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Qualitative analysis of the capacity to consent to treatment in patients with a chronic neurodegenerative disease: Alzheimer's disease

Analisi qualitativa sulla capacità a prestare consenso al trattamento in pazienti con malattie cronico degenerative neuropsicoorganiche Demenza di Alzheimer

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Abstract

Objective: Informed consent is an essential element in doctor–patient relationship. In particular, obtaining valid informed consent from patients with neurocognitive diseases is a critical issue at present. For this reason, we decided to conduct research on elderly patients with Alzheimer's disease (*Diagnostic and Statistical Manual of Mental Disorders*, 5th Edition (DSM-5) to assess their capacity to make treatment decisions.

Methods: The experimental group comprised 70 Alzheimer patients who were admitted to the Neurodegenerative Disease Unit of the University of Bari. The control group consisted of 83 elderly patients without neurocognitive disorders who were hospitalized in the Geriatric Unit at the same university. After providing written consent to participate in the research, each subject underwent the following assessments: (a) assessment of comprehension sheet, (b) Neuropsychiatric Inventory (NPI) and Global Functioning Evaluation (GFE), (c) neurological evaluation, (d) neuropsychological assessment with a full battery of tests, (d) The MacArthur Treatment Competence Study (MacArthur Competence Assessment Tool for Treatment (MacCAT-T); understanding, appreciating, reasoning and expressing a choice) and (e) a semi-structured interview administered by the patient's caregiver.

Results/conclusion: The present survey was designed to analyze possible qualitative and quantitative correlations between cognitive functioning and capacity to consent in relation to different degrees of severity of the

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neurodegenerative disorder. A large portion of the patients in our experimental sample did not appear to have the capacity to provide a valid consent. The authors present initial results of this study and discuss their possible implications.

Keywords
Informed consent, capacity to consent, Alzheimer's disease, competence, treatment decisions, neurocognitive impairment

Introduction

Consent is the *conditio sine qua non* of every medical diagnostic and therapeutic procedure. More generally, it is a cornerstone of the doctor–patient relationship (Faden, Beauchamp, & King, 1986). Competency to consent is the capacity to provide a truly valid consent for medical treatments, surgery, participation as a subject in research or for invasive diagnostic procedures (Felthous, Kröber, & Saß, 2001). In the United States, competence to consent emerged in the latter half of the last century, and in Europe, this has also been a rather recent development with variation between European countries (Koch, Reiter-Theil, & Helmchen, 1996).

As for other competencies and forensic assessments in general, the two-step process articulated by Kurt Schneider in 1948 is recommended. First, determine whether a mental disorder exists and establish the diagnosis. Here, the condition of concern is dementia, Alzheimer's dementia in particular. Second, from the diagnosis and clinical findings, determine how this disorder affects the particular mental capacity (Felthous et al., 2001) – here competence to consent or, more specifically, capacity to make treatment decisions. It is this second step with respect to capacity to make treatment decisions that is the focus of this present research.

The recent Italian Medical Ethics Code (Codice di Deontologia Medica (CDM), 2014, Art. 33) explicitly provides that the informed consent procedure should include 'understandable and comprehensive' information about the proposed treatment, possible diagnostic and therapeutic alternatives, foreseeable risks or complications, as well as actions to be taken by the patient during treatment procedures'. These aspects should be clarified and understood by patients, especially if the prescriptions involve long and complex treatment protocols and if the patient is emotionally affected by reduced life expectancy. It is obvious that in this case, a mental evaluation is needed to determine the patient's ability to knowingly accept the treatment. Therefore, evaluation tools are helpful in determining the patient's capacity to consent to the proposed treatment.

In recent years, several studies have addressed this issue in an attempt to evaluate the patient's mental capacity to give consent in various clinical settings (Aydin, Sehiralti, & Aker, 2013; Bilanakis, Vratsista, Athanasiou, Niakas, & Peritogiannis, 2014; Carabellese et al., 2017; Kerrigan, Erridge, Liaquat, Graham, & Grant, 2014; Mandarelli et al., 2017; Okai et al., 2007; Owen et al., 2013; Raymont et al., 2004; Catanesi, Carabellese, Candelli, La Tegola, & Taratufolo, 2010).

Several factors are necessary for a patient to provide a valid consent for a medical treatment. Patients need to be properly informed about their health condition. They need to understand the risks and benefits related to the proposed therapies and to evaluate the proposed alternatives. In short, they must have the capacity to consent. In general, we can consider such capacity 'a threshold requirement for people to retain the power to make decisions for themselves' (Appelbaum, 2006 Appelbaum, Appelbaum, & Grisso, 1998; Gutheil, 1991).

In recent years, the scientific literature has identified four functional aspects which subtend the patient's mental capacity to provide informed consent for a treatment (Appelbaum, 2006; Appelbaum & Grisso, 1988; Dunn, Candilis, & Roberts, 2006; Dunn, Nowrangi, Palmer, Jeste, & Saks, 2006; Grisso & Appelbaum, 1998; Gutheil, 1991): the ability to understand the main elements of their own medical condition and all useful information regarding treatment options (understanding); the ability to utilize this information to evaluate their own current clinical condition, for example, possible consequences (appreciating); the ability to think about the information, including possible treatment options, and to organize this information in a logical and rational process, for example, to evaluate the treatment information in a consequential and comparative way (reasoning); and the ability to make a choice (expressing a choice). For the capacity to consent to be valid, it is necessary that all the aforementioned conditions are met. Over the years, psychometric tools have been developed to allow a standardized evaluation of the level of capacity needed to provide consent. One of the most commonly used tools for mentally ill patients is the MacArthur Competence Assessment Tool for Treatment (MacCAT-T) (Grisso, Appelbaum, & Hill-Fotouhi, 1997).

The MacCAT-T is a semi-structured interview which explores the above-described four dimensions of patients' mental capacity to make treatment decisions: understanding (subscale ranges from 0 to 6), appreciating (subscale ranges from 0 to 4), reasoning (subscale ranges from 0 to 8) and expressing a choice (subscale ranges from 0 to 2). The MacCAT-T does not provide a total score or a cut-off to define a patient's mental capacity. Patients with MacCAT-T scores that are equal to or greater than one-half of the total possible points for each

parameter are generally assumed to have capacity. Those who meet this threshold for all four subscales would most likely have sufficient decision-making ability to support a judgment that they have the capacity to make most treatment decisions (Appelbaum & Grisso, 2001). The final clinical judgment on treatment decisional capacity is the evaluator's opinion.

These tools are not commonly used in clinical practice, where the capacity or incapacity to give consent is typically assumed without specific verification. However, evidence in the literature suggests that even patients with severe mental illness retain, to some extent, the capacity to consent to make some or all treatment decisions (Appelbaum, 2006). In other words, the incapacity to provide a valid informed consent should not be assumed based only on the presence of a specific physical or mental disease. Instead, it is necessary to determine 'if', 'how' and 'to what extent' a certain disease impairs the patient's underlying cognitive and affective decision-making process (capacity). The relationship between this and the specific proposed treatment should also be examined (Palmer, Dunn, Appelbaum, & Jeste, 2004; Raymont et al., 2004).

The MacCAT-T is increasingly becoming an international reference tool to evaluate a patient's mental capacity to provide consent (Alvarez Marrodan et al., 2014; Bilanakis, Vratsista, Kalampokis, Papamichael, & Peritogiannis, 2013; Hernando Robles et al., 2012). It can be used not only in general psychiatric settings but also to assess patients affected by neurodegenerative diseases. Such disorders are specific and widespread within the geriatric population (Lipman, Kalra, & Kirkpatrick, 2015; Lui et al., 2009; Moye & Marson, 2007; Moye, Marson, & Edelstein, 2013; Palmer et al., 2013). However, little is known about the neurophysiological underpinnings of treatment-related decision-making (Mandarelli et al., 2014) . This issue is becoming increasingly important due to the gradual increase in the elderly population; The Italian National Institute of Statistics (Istituto Nazionale di Statistica, 2009) data show the continuous increase in both the number of elderly individuals and issues associated with dementia. US statistics indicate that there will be 71 million American adults over the age of 65 by 2030, accounting for roughly 20% of the US population (Centers for Disease Control and Prevention and The Merck Company Foundation, 2007). Normal aging is often associated with a decline in various cognitive abilities (Salthouse, 2012). By 2030, 7.7 million adults in the United States over the age of 65 will have dementia due to Alzheimer's disease (AD), and by 2050, over 15 million people will be affected (Hebert, Scherr, Bienias, Bennett, & Evans, 2003). At present, the prevalence of dementia in all adults over the age of 60 is 5%–7% (Prince et al., 2013).[AQ3]

In practice, consent for treatment in Italy is usually obtained orally, except for some special cases provided by the law and the Italian Medical Ethics Code. For instance, written consent is required for treatments associated with high mortality risk or results that can significantly compromise the subject's psychophysical integrity (Art. 35, CDM, 2014). In this regard, the European Commission directive 2001/20/CE (Good Clinical Practice) is the fundamental law that was adopted by the Italian Parliament as *Decreto Legislativo* (Legislative Decree: D.L. 24.6.03 n.211) and the European Convention on Human Rights and Biomedicine (known as Oviedo Convention, Council of Europe, 1997) which Italy incorporated into its own with law as D.L. 28.3.01 n. 145.

In Italy, the doctor assesses the capacity of the patient to properly consent to a specific proposed treatment and evaluates possible limitations and qualitative/quantitative ranges. The rights to health protection and personal freedom are fundamental Constitutional Human Rights. This forces the doctor to evaluate the patient's actual capacity to consent, regardless of the patient's age, to critically accept the proposed treatment or at least to take part in the decisions that affect him or her.

According to the international guidelines (May & Wallhagen, 2009; Raymont et al., 2004; Roberts & Kim, 2014; Rosen & Weitlauf, 2015), informed consent to more complex treatments needs to be in writing. If the patient is illiterate, the consent can be recorded with appropriate tools, such as audio and video recordings. The patient should receive information in an easy-to-understand language and should be free to ask questions anytime. The patient should have enough time to think about his or her decision. Based on national law, in some European countries, only the doctor is qualified to speak to the patient, whereas in some Eastern European countries, other professionals are allowed to perform this task. In either case, a member of the treatment team who has the proper qualification and competence should be the one to have a preliminary talk with the patient.

In Italy, the doctor must additionally propose to the judge forms of legal protection for patients who are considered unable to knowingly adhere to treatment. This is provided by Italian Civil Law no. 6 of 2004 which establishes the role of the Support Administrator who is in charge of protecting the interests of the 'person' who is 'completely or partly lacking autonomy'. In Italy, the Support Administrator is comparable to a court-appointed guardian in the United States.

In light of the above, we tried to investigate the patient's capacity to give consent to treatment when affected by Alzheimer's dementia. For this purpose, we performed our research in 'Services of Excellence', that is, specialized services that serve specific regions of Italy for the diagnosis and treatment of neurodegenerative diseases. For our region, these facilities are the neurology clinic of a hospital in Tricase and the Alzheimer Center at the University of Bari's Policlinico. Planning and implementation of the entire research took more than

1 year. A description of the study and its results are presented below.

Objectives

The main objective of the study was to understand the ability of patients with neurocognitive disorders of different manifestations and severity to evaluate their own health conditions, their treatment needs and the effects of drugs prescribed by the doctor. Basically, it is to determine patients' levels of critical understanding of their own health condition and proposed treatment – in other words, their capacity to consent.

Participants

For our multicenter study, we recruited out-patients who began their treatment over a period of six consecutive months in February 2015 and voluntarily agreed to participate in the research. To participate as subjects in research in Italy and therefore in this study, written consent is required. Any patient who declined to consent was asked whether he wanted to share his reason for refusal.

The experimental group (S) was composed of 70 patients affected by AD (*Diagnostic and Statistical Manual of Mental Disorders*, 5th Edition (DSM-5 criteria), American Psychiatric Association, 2013) who were being treated at the neurology clinic of the Hospital in Tricase and the Policlinico of the University of Bari. Investigators used DSM-5 criteria in diagnosing neurocognitive disorder with AD, and only patients so diagnosed with Alzheimer's disorders were included in S group. All others were excluded.

The control group (C) was composed of 83 patients coming from the Policlinico of the University of Bari, Unity of Geriatric Hypertension clinic who gave their consent to this research during the designated time period. From the latter group, we excluded patients who had records of clinically relevant neurocognitive problems. From the previously mentioned facilities, we recruited only out-patients or day hospital patients and excluded hospitalized patients.

Before initiating the research, we considered a large number of patients, that is, close to 100 patients for each group (experimental and control). We used the following inclusion criteria: out-patient status; minimum primary school education level, having completed eighth grade; good knowledge of Italian; informed consent to participate in the study; and arrival during the indicated period of time to the operating units of neurology and geriatrics mentioned above.

Methods

The study was approved by the respective ethics committees of the healthcare facilities involved.

The researchers involved in this study had a series of preliminary meetings (three research groups, each including a neurologist, a forensic-psychiatrist, a general psychiatrist and a psychologist with expertise in the selected tests) to standardize the collection method in the three different clinical settings. The three research groups met regularly once a month during the patient recruitment phase in order to compare new data and make adjustments in the study, if needed. It was never necessary to make modifications to the planned research method, but on several occasions the researchers had long discussions in arriving at joint decisions, especially regarding the neurological diagnosis to be made.

Every enrolled patient had a protocol that was subdivided into at least two sessions. Before starting to interview potential subjects, the researchers spoke with healthcare providers to collect clinical and historical information.

Assessment instruments

The Consent to Treatment Interview (CTI) was administered. The CTI is an interview schedule that was created by the research group to assess the individual's capacity to participate in the study. The CTI interview compares the patient's awareness with respect to his or her own functionality and neuropsychological condition. It also assesses the patient's ability to manage therapy, using the information provided by the caregiver. This multichoice question interview, which was administered to both the patient and the caregiver, addressed the following topics: general information, patient data, therapy, money management, management of daily activities and day organization. In addition, it assessed the presence of behavioral and/or cognitive disorders.

For the psychiatric evaluation, the Neuropsychiatric Inventory (NPI, Cummings et al., 1994) was administered. The neuropsychological battery of tests included the Mini–Mental State Examination (MMSE, Folstein, Folstein, & McHugh, 1975), the Frontal Assessment Battery (FAB, Dubois & Litvan, 2000), the Rey Verbal Learning test, the Boston Naming Test, the Stroop test, the Poppelreuter test and the Clock Drawing test. Finally, MacCAT-T was used to assess the capacity to make treatment decisions.

Day 1

Patient selection took place at the 'main operative unit' (*Unità Operativa*). The project was presented to each subject individually and information sheets were distributed. All participating subjects signed the consent form indicating their willingness to participate. Patients who decided not to participate were asked why they declined, and a member of the investigative team entered their response on a separate form. The appointment schedule was distributed to patients who agreed to

participate. Subjects were evaluated neurologically using the Clinical Dementia Rating (CDR; Berg, 1988; Morris et al., 1997) Scale and Data Collection form. Finally, the properly signed consent forms for participation in the study were collected.

Day 2

On the second day, the subjects were welcomed into the study and then evaluated, first psychiatrically by administration of the NPI. The Neuropsychological battery was administered (MMSE, FAB, Rey Verbal Learning test, Token Test, Verbal Fluency test, Boston Naming Test, Stroop test, Poppelreuter test and Clock Drawing test). The CTI was administered as was the MacCAT-T.

Statistical analysis

To assess the association between the investigated variables, a univariate analysis was performed using double-entry contingency tables and computing chi square (χ^2) with 95% confidence intervals (95% CIs). The *p*-values considered as significant were <.05. For the assessment of significant differences across the means of continuous variables, we relied on the *t*-test for independent samples, considering as significant those values with $p < .05$. To assess the distribution of the variables, we used Bartlett's test. We used STATA-MP software, version 14.1 for Mac OS X.

Results

Demographic and clinical characteristics

Group S was composed of 70 patients (43 females and 27 males) who completed all the tests. Their mean age was 76.20 years (standard deviation (SD): 7.65) (Figure 1; Table 1). Group C was composed of 83 subjects: 38 females and 45 males (mean age: 70.78 years; SD: 6.03).[AQ4] [AQ5]

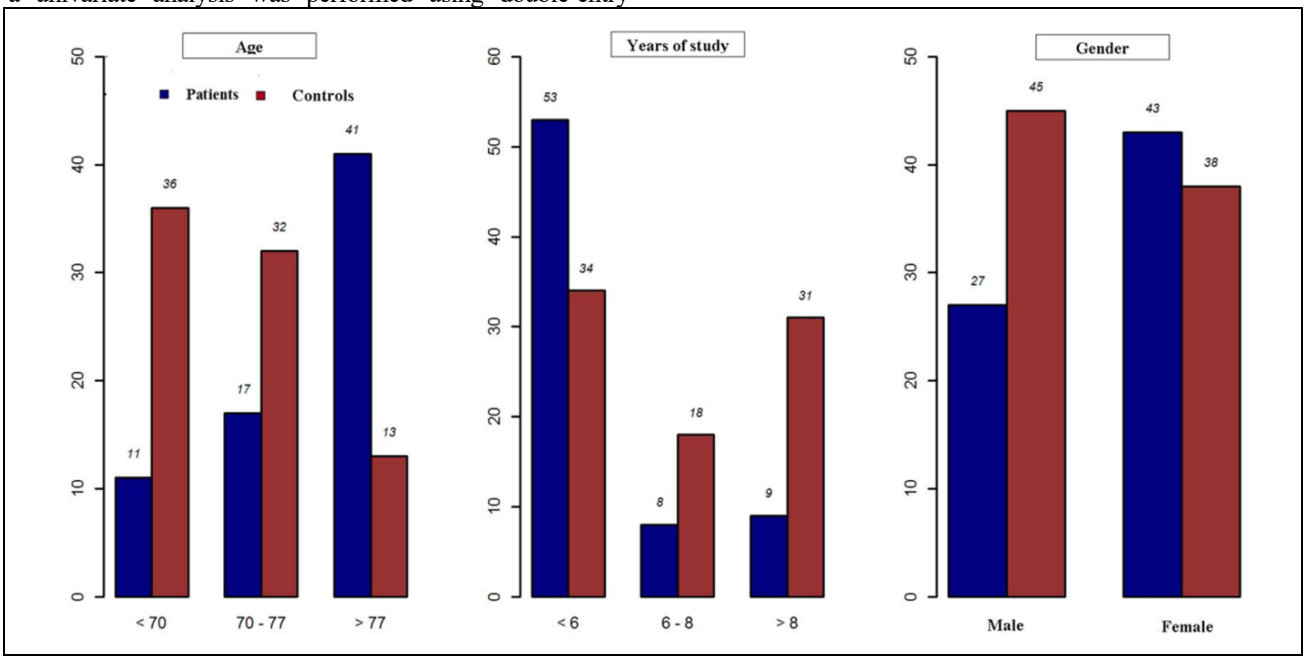

Figure 1. Demographic characteristics.
Group S was composed of 70 patients (43 females and 27 males) who completed all the tests (mean age: 76.20 years; SD: 7.65). Group C was composed of 83 subjects: 38 females and 45 males (mean age: 70.78 years; SD: 6.03).

Table 1. Demographic characteristics.

Variable		Patients	Controls	Total
N		70	83	153
Age (years) (average ± SD)		76.20 ± 7.65	70.78 ± 6.03	73.27 ± 7.32
Years of study (average ± SD)		6.51 ± 3.18	9.07 ± 4.37	7.90 ± 4.06
Gender frequency (%)	Male	27 (38.57)	45 (54.22)	72 (47.06)
	Female	43 (61.43)	38 (45.78)	81 (52.94)

SD: standard deviation.
Group S was composed of 70 patients (43 females and 27 males) who completed all the tests (mean age: 76.20 years; SD: 7.65). Group C was composed of 83 subjects: 38 females and 45 males (mean age: 70.78 years; SD: 6.03).

Over half, 59.4%, of the S subjects were found to have mild AD of moderate (30.4%) to severe degree (10.2%) (DSM-5, American Psychiatric Association, 2013).

MacCAT-T summary scores

Most importantly, data showed that the S patient group, for each level of neurological disease found (mild, moderate and severe mild neurocognitive disorder (M-NCD – DSM-5) compared to the C group, had lower rates of capacity to consent to treatment through the analysis of all four different subscales of the MacCAT-T (understanding, appreciating, reasoning and expressing a choice; Figure 2).[AQ6]

The distribution of MacCAT-T scores for the S group and C group is shown in Figure 3. The summary scores for understanding, appreciation, reasoning and expressing a choice were significantly higher for the control group ($p < .001$; Figure 2). Figure 3 shows that the MacCAT-T Summary Scores correlated with Alzheimer's grading following DSM 5. All those with severe AD could not answer most or all questions on the MacCAT-T interview. Mild and moderate Alzheimer patients differed only in the subscale of Reasoning: mild patients' average score was significantly higher than that of the moderate patients' ($p < .0001$).

MacCAT- T, CDR, MMSE and FAB

Figure 4 shows the correlations between the S group MacCAT-T subscales and neuropsychological test results. In the C group, MMSE and FAB scores were significantly higher than S group scores ($p < .0001$). Mildly impaired patients had significantly higher MMSE and FAB scores than moderate patients ($p < .001$) (Figures 5 to 7).

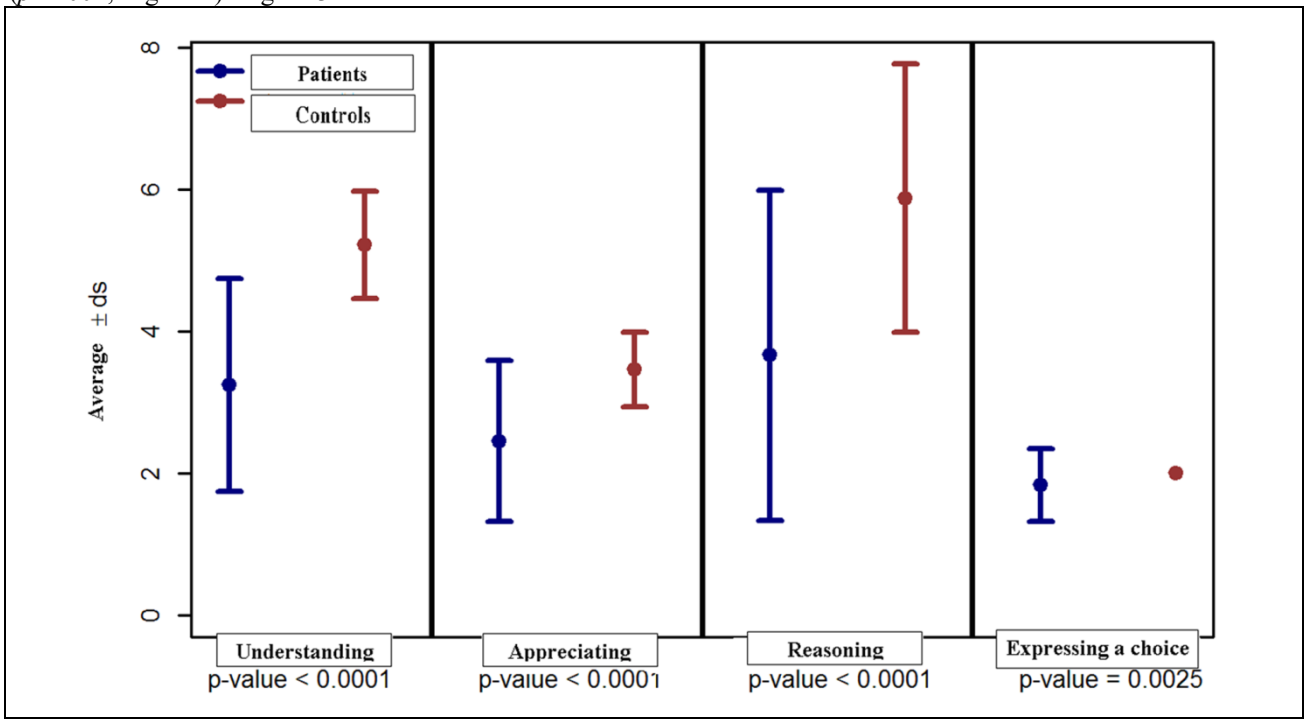

Figure 2. Distribution of MacCAT-T summary scores.
The distribution of MacCAT-T scores for the S group and the C group. The summary scores for understanding, appreciation, reasoning and expressing a choice were significantly higher for the C group than the S group ($p < .001$).

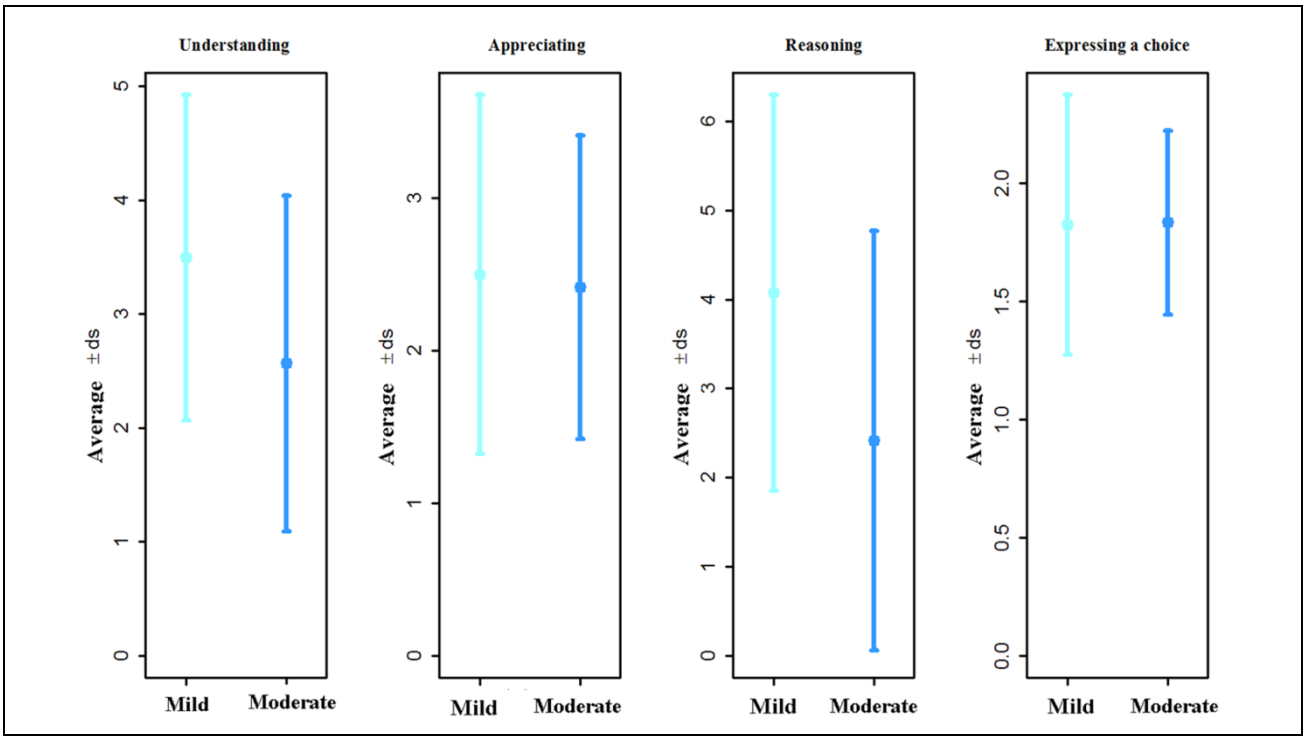

Figure 3. Summary scores of Mac CAT-T and grading DSM-5.
Mild and moderate Alzheimer patients differed only in the subscale of Reasoning: mild patients' average score was significantly higher than moderate patients' ($p < .0001$).

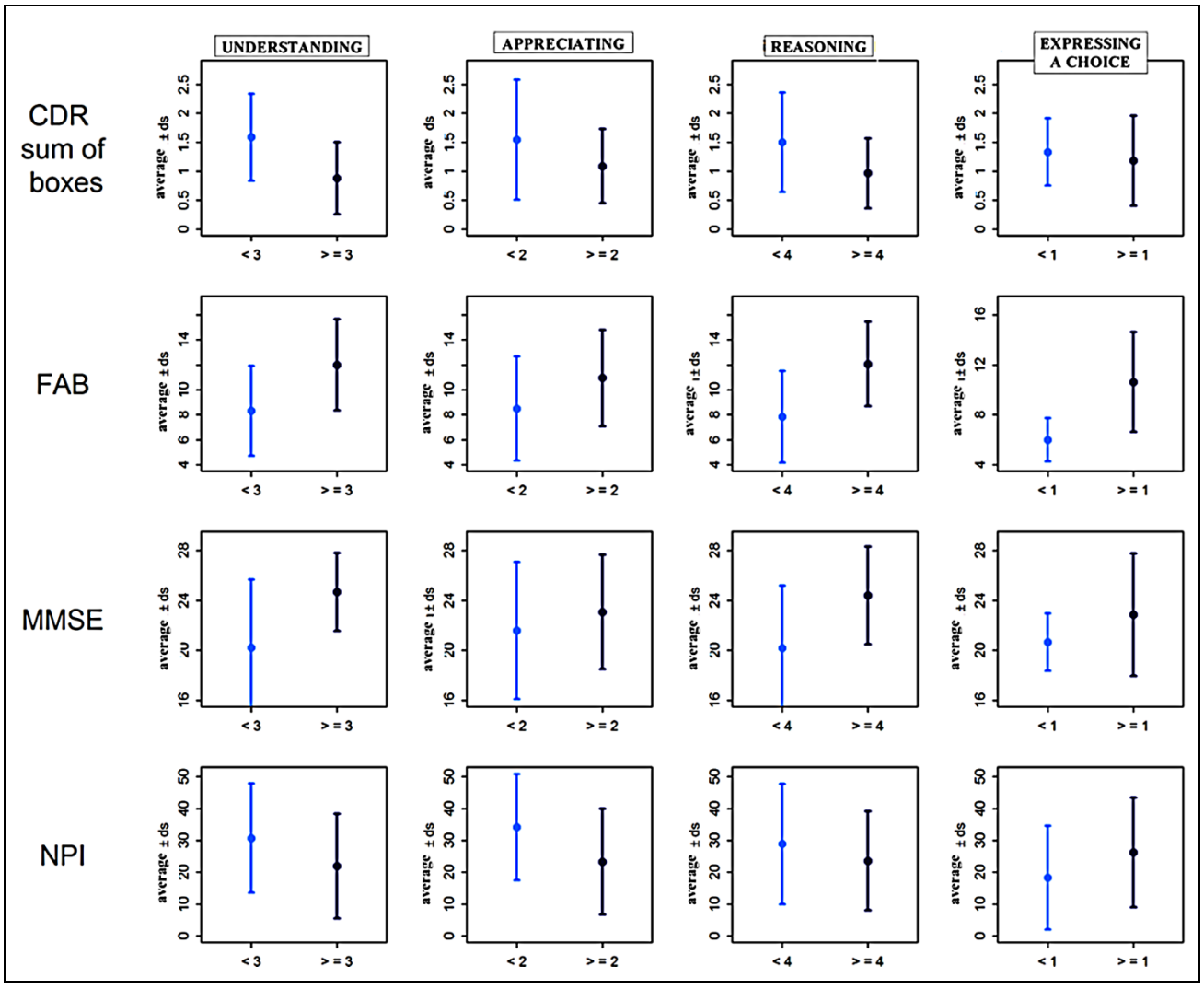

Figure 4. MacCAT-T scale scoring (more and less medium score) in AD patients and CDR, FAB, MMSE and NPI scoring.
In the C group, MMSE and FAB scores were significantly higher than the S group scores ($p < .0001$). Mild patients had significantly higher MMSE and FAB scores than moderate patients ($p < .001$).

Discussion

Patients with neurocognitive impairment may or may not have the capacity to make treatment decisions for their own care. With the growing population of elderly individuals in Western Countries, many of whom have age-related neurodegenerative disorders, AD in particular, treatment decisional incapacity is expected to become an increasingly common occurrence, complicating ethical and efficient treatment and care of such individuals. To overlook a patient's potential incapacity risks over- or under-treatment, disrespect for the person's personhood and violation of the person's autonomy rights.

This study attempted to examine empirically and quantitatively the cognitive limitations that can impair treatment decisional capacity in AD-afflicted patients. In a population of neurological patients referred for assessment and treatment of neurodegenerative disorders, we found that the majority of these patients had mild AD, nearly one-third moderate and about one-tenth severe. Using the MacCAT-T to assess treatment decisional capacity, we found that all levels of neurocognitive impairment from AD were associated with lower rates of capacity to consent in comparison with a non-neurological control group. Lower rates of decisional capacity were supported by lower scores on all four subscales measuring, respectively, the capacity-requisite abilities of understanding, appreciating, reasoning and expressing a choice, with statistically significant differences in each of the four comparisons ($p < .001$).

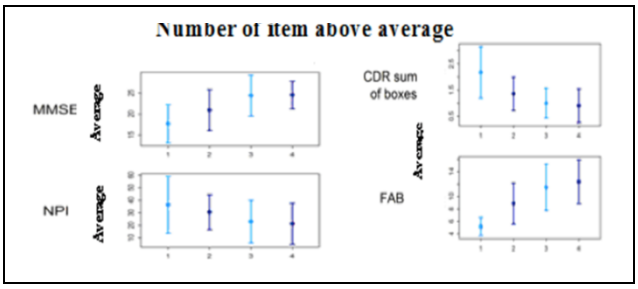

Figure 5. MacCAT-T subscales over medium scores in AD patients and MMSE, CDR, NPI and FAB.
In the C group, MMSE and FAB scores were significantly higher than the S group scores ($p < .0001$). Mild patients had significantly higher MMSE and FAB scores than moderate patients ($p < .001$).

The MacCAT-T also helped to identify differences in the level and quality of treatment decisional incapacity among the three levels of impairment from AD. Mildly impaired patients showed higher scores on reasoning ($p < .0001$) in comparison with moderately impaired patients. The other three subscale scores for these two levels of impairment were comparable. All with severe AD were unable to answer (any) questions on the MacCAT-T interview. Thus, the MacCAT-T not only helped to determine the individual's treatment decisional capacity, it also appeared to help distinguish qualitative differences in the specific components of capacity that were lacking in the three levels of neurocognitive impairment.

As expected, the Alzheimer group performed poorly on the MMSE and the FAB, indicating both global and executive cognitive dysfunction, with moderately impaired patients scoring lower than those with mild impairment.

In general, these findings are as expected. AD, with its neurocognitive impairment, is associated with evidence of treatment decisional incapacity, based on the four subscales of the MacCAT-T. Although subjects in the mild Alzheimer diseased group demonstrated adequate capacity to give consent, a substantial portion of the patients lacked cognitive capacity to give a valid consent. Their physicians apparently provided them with appropriate treatment, but without addressing their treatment decisional capacity. By not addressing their decisional capacity, valid consents were not obtained in violation of civil and criminal codes in Italy.

Particularly in patients with neurocognitive disorders, here demonstrated with AD, it behooves clinicians to assess and document the patient's treatment decisional capacity. This is best accomplished by utilizing objective assessment instruments and, particularly in the case of a neurodegenerative process, monitoring the level of the patient's capacity over time. Physicians in Italy are required by law to petition the court and propose legal protection if the physician determines that the patient lacks capacity and therefore may not be able to validly consent to and follow appropriate treatment. This is mandated by Law Number 6/2004 which also establishes the role of the Support Administrator who is responsible for protecting the interests of the 'person who is completely or partly lacking autonomy'.

If the legal requirement is not fulfilled, the provision of treatment to one who should have been found to lack capacity is an unlawful procedure regardless of the therapeutic needs of the patient and regardless of the benefit, efficacy and success of the treatment. The patient would be deprived of the protection provided by the law to safeguard the patient's rights. The physician could be criminally prosecuted for failure to safeguard the patient's rights.

This research demonstrates that neurocognitively disordered patients with AD are being unlawfully treated. Moreover, this study illustrates the value of using acceptable instruments to assess the level of neurocognitive functioning and functions needed for capacity and competence to consent to treatment.

For international application, comparison with how incapacity and incompetence are handled in the United States may be useful. As a rule, adults, whether young or old, are considered to be competent to exercise their legal rights unless adjudicated incompetent (Kambam, 2017). Medical providers must check to see whether a new or potentially neurocognitively impaired elderly patient already has a durable power of attorney or other previously appointed healthcare proxy to make medical decisions for them (Falls, Tanaka, & Bursztajn, 2017). A finding of incompetence, whether partial or total, can result in appointment of a guardian to make decisions on behalf of the person. Typically, the issue does not arise and is not addressed unless the person is making self-endangering decisions, such as refusing needed treatment, or is otherwise demonstrating inability to care for oneself, to take reasonable measures to protect one's health and safety.

There is some reluctance to find a person incompetent and in need of guardianship because of the restrictions on the person's freedom and the cost to society, as, for example, when a demented person is to be unwillingly placed in a locked nursing home. The forensic assessment can be framed as (in)capacity to live independently rather than as a specific decisional incapacity (Falls et al., 2017). Such adjudications therefore tend to be triggered in practice more on past dispositional 'failures' than current decisional capacity.

An exception is capacity to consent to voluntary psychiatric hospitalization. Until 1990, a patient's voluntary consent to be hospitalized was accepted without question, regardless of whether the patient was psychotic or lacked understanding. Then, the downside of involuntary detention for a patient who was not refusing was appreciated. In *Zinermon v. Burch* (1990), the US Supreme Court held that only patients who are competent to consent should be allowed to voluntarily consent to hospitalization. In practice, the screening ought to be for capacity, not competence, as the court was not referring

only to patients already adjudicated as incompetent. [AQ7]

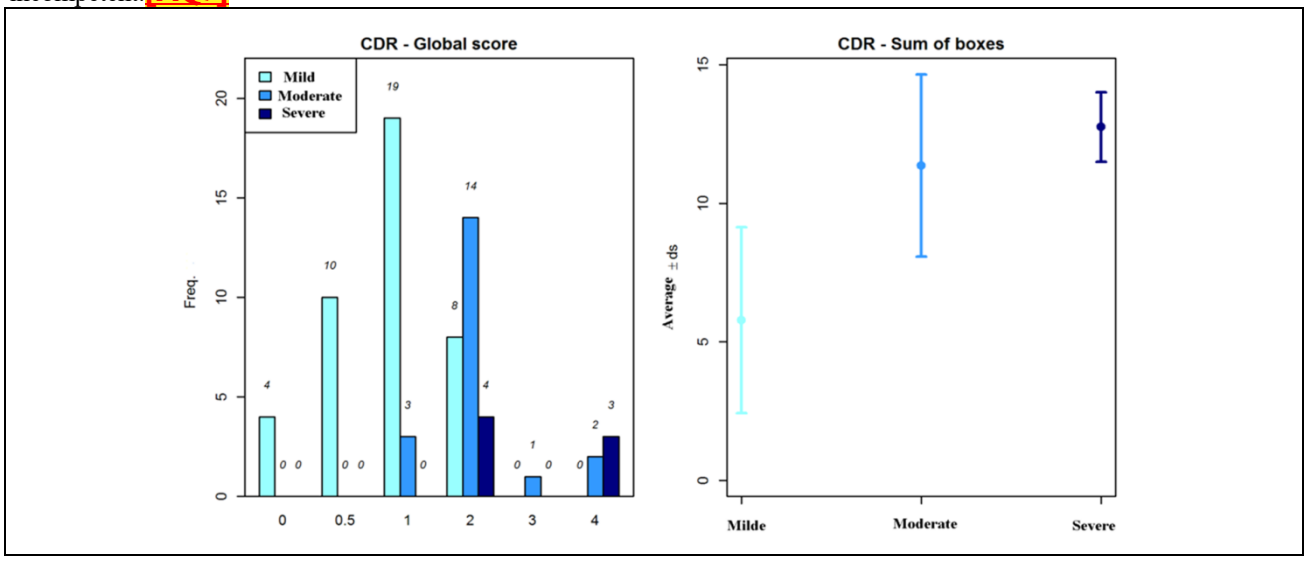

Figure 6. AD patient distribution by Clinical Dementia Rating (CDR) Scale.
In the C group, MMSE and FAB scores were significantly higher than the S group scores ($p < .0001$). Mild patients had significantly higher MMSE and FAB scores than moderate patients ($p < .001$).

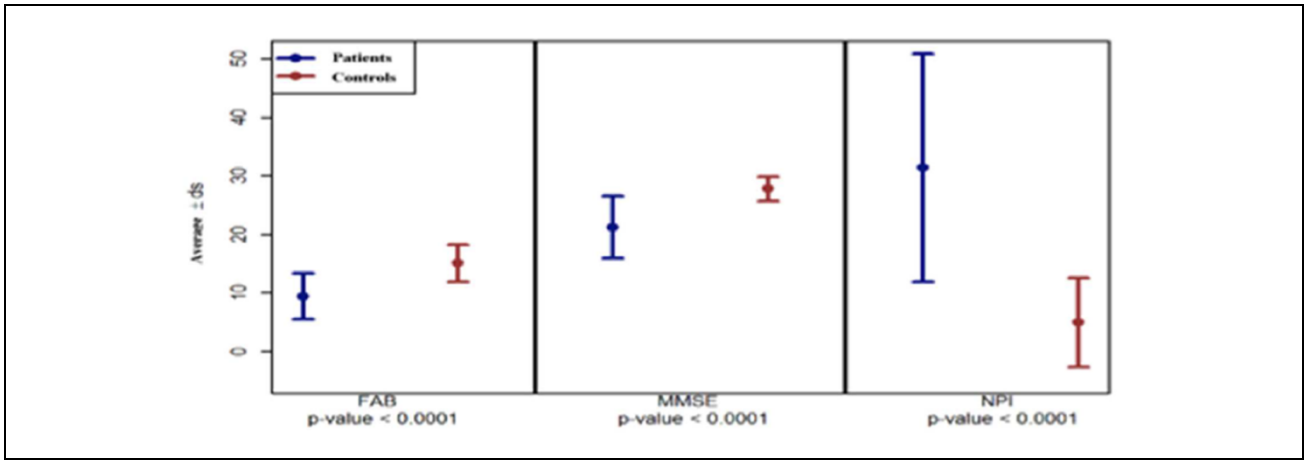

Figure 7. FAB, MMSE and NPI in S group and C group.
In the C group, MMSE and FAB scores were significantly higher than the S group scores ($p < .0001$). Mild patients had significantly higher MMSE and FAB scores than moderate patients ($p < .001$).

Thus, in the United States, differences in state jurisdictional law are amplified by differences in law and practice concerning the treatment/care issue (placement, hospitalization, psychotropic medication, major surgery, etc.). Nonetheless, the present Italian study illustrates the potential value of increased sensitivity to potential incapacity and the potential value of a standardized approach to assessment. Also to be considered is the importance of assessment for improvement or recovery from incapacity for potentially reversible neurocognitive disorders in the elderly (Falls et al., 2017), such as substance/medication-induced neurocognitive disorder (American Psychiatric Association, 2013) or Wernicke–Korsakoff syndrome.

Conclusion

A good portion of the patients in the present samples did not seem to have the proper cognitive capacity to give a valid consent for treatment. The healthcare services provided did not appear to adequately protect the patient's autonomy and did not legitimize the healthcare provider's treatment of the patient. In other words, even though the physicians provided appropriate treatment, this was in violation of the civil and penal codes because it was done without a valid consent. The physicians were not protected by a valid consent from possible legal action.

First, it is necessary in Italy to document the validity of the patient's capacity after proper evaluation with objective tools and to monitor the patient's level of adherence over time.

Second, in Italy, the doctor has the obligation to propose to the judge forms of legal protection for the patient if it is found that the patient cannot adhere to treatment. This is provided by Law No. 6/2004 which established the role of the Support Administrator who is in charge of protecting the interests of the 'person who is completely or partly lacking autonomy'.

If this obligation is not fulfilled, the treatment is regarded as an unlawful procedure regardless of the benefits, the efficacy and the need to treat the elderly patient. The doctor could be prosecuted for misconduct and the patient would be deprived of the protection provided by the law to safeguard the patient's rights.

We think that this work fills an important gap in the implementation of bioethical principles and Italian legal requirements in the clinical setting. Further investigation in this specific field of research is necessary, especially in light of the ethical and medico-legal implications.

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Conflict of interest

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