Consent and Capacity Assessment

The patient has a right to choose his/her treatment; however, the physician also has a duty of care towards his patient while following the principle of first do no harm or *primum non nocere*. The answer to this conundrum lies in the principle of informed consent.

TYPES OF CONSENT

The meaning of the word consent as described by the Oxford dictionary is "permission for something to happen or agreement to do something". But, in the context of a doctor-patient relationship, consent means the grant of permission by the patient on his volition for an act such as a diagnostic, surgical or therapeutic procedure to be carried out by the doctor[1].

When a patient enters a doctor's consultation room and relates his complaints to the doctor, this is implied consent for examination and routine diagnostic tests, which is implied by action. In circumstances such as arranging an appointment with a doctor, keeping the appointment, answering questions relating to history and to submit without objection to physical examination, consent is clearly implied. Express consent (verbal/written) is that which is declared by the patient. But, for complex diagnostic investigations and interventional procedures, which involve risks, a written informed consent is necessary[2].

Informed consent is not just an ethical obligation, it is also a legal pre-requisite today. Patient autonomy constitutes the legal and ethical basis for informed consent, which gives the patient the right to make decisions about their health based on the information given. Failure to give all the necessary facts to the patients regarding their treatment is a violation of their rights. Not taking consent is therefore a gross negligence.

Battery is any act, which is done without permission. It comprises "unpermitted, unprivileged, intentional contact with another's person". Evidence of a bodily harm is not mandatory, "the intended contact itself is the harm"[3]. Hence, battery is a punishable offence[2].

PRINCIPLES OF CONSENT

The three judges' Constitution Bench of the Supreme Court summarized the principles relating to consent in the landmark judgment on consent in the matter of Samira Kohli versus Dr Prabha Manchanda & Anr on 16 January, 2008.

"(i) A doctor has to seek and secure the consent of the patient before commencing a 'treatment' (the term 'treatment' includes surgery also). The consent so obtained should be real and valid, which means that: the patient should have the capacity and competence to consent; his consent should be voluntary; and his consent should be on the basis of adequate information concerning the nature of the treatment procedure, so that he knows what is consenting to.

(ii) The 'adequate information' to be furnished by the doctor (or a member of his team) who treats the patient, should enable the patient to make a balanced judgment as to whether he should submit himself to the particular treatment as to whether he should submit himself to the particular treatment or not. This means that the Doctor should disclose (a) nature and procedure of the treatment and its purpose, benefits and effect; (b) alternatives if any available; (c) an outline of the substantial risks; and (d) adverse consequences of refusing treatment. But there is no need to explain remote or theoretical risks involved, which may frighten or confuse a patient and result in refusal of consent for the necessary treatment. Similarly, there is no need to explain the remote or theoretical risks of refusal to take treatment which may persuade a patient to undergo a fanciful or unnecessary treatment. A balance should be achieved between the need for disclosing necessary and adequate information and at the same time avoid the possibility of the patient being deterred from agreeing to a necessary treatment or offering to undergo an unnecessary treatment.

(iii) Consent given only for a diagnostic procedure, cannot be considered as consent for therapeutic treatment. Consent given for a specific treatment procedure will not be valid for conducting some other treatment procedure. The fact that the unauthorized additional surgery is beneficial to the patient, or that it would save considerable time and expense to the patient, or would relieve the patient from pain and suffering in future, are not grounds of defence in an action in tort for negligence or assault and battery. The only exception to this rule is where the additional procedure though unauthorized, is necessary in order to save the life or preserve the health of the patient and it would be unreasonable to delay such unauthorized procedure until patient regains consciousness and takes a decision.

(iv) There can be a common consent for diagnostic and operative procedures where they are contemplated. There can also be a common consent for a particular surgical procedure and an additional or further procedure that may become necessary during the course of surgery.

(v) The nature and extent of information to be furnished by the doctor to the patient to secure the consent need not be of the stringent and high degree mentioned in Canterbury but should be of the extent which is accepted as normal and proper by a body of medical men skilled and experienced in the particular field. It will depend upon the physical and mental condition of the patient, the nature of treatment, and the risk and consequences attached to the treatment."

COMPONENTS OF A VALID CONSENT

A valid consent must fulfil the following three essential components:

- Disclosure: Provision of relevant information by the clinician and its comprehension by the patient.
- Capacity: Ability of the patient to understand the relevant information and to appreciate those consequences of his or her decision that might reasonably be foreseen.
- Voluntariness: Right of the patient to come to a decision freely, without force, coercion or manipulation.

Consent is not valid if it is given under fear of injury/intimidation, misconception or misrepresentation of facts is an invalid consent[1].

Blanket consent is not legal. This denotes that the consent given by the patient for a diagnostic procedure cannot be extended to a therapeutic procedure unless there is a potentially life-threatening emergency.

This was also the position held by the Supreme Court of India in the matter of Samira Kohli vs Dr. Prabha Manchanda & Anr on 16 January, 2008 Appeal (civil) 1949 of 2004, where the Apex Court said, "*We therefore hold that in Medical Law, where a surgeon is consulted by a patient, and consent of the patient is taken for diagnostic procedure/surgery, such consent cannot be considered as authorisation or permission to perform therapeutic surgery either conservative or radical (except in life-threatening or emergent situations). Similarly, where the consent by the patient is for a particular operative surgery, it cannot be treated as consent for an unauthorized additional procedure involving removal of an organ, only on the ground that such removal is beneficial to the patient or is likely to prevent some danger developing in future, where there is no imminent danger to the life or health of the patient.*"

EXCEPTIONS TO INFORMED CONSENT

If the patient is in a critical condition and is unable to give consent and/or the proxy is not available, then the patient can be treated without his/her consent.

INFORMED REFUSAL

Informed refusal is when a competent patient refuses a recommended medical test or procedure. It is the duty of the treating doctor to ensure that the patient understands the potential adverse consequences of refusal. Like informed consent, informed refusal must also be documented. Failing to obtain an informed refusal before accepting a patient's decision to forego a test or procedure may make the doctor liable to negligence.

ASSESSING PATIENT CAPACITY FOR DECISION-MAKING

Besides clinical examination of the patient, assessment of patient capacity for decision-making also constitutes an important part of the doctor-patient communication. Capacity is determined by cognition and cognitive impairment may also impair decision-making capacity of the patient[4].

Patients with traumatic brain injury or any psychiatric illnesses such as schizophrenia, bipolar disorder and unipolar major depression or neurodegenerative diseases like Alzheimer's disease and Parkinson's disease are likely to have ineffective capacity for decision-making. Older adults, the elderly and inpatients are also at higher risk of having impaired cognition due to underlying chronic medical conditions or aging or delirium[4]. Stress, pain, medication effects and intoxication can also compromise decision-making capacity in healthy people[5]. Hence, respecting the patient's autonomy is important in cognitively impaired patients; at the same time, it is also important to act in the best interest of the patient[4].

Capacity vis a vis Competency

Although decision-making capacity and competence appear similar terms, they are not interchangeable. Competence is a legal notion decided by courts and judges, whereas decision making capacity is clinically judged by a clinician[6].

Four abilities are assessed when determining decision-making capacity[7]:

- **Understanding:** The ability to fully grasp information related to diagnosis and treatment.

- **Appreciation:** Being able to personalize the information given i.e., relating it to one's own situation by evaluating the information.
- **Reasoning:** Being able to rationally compare the treatment options
- **Expressing a choice:** Being able to convey the choice of treatment.

Clinical Tools to Measure Capacity

- Mini-Mental Status Examination (MMSE): A bed-side test which measures cognitive function; scores range from 0 to 30.
- MacArthur Competence Assessment Tools for Treatment (MacCAT-T): It is the gold standard test for assessment of capacity.
- Capacity to Consent to Treatment Instrument (CCTI): Uses hypothetical clinical vignettes to assess capacity across all aforementioned four domains.

Documentation

The observations of the examination and the reasoning employed when judging the capacity must be documented in the medical record of the patient. A summary of the questions asked and answers should be duly recorded. The clinical tools to measure capacity must also be mentioned.

What to do When a Patient Lacks Capacity

If the patient is found deficient in capacity to make decision regarding their treatment, then advanced directives must be taken into consideration. In absence of an advanced directive, a surrogate must be involved in decision-making. If there is no surrogate, then the court may appoint a legal guardian to take decisions on behalf of the patient[6].

Advance Medical Directive

In the landmark judgment "Common Cause versus Union of India, 2018 (5) SCC 1" delivered in 2018, the Hon'ble Supreme Court of India held that the Right to die with dignity is now a fundamental right under Article 21 of Constitution of India. It has legalized passive euthanasia and advance medical directive/ living will. It affords the terminally ill patient the right to die with dignity by allowing them to draft a living will specifying refusal of medical treatment including withdrawal from life-saving devices.

In the said judgment, the Hon'ble Apex Court has laid down certain guidelines and directions w.r.t. advance medical directives which shall remain in force till the Parliament makes legislation on this subject. The Hon'ble Supreme Court has held that:

> *"191. In our considered opinion, Advance Medical Directive would serve as a fruitful means to facilitate the fructification of the sacrosanct right to life with dignity. The said directive, we think, will dispel many a doubt at the relevant time of need during the course of treatment of the patient. That apart, it will strengthen the mind of the treating doctors as they will be in a position to ensure, after being satisfied, that they are acting in a lawful manner. We may hasten to add that Advance Medical Directive cannot operate in abstraction. There has to be safeguards. They need to be spelt out. We enumerate them as follows:*
>
> *(a) Who can execute the Advance Directive and how?*
>
> *(i) The Advance Directive can be executed only by an adult who is of a sound and healthy state of mind and in a position to communicate, relate and comprehend the purpose and consequences of executing the document.*
>
> *(ii) It must be voluntarily executed and without any coercion or inducement or compulsion and after having full knowledge or information.*
>
> *(iii) It should have characteristics of an informed consent given without any undue influence or constraint.*
>
> *(iv) It shall be in writing clearly stating as to when medical treatment may be withdrawn or no specific medical treatment shall be given which will only have the effect of delaying the process of death that may otherwise cause him/her pain, anguish and suffering and further put him/her in a state of indignity.*
>
> *(b) What should it contain?*
>
> *(i) It should clearly indicate the decision relating to the circumstances in which withholding or withdrawal of medical treatment can be resorted to.*
>
> *(ii) It should be in specific terms and the instructions must be absolutely clear and unambiguous.*
>
> *(iii) It should mention that the executor may revoke the instructions/authority at any time.*
>
> *(iv) It should disclose that the executor has understood the consequences of executing such a document.*
>
> *(v) It should specify the name of a guardian or close relative who, in the event of the executor*

becoming incapable of taking decision at the relevant time, will be authorized to give consent to refuse or withdraw medical treatment in a manner consistent with the Advance Directive.

(vi) In the event that there is more than one valid Advance Directive, none of which have been revoked, the most recently signed Advance Directive will be considered as the last expression of the patient's wishes and will be given effect to.

(c) How should it be recorded and preserved?

(i) The document should be signed by the executor in the presence of two attesting witnesses, preferably independent, and countersigned by the jurisdictional Judicial Magistrate of First Class (JMFC) so designated by the concerned District Judge.

(ii) The witnesses and the jurisdictional JMFC shall record their satisfaction that the document has been executed voluntarily and without any coercion or inducement or compulsion and with full understanding of all the relevant information and consequences.

(iii) The JMFC shall preserve one copy of the document in his office, in addition to keeping it in digital format.

(iv) The JMFC shall forward one copy of the document to the Registry of the jurisdictional District Court for being preserved. Additionally, the Registry of the District Judge shall retain the document in digital format.

(v) The JMFC shall cause to inform the immediate family members of the executor, if not present at the time of execution, and make them aware about the execution of the document.

(vi) A copy shall be handed over to the competent officer of the local Government or the Municipal Corporation or Municipality or Panchayat, as the case may be. The aforesaid authorities shall nominate a competent official in that regard who shall be the custodian of the said document.

(vii) The JMFC shall cause to handover copy of the Advance Directive to the family physician, if any.

(d) When and by whom can it be given effect to?

(i) In the event the executor becomes terminally ill and is undergoing prolonged medical treatment with no hope of recovery and cure of the ailment, the treating physician, when made aware about the Advance Directive, shall ascertain the genuineness and authenticity thereof from the jurisdictional JMFC before acting upon the same.

(ii) The instructions in the document must be given due weight by the doctors. However, it should be given effect to only after being fully satisfied that the executor is terminally ill and is undergoing prolonged treatment or is surviving on life support and that the illness of the executor is incurable or there is no hope of him/her being cured.

(iii) If the physician treating the patient (executor of the document) is satisfied that the instructions given in the document need to be acted upon, he shall inform the executor or his guardian/close relative, as the case may be, about the nature of illness, the availability of medical care and consequences of alternative forms of treatment and the consequences of remaining untreated. He must also ensure that he believes on reasonable grounds that the person in question understands the information provided, has cogitated over the options and has come to a firm view that the option of withdrawal or refusal of medical treatment is the best choice.

(iv) The physician/hospital where the executor has been admitted for medical treatment shall then constitute a Medical Board consisting of the Head of the treating Department and at least three experts from the fields of general medicine, cardiology, neurology, nephrology, psychiatry or oncology with experience in critical care and with overall standing in the medical profession of at least twenty years who, in turn, shall visit the patient in the presence of his guardian/close relative and form an opinion whether to certify or not to certify carrying out the instructions of withdrawal or refusal of further medical treatment. This decision shall be regarded as a preliminary opinion.

(v) In the event the Hospital Medical Board certifies that the instructions contained in the Advance Directive ought to be carried out, the physician/hospital shall forthwith inform the jurisdictional Collector about the proposal. The jurisdictional Collector shall then immediately constitute a Medical Board

comprising the Chief District Medical Officer of the concerned district as the Chairman and three expert doctors from the fields of general medicine, cardiology, neurology, nephrology, psychiatry or oncology with experience in critical care and with overall standing in the medical profession of at least twenty years (who were not members of the previous Medical Board of the hospital). They shall jointly visit the hospital where the patient is admitted and if they concur with the initial decision of the Medical Board of the hospital, they may endorse the certificate to carry out the instructions given in the Advance Directive.

(vi) The Board constituted by the Collector must beforehand ascertain the wishes of the executor if he is in a position to communicate and is capable of understanding the consequences of withdrawal of medical treatment. In the event the executor is incapable of taking decision or develops impaired decision-making capacity, then the consent of the guardian nominated by the executor in the Advance Directive should be obtained regarding refusal or withdrawal of medical treatment to the executor to the extent of and consistent with the clear instructions given in the Advance Directive.

(vii) The Chairman of the Medical Board nominated by the Collector, that is, the Chief District Medical Officer, shall convey the decision of the Board to the jurisdictional JMFC before giving effect to the decision to withdraw the medical treatment administered to the executor. The JMFC shall visit the patient at the earliest and, after examining all aspects, authorise the implementation of the decision of the Board.

(viii) It will be open to the executor to revoke the document at any stage before it is acted upon and implemented.

(e) What if permission is refused by the Medical Board?

(i) If permission to withdraw medical treatment is refused by the Medical Board, it would be open to the executor of the Advance Directive or his family members or even the treating doctor or the hospital staff to approach the High Court by way of writ petition under Article 226 of the Constitution. If such application is filed before the High Court, the Chief Justice of the said High Court shall constitute a Division Bench to decide upon grant of approval or to refuse the same. The High Court will be free to constitute an independent Committee consisting of three doctors from the fields of general medicine, cardiology, neurology, nephrology, psychiatry or oncology with experience in critical care and with overall standing in the medical profession of at least twenty years.

(ii) The High Court shall hear the application expeditiously after affording opportunity to the State counsel. It would be open to the High Court to constitute Medical Board in terms of its order to examine the patient and submit report about the feasibility of acting upon the instructions contained in the Advance Directive.

(iii) Needless to say that the High Court shall render its decision at the earliest as such matters cannot brook any delay and it shall ascribe reasons specifically keeping in mind the principles of "best interests of the patient".

(f) Revocation or inapplicability of Advance Directive

(i) An individual may withdraw or alter the Advance Directive at any time when he/she has the capacity to do so and by following the same procedure as provided for recording of Advance Directive. Withdrawal or revocation of an Advance Directive must be in writing.

(ii) An Advance Directive shall not be applicable to the treatment in question if there are reasonable grounds for believing that circumstances exist which the person making the directive did not anticipate at the time of the Advance Directive and which would have affected his decision had he anticipated them.

(iii) If the Advance Directive is not clear and ambiguous, the concerned Medical Boards shall not give effect to the same and, in that event, the guidelines meant for patients without Advance Directive shall be made applicable.

(iv) Where the Hospital Medical Board takes a decision not to follow an Advance Directive while treating a person, then it shall make an application to the Medical Board constituted by the Collector for consideration and appropriate direction on the Advance Directive."

"192. It is necessary to make it clear that there will be cases where there is no Advance Directive. The said class of persons cannot be alienated. In cases where there is no Advance

Directive, the procedure and safeguards are to be same as applied to cases where Advance Directives are in existence and in addition there to, the following procedure shall be followed:

(i) In cases where the patient is terminally ill and undergoing prolonged treatment in respect of ailment which is incurable or where there is no hope of being cured, the physician may inform the hospital which, in turn, shall constitute a Hospital Medical Board in the manner indicated earlier. The Hospital Medical Board shall discuss with the family physician and the family members and record the minutes of the discussion in writing. During the discussion, the family members shall be apprised of the pros and cons of withdrawal or refusal of further medical treatment to the patient and if they give consent in writing, then the Hospital Medical Board may certify the course of action to be taken. Their decision will be regarded as a preliminary opinion.

(ii) In the event the Hospital Medical Board certifies the option of withdrawal or refusal of further medical treatment, the hospital shall immediately inform the jurisdictional Collector. The jurisdictional Collector shall then constitute a Medical Board comprising the Chief District Medical Officer as the Chairman and three experts from the fields of general medicine, cardiology, neurology, nephrology, psychiatry or oncology with experience in critical care and with overall standing in the medical profession of at least twenty years. The Medical Board constituted by the Collector shall visit the hospital for physical examination of the patient and, after studying the medical papers, may concur with the opinion of the Hospital Medical Board. In that event, intimation shall be given by the Chairman of the Collector nominated Medical Board to the JMFC and the family members of the patient.

(iii) The JMFC shall visit the patient at the earliest and verify the medical reports, examine the condition of the patient, discuss with the family members of the patient and, if satisfied in all respects, may endorse the decision of the Collector nominated Medical Board to withdraw or refuse further medical treatment to the terminally ill patient.

(iv) There may be cases where the Board may not take a decision to the effect of withdrawing medical treatment of the patient on the Collector nominated Medical Board may not concur with the opinion of the hospital Medical Board. In such a situation, the nominee of the patient or the family member or the treating doctor or the hospital staff can seek permission from the High Court to withdraw life support by way of writ petition under Article 226 of the Constitution in which case the Chief Justice of the said High Court shall constitute a Division Bench which shall decide to grant approval or not. The High Court may constitute an independent Committee to depute three doctors from the fields of general medicine, cardiology, neurology, nephrology, psychiatry or oncology with experience in critical care and with overall standing in the medical profession of at least twenty years after consulting the competent medical practitioners. It shall also afford an opportunity to the State counsel. The High Court in such cases shall render its decision at the earliest since such matters cannot brook any delay. Needless to say, the High Court shall ascribe reasons specifically keeping in mind the principle of 'best interests of the patient'."

CONSENT-RELATED CHALLENGES[8]

- **Consent must be procedure specific:** A consent taken for a diagnostic procedure, cannot be considered as consent for a therapeutic procedure. Hence, a common consent for both diagnostic and ensuing therapeutic procedures can be taken where they are anticipated. Likewise, consent for a particular treatment procedure is not valid for any other procedure. If required, the other procedure can be done without consent only if it would be life-saving or waiting for the patient to regain consciousness and take a decision is not reasonable option.
- **Consent obtained during the course of surgery is invalid:** Dealing with the allegation of performing sterilisation without consent in the matter of Dr Janaki S Kumar and Anr versus Mrs. Sarafunnisa, the Kerala State Consumer Disputes Redressal Commission held that the patient could not comprehend the associated risks as she was under anesthesia. Hence, she could not have given a valid consent.
- **Consent for blood transfusion:** A written consent for blood transfusion must be taken where it is being contemplated. A consent is not required in emergency cases where blood transfusion may be life-saving.
- **Consent for examining or observing a patient for educational purpose:** Valid consent of the patients must be taken before examining them for the purpose of education.
- **Blanket consent is not valid:** Consent must be specific to the procedure being undertaken. An all-inclusive consent is not valid.

- **Fresh consent should be taken for a repeat procedure:** A fresh written informed consent must be obtained before any surgery including re-explorations.
- **Consent for surgery does not cover anesthesia care:** Informed consent for anesthesia must be taken only by the anesthetist. The consent must be recorded either alongside the surgical consent form or on a separate anesthesia consent form.
- **Patient can refuse treatment:** Competent patients with decision-making capacity have the right to refuse treatment, even in life-threatening emergency situations. Informed refusal must be obtained and documented in such situations.
- **Consent should be properly documented:** The informed consent taking procedure can be video-recorded; however, the patient must consent to this, which should be documented. The patient must sign the consent form.
- **Patient can withdraw his consent anytime:** If the patient withdraws his consent during a procedure, it must be stopped. The procedure should be stopped. The doctor may continue with the procedure after satisfying the apprehensions of the patient, if he agrees. But if discontinuing with the procedure may be potentially life-threatening, it may be continued "till such a risk no longer exists".

TELEMEDICINE GUIDELINES

The Government of India has issued Telemedicine Practice guidelines on 25th March, 2020 which provide a robust framework for practice of telemedicine[9].

These guidelines comprehensively prescribe norms and protocols covering all aspects of telemedicine practice like physician-patient relationship; issues of liability and negligence; management and treatment; informed consent; continuity of care; medical records; privacy and security of the patient records, exchange of information, etc.

The guidelines also provide detailed information on technology platforms and tools to be utilized for effective health care delivery (Press Information Bureau, Ministry of Health and Family Welfare, July 31, 2021).

"*Patient consent is necessary for any telemedicine consultation (3.4). The consent can be implied or explicit depending on the following situations*[9]*:*

- *If the patient initiates the telemedicine consultation, then the consent is implied (3.4.1).*
- *An explicit patient consent is needed if: A health worker, RMP or a Caregiver initiates a Telemedicine consultation (3.4.2).*
- *An Explicit consent can be recorded in any form. Patient can send an email, text or audio/video message. Patient can state his/her intent on phone/video to the RMP (e.g., "Yes, I consent to avail consultation via telemedicine" or any such communication in simple words). The RMP must record this in his patient records (3.4.3).*"

"*Prescribing medications, via telemedicine consultation is at the professional discretion of the doctor. It entails the same professional accountability as in the traditional in-person consult. If a medical condition requires a particular protocol to diagnose and prescribe as in a case of in-person consult then same prevailing principle will be applicable to a telemedicine consult. The doctor may prescribe medicines via telemedicine ONLY when he/she is satisfied that he/she has gathered adequate and relevant information about the patient's medical condition and prescribed medicines are in the best interest of the patient. Prescribing medicines without an appropriate diagnosis/provisional diagnosis will amount to a professional misconduct*[9]*.*"

TELEMEDICINE: DOS AND DON'TS FOR DOCTORS[9,10]

- Patient identification is mandatory during the first consultation.
- Confirmation of patient's identity however is not mandatory during follow-up; this should be done only as per need.
- The identity of the caregiver and authorization should be verified.
- Doctors should themselves to the patient before proceeding with the teleconsultation.
- The registration number must be displayed on prescriptions, website, electronic communication (email or WhatsApp), including receipts.
- Doctor should not continue with teleconsultation if it not appropriate.
- Doctor should maintain patient records of tele-consultation.
- Patient's personal data should not be disclosed or transferred without written consent of the patient.
- Emergency teleconsultation should be restricted to first aid or immediate assistance.
- There is a limitation on prescribing medicines to patients via telemedicine.

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Diabetic Distress and Glycemic Control in Type 2 Diabetes

Type 2 diabetes patients with high distress have high levels of glycated hemoglobin (HbA1c) indicating poor glycemic control. They also have a higher likelihood of diabetic neuropathy compared to those without distress. These findings from a recent study were published online March 6, 2024 in *Scientific Reports*[1]. This study included 1,862 participants from the Korean National Diabetes Program. They completed diabetic complication assessments and responded to the Korean version of the Problem Areas in Diabetes Survey (PAID-K), which is a validated tool used to assess emotional burden and distress associated with managing diabetes. A total PAID-K score of 40 or higher was considered indicative of high distress. Based on this, participants with score <40 were categorized as having low distress, while those with score ≥40 were classified as having high distress.

By analyzing the data collected, researchers aimed to investigate the association between diabetes distress levels, as measured by the PAID-K, and glycemic control and the presence or severity of diabetic complications. A total of 589 participants were found to have high distress levels. They had significantly higher levels of HbA1c (7.4%) compared to those without distress (7.1%). This difference was statistically significant at baseline and also throughout the 3-year follow-up period. The study also identified factors associated with high distress. These included younger age, female patients, long-standing diabetes and higher intake of carbohydrate. Participants experiencing high distress had a higher likelihood of developing neuropathy compared to those without distress. This association remained significant even after adjusting for potential confounding factors with an adjusted OR of 1.63. However, no significant associations were found between distress levels and other diabetes-related complications, such as retinopathy, nephropathy, and carotid artery plaque. To conclude, this analysis of data from the Korean National Diabetes Program highlights the significant association between high levels of diabetes distress and adverse outcomes in patients with type 2 diabetes. Specifically, it has shown that high diabetic distress was linked with poor glycemic control and increased odds of diabetic neuropathy. It has also identified factors associated with high distress. Persons with diabetic distress may struggle to manage their disease on a day-to-day basis. It is therefore essential to recognize and address the emotional burden associated with diabetes in addition to the traditionally used clinical parameters. Effective strategies to support patients experiencing high levels of diabetes distress may not only improve their psychological well-being but also lead to better glycemic control potentially reducing the risk of diabetic complications. Hence, clinicians managing patients with type 2 diabetes should routinely screen them for distress and offer appropriate interventions as part of standard diabetes care so that patients can better cope with their disease.

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