treatment [24]. Similar to what was mentioned in Howlader's study, we acknowledge that recall biases were not avoidable in this work, and patient or their kin might have forgotten the way that IC was obtained.

Conclusion

This paper revealed some weak or uninformed areas of IC obtaining. However, great trust in the physicians was notable. The physician-patient relationship had the highest score while the voluntary IC achieved the lowest. Further studies are required to improve the IC process.

Ethical Considerations

Compliance with ethical guidelines

Ethics approval was obtained from the Research Ethics Committee of Guilan University of Medical Sciences (Ref: IR.GUMS.REC.1397.358). All study procedures were in compliance with the ethical guidelines of the 2013 version of the Declaration of Helsinki.

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Authors contributions

Conceptualization: Hossein Khoshrang; Methodology: Cyrus Emir Alavi; Investigation: Zoleikha Bayat, Robabeh Soleimani; Writing the original draft: Mohammad Reza Habibi; Writing, review, and editing: Morteza Rahbar Taramsari, Siamak Rimaz; Supervision: Abbas Sedighinejad.

Conflict of interest

The authors declared no conflict of interest.

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