Geriatricians' Standpoint of the Informed Consent Process among Patients with Alzheimer's Disease: The Lebanese Context

Mohammed Ali Fakhro (✉ m.fakhro@lgu.edu.lb)

Lebanese German University

Research Article

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Abstract

Background

Despite the existence of laws that ensure that patients' capacity to consent is assessed systematically, many gray areas remain with that regard. As dementia progresses, some patients lose their capacity to make decisions. The aim was to characterize Lebanese geriatricians' perspectives about decision-making capacity (DMC) of their patients with Alzheimer's disease (AD). Moreover, to propose an algorithm for a reliable, comprehensive, and valid assessment of DMC.

Methods

A cross-sectional descriptive study was designed to empirically collect data via an e-survey. Accordingly, a comprehensive list of geriatricians was provided by the Lebanese Order of Physicians. Geriatricians were approached via a phone call, to provide them with study-specific information. Those who accepted to participate received a link to the study's survey via an e-mail.

Results

Among the eligible geriatricians, 75% had successfully completed the e-survey, with a mean of 14.7 ± 9.6 years of experience. More than half of the geriatricians failed to recognize that assessing the patients' DMC is an integral component of the informed consent (IC) process. Yet, 88.9% assessed the DMC of their patients with AD using different modalities. However, the majority were unable to clearly justify their judgment of DMC based on the tools they have selected.

Conclusion

Lebanese geriatricians have demonstrated a poor understanding of the concept of autonomy and the need for the DMC assessment as part of the IC's process. Moreover, they were unable to select adequate tools to assess and judge the DMC of their patients with AD.

Background

The decline in the global fertility rates, combined with the increase in life expectancy is causing the global population to age rapidly¹. Alzheimer's disease (AD) is a degenerative brain disease and the most common cause of dementia among older adults². According to Alzheimer's Disease International organization 2015's statistics, an estimated 46.8 million people worldwide are living with dementia, and this number will almost double every 20 years to reach 75 million by 2030.

Autonomy, also known as respect for persons, is a fundamental ethical principle in healthcare³. Autonomy is "a person's ability and opportunity to make decisions relating to his/her own wishes"⁴, or "an act of self-determination exercised by a competent person"⁵. As determined by the Belmont's report, the autonomy principle requires three elements to validate the process of informed consent (IC): (1) disclosure of sufficient relevant information for decision-making, (2) patient's comprehension, and (3) voluntariness³.

As dementia progresses, it leads to several functional and cognitive alterations, making patients vulnerable, and reducing their quality of life⁶. In practice, one of the most significant components of vulnerability among these patients is the loss of the decision-making capacity (DMC)^{6,7}. Evaluation of the patients' capacity to consent to either a treatment or participating in a trial, is a dilemma that commonly emerges during the patients' management process⁸. It is critical to carefully assess the patients' DMC since the loss of this capacity can affect their autonomy, what have considerable legal or ethical consequences⁶.

The "comprehension" element of the informed consent, requires an adequate understanding of the provided information³, and a capacity to make a decision⁹. It is noteworthy that even though capacity is dependent on cognition, it is not the same as cognition¹⁰. For instance, high scores on Mini-Mental State Examination (MMSE) may indicate a better decision-making ability, however, a normal MMSE does not rule out impaired capacity¹⁰. It would be preferable to use the MMSE in conjunction with other tests to improve the patient's comprehension of the tasks¹⁰. Furthermore, cognitive function and decisional ability might vary with

time. This fact warrant consideration since it might affect the judgment of DMC^{10,11}. Therefore, during the evaluation process of patients with dementia, it is important to assess their cognitive capacities, and decisional abilities, at a specific time and context⁹.

DMC is evaluated through a two-steps process. At first, the clinician assesses a person's decisional abilities, then judges the patient's capacity to take a specific decision (e.g., consent)¹⁰. The consensus is that DMC is based on four different aptitudes, which are, the ability to choose, understand, appreciate, and reason. Understanding reflects the ability to know the meaning of disclosed information. Appreciation describes the ability to recognize that that information applies to the person. Reasoning describes the ability to compare and describe alternative options and their consequences. Choice describes the ability to consistently select a decision⁶. It is noteworthy that no single test exists that could be considered as the gold standard for DMC assessment². However, the MacArthur Competency Assessment Tool (MacCAT) is the most commonly used and the best validated semi-structured interview to assess the DMC². Moreover, MacCAT assesses a person's capacity to make a choice, understand, appreciate, and reason².

An objective and comprehensive evaluation of patients with dementia eliminates the doubt as to the validity of the consent and ensures that the inclusion of subjects to clinical trials or the administration of treatment is ethical and respectful of their rights⁶.

Geriatricians' standpoint of the application of the ethical principle of autonomy among persons with AD was not yet studied in the Lebanese context. Therefore, the primary aim of this study was to investigate the geriatricians' perspectives of the informed consent process among their patients with AD. The secondary aim was to propose an algorithm for a reliable, comprehensive, and systematic assessment of the DMC.

Methods

Design

In order to serve the study's aims, a cross-sectional descriptive e-survey was designed for data collection. Ethical approval was obtained from the Lebanese University institutional review board (IRB). For confidentiality reasons, all collected data (logged, analysed) were kept in a concealed place, and reviewed only by the principal investigator.

Participants and selection criteria

It is noteworthy that there is a major deficit in the number of physicians specialized in Geriatrics in Lebanon¹². Moreover, Lebanese geriatricians who are members of the Lebanese Society for Geriatric Medicine (LSGM), constituted the target population of this study. Only geriatricians who worked with patients with AD either clinically or through research and practicing within Lebanese territories were invited to participate in this study (Figure 1).

Procedure

Google Forms platform was utilized to create an e-survey to collect the geriatricians' data. Furthermore, contact information about geriatricians, members of the LSGM, was requested and obtained from the Lebanese Order of Physicians in Beirut.

Each member of the Society was approached via a phone call, where study-specific information was delivered. Those who accepted to participate received a link to the study's survey via an e-mail. Moreover, follow-up phone calls were conducted twice a week, over a whole month, to make sure that the geriatricians completed the survey.

Geriatricians' implied consent was obtained with the completion of the survey. It is noteworthy, that geriatricians' participation was fully voluntary and they had the freedom to withdraw from the survey whenever they wanted to.

The survey started with a brief introduction to the study. The introduction described the current situation regarding aging and the increased prevalence of dementia among the elderly. It also drew attention to the ethical issues that might arise in treating with AD, or by including them as potential participants in research studies. The aim of the study followed in the next part. The remaining

section of the survey included: (a) section one, socio-demographic data; (b) section two, autonomy and IC related information; (c) section three, DMC.

Section one: socio-demographic data.

This section intended to collect socio-demographic data related to the geriatricians, such as their years of experience, their gender, and their area(s) of practice [(a) academic, (b) research, (c) clinical, (d) administrative, or (e) consultation]. The last question was related to the clinical/research practice setting (s) [(a) university-hospital, (b) private clinic, (c) or specialized geriatric center].

Section two: autonomy & informed consent.

This section was designed to capture the geriatricians' understanding of the ethical concept of autonomy. Their perspectives of the IC process were also evaluated in this section through the provided questions (Table S1).

Section three: decision-making capacity.

At the beginning of this section, a clear distinction between both of the concepts of capacity and competency was provided. The term "capacity" was defined as referring to "a person's performance on measures of decision-making abilities"². Capacity was also defined as "a person's ability to make a particular decision at a specific time or in a specific situation"¹⁰. The term "competency" was defined as being "the judgment that a person's capacity is adequate to make the decision in question"², and by "a legal capacity that is determined by a judge in a court, where it is a threshold requirement imposed by society for an individual to retain decision-making power in a particular activity or set of activities".

Three questions were designed to investigate the geriatricians' standpoint regarding the DMC's assessment in this section (Table S2). If the geriatrician answered by "No" on the first question (Table S2), he/she was systematically directed to submit their answers and finish the survey.

Statistical Analysis

Data were analyzed using the Statistical Package for the Social Sciences (SPSS) Version 21.0 for Windows. Descriptive statistics (mean, standard deviation, proportions) were calculated for the geriatricians' socio-demographic, autonomy and informed consent, and DMC resulting data.

Results

Twelve geriatricians successfully fulfilled the selection criteria. However, only nine agreed to participate. The majority of geriatricians who participated in this study were males (66.7%). The mean of geriatricians' experience recorded was 14.7 ± 9.6 years. More than half (55.6%) of the geriatricians followed mixt areas of practice (academic + clinical + research + administrative + consultation) (Figure 2). It's noteworthy that all geriatricians who participated in the study had an initial specialization in fields other than the geriatrics (internal medicine, family medicine, endocrinology, and metabolism). They completed afterwards their training in gerontology, and eventually joined the LSGM.

Most of the geriatricians (66.6%) recruited for this study worked in a mixt setting. Among the total percentage of the geriatricians, 44.4% were working in a university hospital, specialized geriatrics center, and private clinic at the same time (Figure 3).

Less than half (33.3%) of the geriatricians were able to correctly identify the statements that reflect the principle of autonomy. Among those who failed to do so, the majority (75%) didn't recognize that in case of no-emergency, and when the patient's decision-making incapacity was confirmed, decision-making is taken by a surrogate defined by a "person of trust" who reflect the patient's own wishes. All of the geriatricians agreed that the process of acquiring the IC among patients with AD is a must in the research or clinical settings. Yet, no one successfully identified all the necessary criteria that constitute the IC process (Question 4, Table 1), and only 66.7% knew that legislation for IC exists in Lebanon.

Moreover, more than half of the geriatricians (66.67%) failed to recognize that "a confirmation of a patient's competency to make a decision", is required by the process to IC. However, the majority (88.9%) assessed the DMC among their patients with AD, and they

have used only one method in doing so (Table 3). Furthermore, the geriatricians had different considerations to determine whether or not their patients with AD had adequate capacity. Among those who used the MMSE test (37.5%) (Table 3), they have selected different cut-offs to judge their patient as having the adequate DMC (score above 20; 24; and 25). The remaining geriatricians didn't have the ability to clearly justify their judgment (Table 3).

Discussion

Ethically, it is every person's right to make their own decisions. Embedded in this right, is the freedom to make healthcare-related decisions. The imposition of limits is a complicated issue, particularly in healthcare, where the practitioner must demonstrate whether or not the patient has the adequate capacity to make the decision in question (i.e. consent to treatment or research participation)¹³.

The findings of this study revealed that less than half of the geriatricians were able to correctly identify the statements that reflect the principle of autonomy. Among those who failed to do so, the majority didn't recognize that in case of no-emergency and when the patient's decision-making incapacity was confirmed, decision-making is done by a surrogate defined by a "person of trust" that reflect patient's own wishes. This was similar to a study conducted by Tarabey et al. (2018)¹⁴, where psychiatrists had a poor understanding of the concept of autonomy.

All geriatricians in this study agreed on the need for IC among patients with AD in both research or clinical settings. However, no one was able to denote all the necessary criteria required by the IC's process. This fact was supported by the findings of a Lebanese national survey conducted by Abou-Mrad (2008)¹⁵ who highlighted the absence of the informed consent process in around 83% of Lebanese hospitals. It is noteworthy that only one participant knew that disclosing adequate information to patients, is directly linked to the process of IC. Appelbaum (2007)¹⁶ has stated that physicians must prove good communication skills in ways that patients understand, and not just tell patients about a proposed procedure or therapy and its risks and benefits. Furthermore, not all of the geriatricians (66.7%) were knowledgeable of the fact that legislation exists in Lebanon regarding the process of IC (Law 574/2004, patients' rights, an informed consent)¹⁷. Moreover, more than half of the geriatricians (66.67%) failed to recognize that "a confirmation of a patient's competency to make a decision", is required by the process to IC. Yet, all but one of the geriatricians assessed the DMC of their patients with AD. This reveals a severe mismatch between common knowledge and common practice.

Assessing for DMC is used to determine the extent of an individual's ability to make a decision¹⁸. Therefore, making a judgment based on only one assessment method (i.e. MMSE) would be erroneous¹⁸. However, the study's findings showed that all of the geriatricians relied on only one method to assess the DMC, either a tool or their clinical experience. For instance, some had chosen the MMSE and had selected different cut-offs (score above 20; 24 and 25) to judge that their patients possess an adequate DMC. Appelbaum (2007)¹⁶ stated that when scores of less than 19 were presented, the MMSE has been found to correlate with clinical judgments of incapacity. However, studies vary in suggesting that scores of 23 to 26 or higher are strongly indicative of competence¹⁶.

Regarding the final judgment of the DMC, geriatricians were unable to make a clear judgment when they used either of MacCAT-CR/MacCAT-T, UBACC, or their clinical experience solely. This is justified by the fact that the MacCAT tool does not establish a cut-off score for capacity, and the validity of the final judgment will depend on other clinical variables combined with the clinician judgment¹⁶. Moreover, the UBACC seems interesting for routine practice due to its simplicity, relevance, and applicability in older patients¹⁸. Moreover, it is potentially useful for screening purposes and might identify the need for a more comprehensive decisional capacity assessment, rather than come up with a final determination of capacity⁶. Similarly, the sole use of clinical expertise to make a judgment of the patients' DMC was shown to be imprecise¹⁸.

Algorithm for the decision-making capacity assessment process

The findings of this study set a motivation to propose a set of recommendations to improve and standardize the assessment of DMC. The decision of an impaired DMC should rely on the severity of the cognitive impairment, context, decision that needs to be

taken, and risk-benefit ratio of the various options¹⁰. Accordingly, in practice, this involves subjecting patients who are facing more serious procedures and therapies, to a more rigorous process of DMC testing (Table 4).

Strict guidelines may promote the principle of justice through ensuring consistency, meaning, they allow treating similar cases in the same way by implementing a process that results in a reliable assessment of DMC⁹. Yet, these guidelines can impede the clinician's ability to tailor adequate care based on the patient's personal circumstances, values, and medical history⁹. Adopting policies that are too flexible, that rely solely on the clinician experience and personal judgment, tend to compromise on reliability and with it the ethics of justice⁹.

Regarding cognitive testing, the Montreal Cognitive Assessment (MoCA) tool outmatched the MMSE due to its high sensitivity in the early detection of dementia, mild cognitive impairment, and AD^{20,21}. MoCA evaluates different types of cognitive abilities^{20,21}. Furthermore, when a cut-off score (23) was used, both sensitivity and specificity were excellent (0.96 and 0.95, respectively)²². Substantive criticism takes place when the assessment of DMC relies exclusively on the patients' cognitive processes while discarding their emotions since emotions often provide a valid reason for action²³. Furthermore, strategies to alleviate a patient's fear and anxiety should be considered, since it might interfere with his/her ability to attend to and process information. Therefore, introducing a known and trusted confidant or adviser to the DMC process, may help the patient in making an educated decision¹⁶.

It is noteworthy that the "Understanding" capacity is affected the earliest, followed by reasoning and appreciation while making a "choice" is preserved the longest¹⁸. The simplified three-item questionnaire (cut-off of 2.5), showed a sensitivity of 100% and specificity of 77.3% when compared to MacCAT-CR on the testing of "Understanding subscale". This finding suggests that this tool might allow healthcare professionals to screen for those with an understanding deficit, which will save time and requires less training than the MacCAT tool^{18,24}.

When feasible, it is suggested that patients are assessed several times before labeling them as lacking DMC¹³. However, if despite such efforts, the patient's incapacity to make a decision persists, a proxy must be sought¹⁶. In emergency situations, physicians can take a decision on behalf of the patient, under the presumption that a reasonable person would have consented to such treatment¹⁶.

It is the clinician's duty to ensure that contextual and personal factors are taken into consideration, to enable the patients to make the appropriate decisions. This includes: spending time educating patients, and their families; ensuring that patients adequately understand the disclosed information; alleviating patients' anxiety; and taking into account lucid intervals, financial coverage¹¹, and any disease that may interfere with DMC.

Clinical experience combined with neuropsychological testing (including the executive function), and a capacity testing tool, in a particular context, and weighed against the benefit to the risk ratio, should be considered to optimise the DMC assessment process. If despite such efforts, the patient's decisional incapacity persists, a proxy must be sought. Finally, in emergency situations, physicians can provide the appropriate decision that would warrant the patient's best interest.

Disclosure Statement

Abbreviations

Alzheimer's disease (AD)

Decision-making capacity (DMC)

Informed consent (IC)

Mini-Mental State Examination (MMSE)

Mild cognitive impairment (MCI)

Montreal Cognitive Assessment (MoCA)

MacArthur Competency Assessment Tool (MacCAT)

University of California, San Diego Brief Assessment of Capacity to Consent (UBACC)

Institutional review board (IRB).

Consent for Publication

Not applicable.

Availability of Data and Material

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Competing Interests

The author declares that he has no competing interests.

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Tables

Table 1 Questions related to section two: autonomy & informed consent.

Question 1	Which among the following statement(s) reflect on the principle of "Autonomy"?
	☐ An act of self-determination exercised by a competent person. An ability and opportunity to make decisions related to the patient's own wishes.
	☐ In the case of confirmed incompetence, and no emergency, the decision is taken by a legal surrogate defined by a "person of trust" that reflect the patient's wishes.
	☐ In the case of confirmed incompetence, and no emergency, the decision is taken by the treating Physician.
	☐ None of the above.
Question 2	Is the process of "Informed Consent" of patients with AD, considered a must in the research or clinical settings?
) Yes	
) No	
Question 3	Does a Legal text exist in Lebanon regarding the process of "Informed Consent"?
) Yes	
) No	
Question 4	Select the necessary element(s) as required by the process of "Informed consent".
) Adequate disclosure of information.	
) A context free of undue influence, allowing the patient to make a voluntary choice.	
) Confirmation of a patient's competency to take a decision.	
Table 2 Questions related to section three: decision-making capacity.	
Question 1	Do you test for decision-making capacity (DMC) among your patients with AD?
) Yes	
) No	
Question 2	How do you measure the DMC of your patients with AD?
) Mini-mental state examination (MMSE)	
) MacArthur Competency Assessment Tool for clinical research or Treatment respectively (MacCAT-CR or MacCAT-T)	
) Other (narrative answer)	
Question 3	How do you determine if your patient with AD has an adequate decision-making ability based on the above scores of the DMC testing?
) Narrative answer	

Table 3. Representation of the decision-making tools used by the Geriatricians in percentage.

Tool	Percentage (%)
UBACC	25
MacCAT-T	12.5
MMSE	37.5
Clinical judgment	25

Table 4. Sliding scale approach grading. Modified from Drane (1985).

	Decisions	Competency
Standard 1	1.Consent where risk/benefit balance is favorable	LOW
	2.Refusal where risk/benefit balance is unfavorable	
Standard 2	Consent or refusal where risk/benefit balance is unclear	MODERATE
Standard 3	1.Acceptance where risk/benefit balance is unfavorable	HIGH
	2.Refusal where risk/benefit balance is favorable	

Figures

Figure 1

Flowchart representing the recruitment pool.

Figure 2

Distribution of the areas of the practice that are occupied by the geriatricians.

Figure 3

Distribution of the settings where the geriatricians work.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [STROBEchecklistcrosssectional.doc](#)
- [Table1.docx](#)
- [Table2.docx](#)