

Informed consent in elderly people: assessing the patient's decision-making capacity

Consenso informato al trattamento medico: valutazione della capacità decisionale del paziente anziano

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ABSTRACT

OBJECTIVE

Elderly patients are legally assumed to be competent to give consent to medical treatment. When patients are unable to make a decision on assenting or refusing treatment; if they cannot understand and remember the information provided, and/or cannot use that information when considering their decision, the decision-making capacity of the patient should be evaluated with specific clinical tools, since consent obtained from an incompetent patient is invalid. The clinical tool should be simple and easy to use, be replicable, and should require a short administration time and, possibly, no formal training.

MATERIALS AND METHODS

We have considered frequently used clinical screening methods for cognitive impairment, such as the MacArthur Competence Assessment Tool for Treatment (MacCAT-T), the Aid to Capacity Evaluation (ACE) and the Mini Mental State Examination (MMSE), to evaluate the decision-making capacity of the patient.

RESULTS

The MMSE is a very simple bedside clinical tool, does not require specific training, takes less than 10 minutes to complete, is objective and uses scores indicating decreasing cognitive

RIASSUNTO

OBIETTIVI

La capacità di un paziente anziano di prendere delle decisioni mediche deve essere considerata sempre valida, indipendentemente dall'età. Quando il paziente, però, non è in grado di accettare o rifiutare un trattamento, non può comprendere e ricordare le informazioni ricevute e/o non può utilizzare tali informazioni quando deve esprimere la propria decisione, è necessario valutare la sua capacità decisionale mediante strumenti clinici obiettivi, poiché il consenso ottenuto da un paziente privo di capacità decisionale non è legalmente valido. Lo strumento per la valutazione della capacità decisionale dovrebbe essere semplice e di facile uso, obiet-

tivo e replicabile; dovrebbe poter essere somministrato in breve tempo e, possibilmente, non richiedere alcun addestramento formale.

MATERIALI E METODI

Nel presente lavoro sono stati presi in considerazione i metodi di screening più frequentemente utilizzati per valutare la capacità decisionale del paziente: il MacArthur Competence Assessment Tool for Treatment (MacCAT-T), l'Aid to Capacity Evaluation (ACE) e il Mini Mental State Examination (MMSE).

RISULTATI

Il MMSE è uno strumento clinico di semplice utilizzo, non richiede una formazione specifica, può essere somministrato in meno di 10 minuti,

function. The scores range from 0 to 30: a MMSE score of 0 to 17 increases the likelihood of lack of capacity, a score of 18 to 23 indicates mild cognitive impairment, while a score of 24 to 30 significantly reduces the likelihood of incapacity.

CONCLUSIONS

The Mini Mental State Examination can be considered the clinical tool more suitable for the physician in the daily practice. In patients with a low MMSE score, suggesting likelihood of lack of capacity, it will be necessary that the consent to medical proce-

dures be granted by a surrogate decision maker, according to the laws and jurisdiction of the country involved.

KEY WORDS

- Elderly
- Decision-Making Capacity
- Aid to Capacity Evaluation (ACE)
- MacArthur Competence Assessment Tool for Treatment (MacCAT-T)
- Mini Mental State Examination (MMSE)

è un test obiettivo e, anche se non è stato creato specificamente per valutare l'incapacità, utilizza punteggi facilmente fruibili dal medico. Il punteggio va da 0 a 30: un punteggio MMSE da 0 a 17 si associa a elevata probabilità di incapacità decisionale; un punteggio da 18 a 23 indica un lieve deficit cognitivo, mentre il punteggio da 24 a 30 riduce significativamente la probabilità di perdita dell'autonomia decisionale.

CONCLUSIONI

Il Mini Mental State Examination può essere considerato lo strumento clinico più adatto per il medico nella pratica quotidiana. Nei pazienti con

un basso punteggio MMSE, che suggerisce la probabilità di mancanza di capacità decisionale, sarà necessario che il consenso alle procedure mediche sia concesso da un tutore legale o dall'amministratore di sostegno, secondo le leggi e la giurisdizione del paese coinvolto.

PAROLE CHIAVE

- Paziente anziano
- Capacità decisionale
- Aid to Capacity Evaluation (ACE)
- MacArthur Competence Assessment Tool for Treatment (MacCAT-T)
- Mini Mental State Examination (MMSE)

1. INTRODUCTION

Obtaining informed consent is a cornerstone of the practice of medicine, and every physician is legally and ethically obliged to seek consent from a patient before medical interventions.

The informed consent is the process by which patients agree to a medical procedure or treatment with regard to their health care. The process includes an appropriate discussion between the clinician and the patient, and covers all relevant aspects of the proposed treatment. Consent is valid if it is given voluntarily, by an appropriately informed and competent patient.

Appelbaum and Grisso defined decision-making capacity as the ability to understand relevant information and to appreciate the consequences of such a decision^[1]. In order to consent to a medical procedure, a patient must:

- receive accurate, meaningful, and relevant information regarding the nature and purpose of the treatment, as well

as the risks, benefits, and alternatives to the proposed therapy, including no treatment (informed element);

- be free from coercion (voluntary element);
- have medical decision-making capacity (competence element), that is the capacity to understand and communicate, the capacity to reason and deliberate, and the possession of a set of values and goals^[2].

In the process of obtaining the informed consent, it is critical to assess the patient's decision-making capacity in order to determine his/her ability to provide the consent. In the geriatric population, the most rapidly growing segment of the European population, assessing competence/capacity (*competence* is a term widely adopted in American legal writing and corresponds to the term *mental capacity* in British legal writing; in the text, they are used interchangeably) can be a complex task, and the physician needs

to understand whether the patient is able to take a medical decision and give the consent.

Every adult patient is legally assumed to be competent, however, in the clinical practice, failure to detect incompetence is quite common^[3,4]. Where any doubt exists, the capacity of the patient to give medical consent should be assessed using specific tools appropriate to assess decision-making capacity.

Concerning the medical/surgical/anaesthesia consent, the evaluation should be made by the physician responsible for the treatment. Consultation with psychiatrists, geriatricians and ethicists should be indispensable only in very complex cases or when mental illness is present, and participation in the decision taking process constitutes a burden.

In this article we will discuss the most appropriate and, possibly, the easiest way to assess patient's decision-making capacity especially in the elderly population.

2. MATERIALS AND METHODS

We have consulted PubMed (Medline), Google Scholar, and the Cochrane databases in search for original articles describing screening methods for the assessment of cognitive impairment in elderly patients.

Existing literature reviews on the topic were also considered as additional information. For this narrative review, we have considered the most frequently used clinical tools to evaluate the decision-making capacity of the patient, such as the MacArthur Competence Assessment Tool for Treatment (MacCAT-T), the Aid to Capacity Evaluation (ACE) and the Mini Mental State Examination (MMSE).

In the majority of the cases, elderly patients are able to reach reasonable risk-taking decision to the same degree than young adults^[7].

Many patients, however, may have no longer decision-making capacity because of learning disabilities, depression, brain injury and other forms of dementing illnesses affecting cognition^[9].

Sessums et al. performed a meta-analysis evaluating instruments to assess medical decision-making capacity for treatment choices, and found that less than 3% of healthy older adults lacked decision-making capacity, compared with 20% of persons with mild cognitive impairment and 54% of persons with Alzheimer disease^[4].

The assessment of decision-making capacity should be performed during the preoperative visit examination, and very often does not require specific evaluation^[4], provided that clinicians have implemented effective strategies to improve communication in the elderly.

Assessing decision-making capacity

There are no formal guidelines from scientific societies for the assessment of capacity to consent to treatment^[12], although wide variety of criteria for assessing competency have been suggested and investigated in the literature^[4,13]. To reliably identify capacity impairment, the assessment should integrate three components: information acquired from observing and talking to the patient; information acquired from talking with caregivers; information from the results of standardised tests.

How to manage the discussion with the elderly patient and caregivers

During the visit, the elderly patient is in an unfamiliar environment, and very often the underlying disease can lead to confusion and agitation. To improve the patient's perception, the visit should be performed in a room with adequate lightning and minimal distracting stimuli. It is necessary to emphasize that, in order to evaluate decision-making capacity, all reversible causes of incapacity should be removed, and correction of presumed sensory deficits should be made. Since understanding is a key step in the cognitive process leading to decision, every effort should be made to let the senior patient understand the medical information. Patients should be reminded to using their assistive devices (hearing aids, glasses, dentures) during the visit^[14].

THE USE OF STRUCTURED APPROACHES TO ASSESS THE ABILITIES IN ELDERLY PEOPLE CAN BE VERY HELPFUL FOR THE CLINICIAN

Informed consent in the elderly

Informed consent in elderly patients presents many ethical and legal challenges^[6]. The aging population is at risk of having cognitive impairment and therefore impaired decisional capacity. Cognitive ageing is difficult to define, hard to measure, and impossible to predict; however, diminished understanding of information in patients with older age is frequent and widely reported in the literature^[6]. Before disclosure of information, the patient should be assessed for his/her ability to understand the information, and communicate his/her wishes to the physician.

Capacity is influenced by a variety of factors, including situational, psychosocial, medical, psychiatric, and neurological factors^[9]. Lower educational level and physical illness strengthen the link between increasing age and impaired decision-making capacity^[9]. Some patients lack capacity for specific periods of time, such as when critically ill, but not permanently. Decision-making capacity may be mostly compromised by incipient dementia; patients with amnesic mild cognitive impairment and patients with Alzheimer's disease have high rates of incompetence with regard to such a decisions^[4,10,11].

When reversible problems interfere with the informed consent process, physicians are ethically obliged to try to reverse or mitigate these factors. Obstacles, such as pain, undue anxiety, and language barriers should be relieved. When fear or anxiety appear to interfere with ability to process the information during the visit, the presence of a known and trusted confidant or adviser (e.g., family member, caregiver) may improve the patient's decision-making capacity.

There might be communication difficulties, due to level of education, hearing or visual impairment (that affect communication even when cognition is intact), or expressive aphasia. Clinicians need to explain the procedure repeatedly, speaking more slowly/louder and answering all questions. Simple measures that can improve understanding include disclosure of information using simple and direct language; giving information in small units; using assessment methods that are less dependent on verbal expression; using a variety of novel formats (e.g., storybook, video) and procedures (e.g., use of health educators, quizzing subjects, multiple disclosure sessions) to improve understanding of the medical information^[6].

In clinical practice, mental capacity is presumed, unless the patient shows very obvious signs of a mental or cognitive disorder. Forms of dementing illnesses affecting cognition can be suspected when patients reveal impaired fluency of language, are vague with dates and sequence of events, repeat phrases, or have a tendency to dwell distant events^[15].

Patients with loss of interest, poor concentration, forgetfulness, negative outlook with feelings of hopelessness, and diminished capacity for enjoyment can

suffer depression which results in lesser cognitive capacity and, for patients with diminished but not permanently impaired cognitive capacity, participation in the decision taking process constitutes a heavy burden. Many patients with some degree of mental impairment are still capable of participating in medical decision-making and should be treated using their will. Asking the patient to rephrase the information received (e.g., plan and risks of the procedure) can help assess capacity; however, interviews, formal algorithm and rating scales have been devised to assess capacity for cognitive assessment^[16], and the use of a structured approach to assess decision-making capacities can be very helpful.

Cognitive assessment

Cognitive assessment may involve examination of higher cortical functions, particularly memory, attention, orientation, language, executive function (planning activities), and praxis (sequencing of activities). An ideal clinical cognitive assessment tool should be brief and reliable, and facilitate documentation of the four capacity abilities: understanding the information regarding the proposed treatment and its risks and benefits, appreciating treatment methods and their consequences, reasoning about the different treatment options and communicating a choice^[4,17]. Table I describes these four criteria and how they can be assessed^[2].

Understanding

The patient needs to recall conversations about treatment, to make the link between causal relationships, and to process probabilities for outcomes. He/she must understand the known risks and benefits of the treatment and its alternative. Problems with memory, attention

span, and intelligence (capability to understand) can affect the understanding.

Appreciation

The patient should be able to appreciate his/her clinical situation, his/her illness, treatment options, and likely outcomes as things that will affect him/her directly. A lack of appreciation usually stems from a denial based on lack of capability to understand, or emotion, or a delusion that the patient is not affected by this situation the same way and will have a different outcome.

Rationalization or reasoning

The patient needs to be able to weigh the risks and benefits of the treatment options presented in order to come to a conclusion in keeping with his/her goals and best interests, as defined by his/her personal set of values. The patient must demonstrate the ability to both ask and answer appropriate questions relating to the decision. Rationalization/reasoning often is affected in psychosis, depression, anxiety, phobias, delirium, and dementia.

Communication/expressing a choice

The patient needs to be able to express a treatment choice, and this decision needs to be stable enough for the treatment to be implemented. Changing the decision in itself would not bring a patient's capacity into question, so long as the patient is able to explain the rationale behind. Frequent changes in the decision-making, however, could suggest underlying psychiatric disorders or extreme indecision, which could bring capacity into question.

The use of structured approaches to assess these abilities can be very helpful for

the clinician, and various interviews and rating scales have been devised to assess capacity, many of which focus on these four (or similar) dimensions (**table I**)^[4,12,18].

Clinical tools to assess capacity

Over the year, several clinical tools have been developed to assess decisional capacity to consent to medical treatment^[4,13,18]. There has been ongoing debate regarding competence assessment, and to-date, the quest for a simple neuropsychological instrument to screen patients for impaired capacity has not yielded consistent findings.

MacArthur Competence Assessment Tool for Treatment

In a review describing structured assessments of capacity in adult patients, Dunn et al. identified 23 instruments, 15 of which could be suitable for assessing capacity to consent to medical treatment^[18]. The authors demonstrated that each instrument has limitations, and as a gener-

al recommendation they suggested, as best choice, the MacArthur Competence Assessment Tools for Treatment (MacCAT-T), given the comprehensiveness and the supporting psychometric data^[18].

The MacCAT-T may provide reliable and valid estimates of patients capacities^[19]. The MacCAT-T is a semi-structured interview that takes approximately 20 min for clinicians with experience with the format^[12].

The MacCAT-T is used to assess the four major abilities related to competence to consent to treatment, and assists in the detection of inadequacies in any of the four areas (**table I**)^[19]. The MacCAT-T has been validated in a broad population. It is probably one of the most clinically useful tools currently available, and is among the few instruments for which extensive training materials are available.

It is designed not as a stand-alone tool for capacity, and is supposed to be used in conjunction with clinical assessment. Unfortunately, the MacCAT-T tool does not give a global rating, lacks of a pre-

termined cutoff separating capacity and incapacity and appears difficult to use and time-consuming^[11].

Aid to Capacity Evaluation

Sessums et al. searched for a valid, reliable, and clinically useful tool for assessing and documenting patient’s capacity and concluded that the Aid to Capacity Evaluation (ACE) instrument is the best evaluation tool, because it is the only instrument evaluated against a *gold standard* with consistent correlation with validation studies and robust test characteristics^[4]. The purpose of the Aid to Capacity Evaluation (ACE) is to help clinicians systematically estimate capacity when a patient needs to take a medical decision^[20]. The ACE is based on the actual decision the patient is facing, uses the patient’s medical situation and diagnosis or treatment decision.

The ACE is a structured interview that assess understanding of the problem, treatment proposed, treatment alternatives, the option to refuse treatment, possible

Table I Relevant criteria for decision-making capacity during patient assessment (modified from Grisso and Appelbaum) ¹⁹				
Component	Patient’s role	Physician’s approach	Sample questions	Impaired in
Understanding	Recall information, link causal relationships, process general probabilities	Encourage patient to paraphrase his/her view of the information	Can you tell me: how you view the current situation? The possible benefits/risks of the treatment?	Problems with memory, attention span, intelligence
Appreciation	Identify illness, treatment options, and consequences of treatment options	Ask patient to describe the disease, the proposed treatment, and likely outcomes	What do you believe is wrong with your health? What treatment do you think would help? What other options do you have?	Delusional disorder or pathologic levels of distortion or denial
Rationalization	Weigh risks and benefits to come to a conclusion in keeping with patient’s goals	Ask the patient to compare risk vs benefits of the proposed treatment and alternatives	What made you choose option “A”? Why do you think opinion “A” is better than option “B”?	Depression, psychotic thought disorder, anxiety, phobia, delirium, dementia
Communication	Express a treatment choice	Ask patient which treatment, option he/she prefers	Have you decided whether to get “A” or “B” treatment?	Psychiatric disorders, pathological indecision

consequences of the decision, and the effects on the final decision of an underlying mental disorder (major depression and psychosis). Based on the answers, the examiner gives an overall impression of “definitely capable”, “probably capable”, “probably incapable”, or “definitely incapable”^[20]. The Aid to Capacity Evaluation can be performed in less than 30 minutes^[4], is available for free online (http://www.jcb.utoronto.ca/tools/ace_download.shtml, accessed July 2017) and includes training material and a manual that provides objective criteria for scoring responses.

Mini Mental State Examination

The Mini Mental State Examination (MMSE) tool is a brief bedside screening test of patient’s cognitive function, and has been found to correlate with clinical judgments of incapacity^[3,21]. The MMSE is designed to be administered by any clinician, including physicians or nurses,

and may be administered by trained lay interviewers.

The MMSE is a well validated, 30 points cognitive test that comprises 11 items, does not require formal training, and takes less than ten minutes to complete. The scores range from 0 to 30, with lower scores indicating decreasing cognitive function: specifically, a MMSE score of 0 to 17 increases the likelihood of lack of capacity, a score of 18 to 23 indicates mild cognitive impairment, while a score of 24 to 30 significantly reduces the likelihood of incapacity^[20]. The MMSE, corrected for the level of education, can be used as a very easy screen for identifying patients at the high and low ends of the range of capacity, especially among elderly persons with some degree of cognitive impairment^[10,22].

The MMSE quantitatively assesses the severity of cognitive impairment, and documents cognitive changes occurring over time^[23]. The MMSE test does not

address any specific aspects of informed consent, such as understanding or choice; it was not developed for assessing decision-making capacity, however it has been compared with expert evaluation for assessment of capacity and the test performs reasonably well, particularly with high and low scores^[10]. The MMSE can be used as a very simple screening test, and for any patient with MMSE below 24 a combination of the MMSE and a brief question based interview (such as the ACE) may be sufficient to determine decision-making capacity^[4,24]. Copyright protection is now enforced, and the Mini Mental State Examination must be purchased from the publishers.

The Administration and Scoring Manual contains detailed information about administration, scoring, and choosing which version of the MMSE to use (<http://www.parinc.com>, free training on-line, accessed July 2017).

3. CONCLUSIONS

Any physician should be familiar with how to assess capacity, and the selection of the right assessing instrument depends on the context in which it is to be used. Decisions about capacity by the physicians are often made in the absence of any documented assessment of cognition or other objective evidence that could support their decision, in the event of dispute. Determination of capacity is a function for which most physicians have little experience and training. Although the clinician does not need to make “definitive” capacity determinations, he/she needs to discriminate between patients able to consent to medical treatment and patients who require further evaluation or remediation.

We think that MMSE can be the easiest choice to use in the daily practice to assess capacity to consent to medical treatment for elderly patients^[25].

The MMSE is simple to use, is objective because it is based on fixed scores, it allows the evaluation of patients who are unable to complete more detailed cognitive tests, its administration takes only few minutes (<10 min), it is easily replicable, and has been translated in several languages. Most importantly, it does not require a specific training of personnel and provides a score easily exploitable by the physician.

In cases of low MMSE score, suggesting likelihood of lack of capacity^[20], the informed consent to be valid must be provided by a legal representative. Individuals who are likely to lose capacity may assign a surrogate who will take on an increasingly active role in decision making, as the subject declines. In presence of advance directives indicating a treatment choice, the person designed by the patient can make a decision on his/her behalf. In absence of advance directives, a substitute is designed according to local law and jurisdiction^[25]. ■

CONFLICT OF INTEREST

The authors confirm that there are no known conflicts of interest associated with this publication.

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Long Abstract

INTRODUZIONE

Il consenso informato è il processo attraverso il quale i pazienti accettano una procedura medica o un trattamento riguardante la loro salute. Il processo include una discussione approfondita tra il clinico e il paziente e copre tutti gli aspetti rilevanti del trattamento proposto. Il consenso è valido se è dato volontariamente da un paziente adeguatamente informato e in grado di comprendere. Nella popolazione geriatrica la valutazione del-

la competenza/capacità può essere un compito complesso e il medico deve poter capire se il paziente è in grado di prendere una decisione medica e dare il proprio consenso.

MATERIALI E METODI

I database PubMed (Medline), Google Scholar e Cochrane sono stati utilizzati per cercare articoli originali che descrivono i metodi di screening per la valutazio-

ne del deterioramento cognitivo nei pazienti anziani. Anche le revisioni della letteratura esistenti sull'argomento sono state considerate come informazioni aggiuntive. In questa revisione della letteratura, sono stati considerati i metodi di screening più frequentemente utilizzati per valutare la capacità decisionale del paziente: MacArthur Competence Assessment Tool for Treatment (MacCAT-T), Aid to Capacity Evaluation (ACE) e Mini Mental State Examination (MMSE).

DISCUSSIONE

Il consenso informato nei pazienti anziani presenta molte sfide etiche e legali. L'invecchiamento dell'individuo comporta il rischio di decadimento cognitivo e quindi di una capacità decisionale più o meno compromessa. L'invecchiamento cognitivo è difficile da definire e da misurare e impossibile da prevedere; tuttavia, una ridotta comprensione delle informazioni in pazienti con età avanzata è frequente e ampiamente riportata in letteratura. Non ci sono linee guida ufficiali delle società scientifiche per la valutazione della capacità di consenso al trattamento. Durante la visita, il paziente anziano si trova in un ambiente non familiare e molto spesso la sua malattia può portare a confusione e agitazione.

CONCLUSIONI

Tutti i medici dovrebbero avere le competenze per individuare lo strumento di valutazione più adatto allo specifico contesto in cui deve essere utilizzato. L'MMSE potrebbe essere considerata la scelta più semplice da utilizzare nella pratica quotidiana per valutare la capacità di consentire il trattamento medico per i pazienti anziani. L'MMSE è semplice da usare, è oggettivo perché basato su punteggi fissi, consente la valutazione di pazienti che non sono in grado di completare test cognitivi più dettagliati, la sua somministrazione richiede solo pochi minuti (<10 minuti), è facilmente replicabile ed è stato tradotto in diverse lingue. Soprattutto, non richiede una formazione specifica e fornisce un punteggio facilmente fruibile dal medico.

SIGNIFICATO CLINICO

Ogni paziente adulto è considerato legalmente competente; tuttavia, nella pratica clinica ci si trova sovente a dover valutare la capacità decisionale dei soggetti. In caso di dubbio, la capacità del paziente di fornire il consenso medico dovrebbe essere valutata utilizzando strumenti specifici appropriati, funzione per la quale la maggior parte dei medici ha poca esperienza e formazione. Sebbene il clinico non debba effettuare determinazioni di capacità "definitive", deve avere le competenze per discriminare tra i soggetti in grado di prendere delle decisioni mediche e quelli che richiedono la messa in atto di ulteriori procedure secondo le leggi e la giurisdizione del paese coinvolto.