Renal Replacement Therapy

REVIEW

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Consensus-based proposal for forgoing dialysis therapy in Japan

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Abstract

The Japanese Society for Dialysis Therapy published a proposal in 2014 and revised it to Shared Decision Making for the Initiation and Continuation of Dialysis: A Proposal from the Japanese Society for Dialysis Therapy in 2020 to strictly adhere to guidelines of the Ministry of Health, Labour and Welfare, because forgoing life-sustaining treatment to respect the will of patients in end-of-life care is not stipulated by law in Japan. The revised proposal describes the process of providing information about renal replacement therapy, the natural course of end-stage kidney disease, and conservative kidney management (CKM), the conditions when providing CKM information to be considered by healthcare teams, the process of providing information about CKM if patients with decision-making capacity or families of patients without decision-making capacity wish to make the decision to forgo dialysis, the process of shared decision making for choosing CKM, and the importance of performing advance care planning (ACP) with patients and their families for making advance directives, etc. We need to promote ACP and to establish the content and practice of palliative care for patients after choosing CKM in collaboration with home-cased care doctors.

Keywords: Dialysis, Forgoing, Shared decision making, Advance care planning

Background

In Japan, forgoing life-sustaining treatment to respect the will of patients who are terminally ill is not stipulated by law. The Ministry of Health, Labour and Welfare (MHLW) recognizes the importance of such respect, however, and in 2007 published Guidelines for the Decision-Making Process in Terminal-Stage Healthcare, which emphasized the importance of shared decision making (SDM) at end-of-life (EOL) [1]. Then, in 2018, to reflect the aging of the population and the accompanying increase in deaths, the guidelines were revised to emphasize the importance of advance care planning (ACP) in addition to SDM and were published as Guidelines for the Decision-Making Process in End-of-Life Healthcare Management and Care [2]. However, the MHLW guidelines that guide the process of forgoing life-sustaining treatment are based on respecting the patient's own wishes; they do not specify criteria for immunity from criminal prosecution for physicians that enable patients to forgo life-sustaining treatment based on advance directives [1, 2].

As early as 2009, the Japanese Society for Dialysis Therapy (JSDT) began working on a proposal to enable patients to forgo dialysis if they wished. The proposed clinical practice guidelines were consensus-based rather than evidence-based. In 2014, JSDT published the Proposal for the Shared Decision-Making Process Regarding the Initiation and Continuation of Maintenance Hemodialysis, which excluded dementia and was limited to terminally ill patients [3]. This was later revised in accordance with Japanese law and mindful of societal conditions and was published in 2020 as Shared Decision Making for the Initiation and Continuation of Dialysis: A Proposal from the Japanese Society for Dialysis Therapy, to cover all patients with end-stage kidney disease (ESKD) [4].

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This review article outlines the content of lectures about its proposal given at the 67th Annual Meeting of JSDT.

The temporary decision to forgo dialysis

In Japanese, the temporary decision to forgo dialysis that allows for the later initiation or reinitiation of dialysis depending on changes in the patient's decision or disease status is widely known as the *Miawase* approach. Notably, this approach is different from permanently forgoing dialysis.

Miawase trends after the 2014 proposal from JSDT

A nationwide survey in 2016 revealed that 47.1% of dialysis facilities reported cases of *Miawase*, with 89.7% of cases involving patients who were elderly, 46.1% involving those with dementia, and 7.5% involving those who later initiated or reinitiated dialysis. Although the proposal was limited to terminally ill patients, the *Miawase* approach was also selected by non-EOL patients expressing a firm temporary decision to forgo dialysis, with their families' agreement [5]. At this time, JSDT's proposal was limited to patients on maintenance hemodialysis who were receiving EOL care and excluded patients who were receiving peritoneal dialysis and patients with dementia or acute kidney disease. However, in recognition of humans having intentions and desires even when their cognitive function is impaired, MHLW published Guidelines for Supporting Decision Making in Daily and Social Life for Individuals with Dementia in 2018 [6], highlighting that patients' decisions should be respected and their decision making should be supported based on an appropriate assessment of their decision-making capacity. In 2019, a social issue arose around these guidelines following the death of a non-EOL patient on maintenance dialysis who had decided to discontinue dialysis. The bereaved family filed a civil suit in the Tokyo District Court and this prompted JSDT to start revising the 2014 proposal to encompass all patients with ESKD or acute kidney disease requiring dialysis, including non-EOL patients and patients with dementia.

Main contents of the 2020 proposal from JSDT

A summary of the 2020 proposal is shown in Table 1. Before dialysis is initiated, healthcare teams should consider how to provide information about conservative kidney management (CKM) that includes nondialysis medical management and care for ESKD in the following situations: when patients submit advance directives to healthcare teams; when patients and their families request to forgo dialysis; and when healthcare teams judge that patients are at a stage where the Japanese *Miawase* approach is an option (Table 2). As stated in the 2020 proposal [4], it is advisable for healthcare teams to encourage the families of patients with impaired comprehension and cognition to engage in ACP with patients at an early stage when the patients still have some decision-making capacity. Patient-centered discussions should therefore be held about future prospects and healthcare management and care at EOL, and an advance directive should be prepared. When dialysis needs to be initiated, healthcare teams should provide information about CKM to patients who decide against having renal replacement therapy (RRT) and when the patients and their families request to forgo dialysis. Healthcare teams should then engage in the decision-making process with patients and their families so that decisions are made through SDM. If patients or their families request CKM, it is important for healthcare teams to understand the patients' personal values and intentions, tell the patients and their families that the patient's satisfaction in life is most important, and aim for consensus building through discussions, thereby supporting patients in making the best decisions for them.

Process for providing comprehensive information for decision making to patients in the pre-dialysis stage

According to the 2020 proposal [4], when the estimated glomerular filtration rate decreases to < 30 mL/min/1.73 m^2 with progressive deterioration of kidney function, healthcare teams should provide information about RRT that will become necessary when kidney function further deteriorates in the future.

When RRT is expected to be initiated soon, healthcare teams should provide RRT-related information, explain the natural course of ESKD, and discuss the information with patients until they understand the advantages and disadvantages of opting or not opting for RRT. It is important for patients to understand their situation and live their lives. If they are unsure in their decision making, healthcare teams should provide support during healthcare visits.

It is important for healthcare teams to understand all aspects of the patients' lives and their anxieties and problems. Through discussions with the patients and their families, the teams should identify measures that align with the patients' interests, ensuring that everyone involved is satisfied. It is important to consider appropriate interventions if patients have mental and/or social problems. In the consensus-building process, healthcare teams should provide information about the disease status and other relevant information, propose measures to enable patients to live their lives with dignity, and have clear discussions to help patients accept that the proposed measures are necessary.

Table 1 Shared decision making for the initiation and continuation of dialysis: A Proposal from the Japanese Society for Dialysis Therapy [4]

Proposal 1. Respect for patients' decision making by healthcare teams

1. Respect patients' decisions about healthcare management and care strategies
2. Obtain a consent form for the initiation of dialysis from patients before initiating dialysis
3. Provide information to patients about their right to prepare advance directives

Proposal 2. Shared decision making with patients

1. Provide patients with adequate information
2. Collect adequate information from patients
3. Have thorough discussions to support patients in making the best possible choices
4. Provide patients with adequate information about renal replacement therapy (RRT)
   (1) At the appropriate time, provide information about RRT becoming necessary when kidney function deteriorates in the future
   (2) For patients for whom dialysis will become necessary in the near future, provide information about RRT and the natural course of end-stage kidney disease (ESKD)
5. If patients do not opt for RRT when dialysis needs to be initiated, have repeated discussions with patients and their family members (including heirs) for consensus building
   (1) Continue discussions until the advantages and disadvantages of conservative kidney management (CKM) and the initiation of dialysis are understood
   (2) Have discussions in accordance with the decision-making process (Fig. 1)
   (3) When patients make a final decision to opt for CKM, obtain a confirmation form for the "*Miawase*" approach to dialysis if necessary
   (4) Reassess patients for their changes in decisions when they visit healthcare facilities
6. Assess whether patients are receiving healthcare management and care in compliance with the decisions they have made

Proposal 3. Advance care planning with patients

1. Have thorough discussions on various occasions about future healthcare management and care
2. Have thorough discussions on patients' preferred healthcare management and care in accordance with the decision-making process (Fig. 1)
   (1) Provide patients with information about the expected symptoms and prognosis after implementing the temporary decision to forgo dialysis
   (2) When patients choose to have their final moments at home, cooperate with the doctors responsible for home-based healthcare
   (3) Assess patients' changes in their decisions in response to changes in disease status

Proposal 4. Proposal of the temporary decision to forgo dialysis at the EOL stage by healthcare teams

1. Judge the patient's condition regarding whether the temporary decision to forgo dialysis should be considered by referring to Table 2
2. Engage in the decision-making process (Fig. 1)
3. Provide adequate palliative care after CKM is chosen and the temporary decision to forgo dialysis is implemented

Proposal 5. Request for the temporary decision to forgo dialysis by patients with decision-making capacity or by the families of patients without decision-making capacity to healthcare teams

1. Confirm the decision through discussion with patients with decision-making capacity or through the examination of any prior instruction (written or oral) made by patients without decision-making capacity
2. When healthcare teams judge that patients are not at the EOL stage, ESKD that requires maintenance dialysis for survival should be diagnosed
   (1) When CKM is chosen through the decision-making process (Figure) and when consensus is reached among the relevant parties, obtain a confirmation form for the temporary decision to forgo dialysis if necessary and continuously provide adequate palliative care
   (2) When patients' decisions cannot be inferred or when consensus is not reached among the relevant parties, continue discussions to build consensus
   (3) Reassess patients for changes in their decisions when they visit healthcare facilities

Proposal 6. Requests from patients that their family, etc., not be notified about their disease status

1. Determine the reasons why patients do not want their families to be notified and evaluate patients' decision-making capacity
2. Refrain from contacting families if patients have decision-making capacity, but contact them if they do not have decision-making capacity
3. When uremic symptoms are confirmed or when CKM is chosen and the temporary decision to forgo dialysis is to be implemented, inform patients that their family members will be contacted and then provide them the information about the disease status

Proposal 7. Support for decision making by patients with impaired comprehension and cognition by healthcare teams and patients' families

1. Respect and support patients' decision making and provide them with the best possible healthcare management and care that are consistent with their wishes
2. Encourage patients' families to engage in advance care planning with patients while they still have decision-making capacity

Table 2 Conditions when healthcare teams should consider the temporary decision to forgo dialysis [4]

1. When there are difficulties in the safe performance of dialysis and the patient's life is at risk
(1) The patient is in a condition where dialysis is harmful rather than beneficial to life because of multiple organ failure causing circulatory and respiratory problems, sustained hypotension, or other problems that make sustaining life extremely difficult
(2) The patient is in a condition where dialysis can be performed safely only with the use of physical restraint and sedation
2. When the patient's general condition is extremely poor and his or her decision on the temporary decision to forgo dialysis is clearly expressed or when family members can infer the patient's decision
(1) The patient is in a condition where serious cerebral dysfunction due to sequelae of cerebrovascular disease, head injury, etc., prevent him or her from having the comprehension necessary to undergo dialysis and recuperation
(2) The patient is in a condition where death is imminent because of an incurable malignant comorbidity, such as a malignant tumor
(3) The patient is not capable of oral intake, and long-term life-sustaining artificial hydration and nutrition are expected

If RRT has not yet been implemented when kidney disease reaches the end stage and life-sustaining dialysis needs to be initiated, patients then need to make a decision about RRT. Healthcare teams should help patients in their decision making by providing information on the timing of RRT initiation and the modalities available if they opt for RRT, the natural course of the disease if they do not opt for it, and the advantages and disadvantage of opting or not opting for RRT. When patients request to forgo RRT, healthcare teams should provide information about CKM and have discussions with patients and their families following the SDM process (Fig. 1). If patients and their families choose CKM and the *Miawase* approach is implemented, healthcare teams should provide information to ensure that patients and their families fully understand the possibilities related to death due to uremic symptoms, avoiding severe uremic symptoms by initiating dialysis, the suffering associated with dialysis, reducing suffering through palliative care, initiating or continuing dialysis by withdrawing the temporary decision to forgo dialysis, the possibility of death even after initiating dialysis, and a time-limited trial of dialysis. When patients' decision-making capacity is in question, healthcare teams should encourage patients and their families to visit specialists.

If patients participate in SDM and eventually opt for CKM, patients and their families should sign a confirmation form for the temporary decision to forgo dialysis if deemed necessary. Obtaining a confirmation form is not mandatory and is sometimes omitted to respect patients' decisions. It is important that all healthcare team personnel record the content of discussions with patients and their families and prepare summary reports to share them with them. Even after confirmation forms are provided, the patient's decision needs to be reviewed when their disease status changes. It is also important to provide psychological care to family members and grief care.

For patients that opted for CKM but still visit healthcare facilities regularly, healthcare teams should assess their disease status, provide necessary palliative care, and confirm whether their decision has changed. If patients now request dialysis, healthcare teams should initiate it in accordance with their verbal instruction, discuss healthcare management and care strategies again with the patients and their families, and obtain a confirmation form for withdrawal of the decision if deemed necessary [4].

Considerations when providing information on CKM (Table 2)

In cases where the *Miawase* approach is judged to be one of the best options for respecting patients' dignity at EOL, healthcare teams should propose the approach to patients with decision-making capacity or to the families of patients who do not have such capacity. The teams should support them, following the decision-making process laid out in the proposal. Healthcare teams should provide information not only about CKM, but also about reducing the duration and frequency of dialysis therapy [4].

(See figure on next page.)

Fig. 1 Decision-making process when renal replacement therapy becomes necessary [4]. *1: When consensus is not reached among the patient, family, and healthcare team, the team will consult with the head of the facility to hold a nonregular committee comprising multiple specialists including a doctor, nurses, clinical engineers, and a healthcare ethics specialist or a standing ethics committee. This committee advises the team, which aims to reach consensus with patients and their families. Depending on the situation, a conference can be held by medical staff and long-term care workers other than the doctor, nurse, and clinical engineer in charge. *2: Reasons for the temporary decision to forgo dialysis that are solvable concern patient suffering that can be addressed through appropriate intervention (e.g., difficulties visiting a healthcare facility, hypotension during dialysis, and piercing pain)

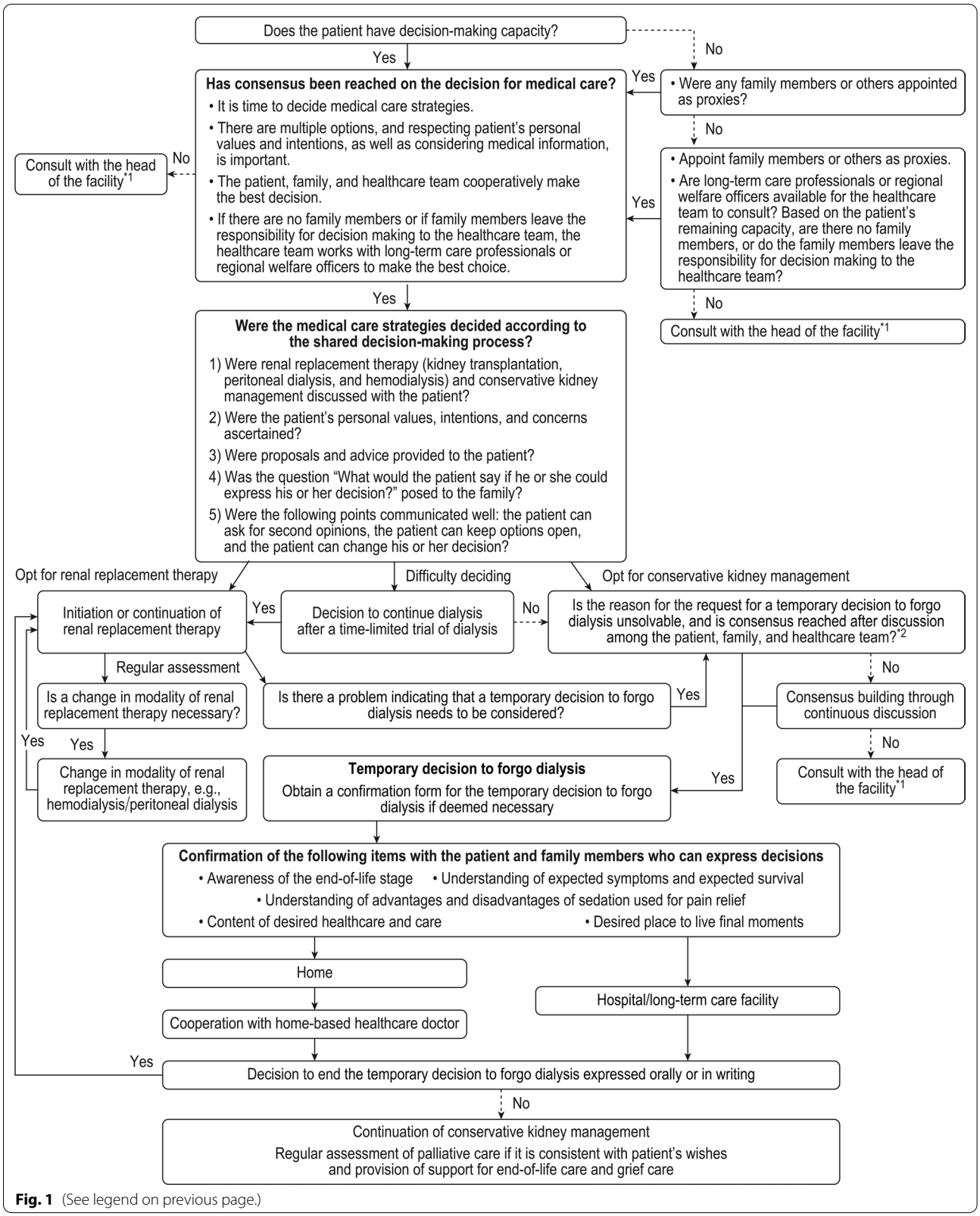

Fig. 1 (See legend on previous page.)

Process for providing information about CKM to patients or their families who opt for Miawase

As explained in the proposal [4], patients have the right to decide and when they opt for the *Miawase* approach, the reasons for that decision should be identified through adequate discussions. If patients whose life can be sustained by initiating or continuing dialysis opt for *Miawase*, it is advisable to provide easy-to-understand written information on the advantages and disadvantages of medical care and obtain an advance directive from them.

In cases where the families of patients without decision-making capacity request *Miawase*, healthcare teams should consult any advance directives made or verbal instruction given when the patients had decision-making capacity and then confirm their decision and the reasons for it.

Healthcare teams should try to understand patients' anxieties and various problems, have discussions with them and their families so that they are motivated to live, and thus identify measures aligned with the patients' interests. For patients with psychological or social problems, specific interventions should be considered.

Patients with decision-making capacity have the right to receive clear and appropriate information and the right to accept or decline healthcare based on their own decisions, regardless of whether they are in the EOL stage. For patients not yet in the EOL stage who request *Miawase*, EOL is considered to begin when a physician diagnoses ESKD that requires maintenance dialysis as life-sustaining treatment. The patient's decision is the final decision at that time and must be respected. Healthcare teams must be aware that patients may change their decision, and therefore, they must continuously be ready to initiate dialysis for them and to provide them with information about a time-limited trial of dialysis. The most important element of human dignity is autonomy, and the decision to opt for CKM must be respected in cases where consensus was reached among the patient, family, and healthcare team following a thorough discussion of all options based on appropriately shared, essential information. If deemed necessary, healthcare teams should obtain a confirmation form from the patients and their families about the decision to opt for *Miawase*, and the teams should provide palliative care consistent with patients' wishes. In fact, palliative care is necessary even before the *Miawase* decision is made, and appropriate palliative care must be provided on an individual basis. When any healthcare team member discusses the selection of healthcare management and care with patients or their families, the discussion must be documented and a summary of the content shared with them.

Families of patients without decision-making capacity become surrogate decision makers about healthcare management and care. In cases where families respect the patients' dignity by making decisions in accordance with the patients' prior instruction and when consensus to opt for CKM is reached following adequate information sharing and repeated discussions among the family members and healthcare teams, the consensus-based decision should be respected. Healthcare teams should handle requests for *Miawase* made by families similarly to how they handle requests for it made by patients with decision-making capacity: A confirmation form should be obtained if deemed necessary and palliative care consistent with the patients' prior instruction should then be provided.

If families and healthcare teams cannot infer what the patients themselves would decide, the healthcare teams should continue discussions so that family members can understand the patients' condition and provide the healthcare management and care deemed best for them. If consensus is reached, the decision should be respected and reported to the heads of facilities. If consensus is not reached, the healthcare teams should consult with the heads of their facilities and work toward consensus building. Healthcare teams should consult with the heads of their facilities in cases where they do not have sufficient time for repeated discussions.

Some pre-dialysis patients with ESKD who regularly visit healthcare facilities have strong feelings against dialysis and want to opt for CKM. In such cases, healthcare teams should evaluate their disease status, provide the necessary palliative care, and confirm whether their decision has changed.

If patients on dialysis no longer visit healthcare facilities, healthcare teams should contact them to ascertain their reasons for not visiting, inform the families of the reasons, and proceed with SDM as far as possible to reach a decision. When dialysis is declined, healthcare teams should inform patients and their families that the patients may die within a few weeks, if not days, and that they should contact healthcare facilities if they wish to reinitiate dialysis. If patients or their families are not reachable or if there are no family members, healthcare teams should consult with care workers and regional welfare officers and consider contacting the police to confirm patient safety [4].

Results of civil litigation in the Tokyo District Court

The civil litigation in 2019 was agreed upon in 2021, with the presiding judge recommending settlement. In relation to the families' claim that the hospital did not adequately explain or confirm the patient's intention to discontinue dialysis, which is a serious matter of life and

death, the opinion of the presiding judge was that the hospital involved did not have a history of actively inducing patients to die when patients asked their physicians to stop maintenance dialysis. Although the court gave no definitive finding of fact because of the settlement, when providing CKM information and engaging in the SDM process, healthcare providers must comply with JSDT's revised proposal published subsequently in 2020 in order to avoid being found to have induced death. When patients request *Miawase*, EOL begins when they and their families understand and accept the diagnosis of EOL after a physician has given diagnosed ESKD that permanently requires dialysis to sustain life. Nevertheless, careful handling is needed to ensure that providing CKM information to pre-dialysis patients with ESKD who are not at the EOL stage is not judged as inducing death.

Conclusions

As stated in the 2020 proposal [4], if CKM is among the medical care options for ESKD, four medical care options should be provided (kidney transplantation, peritoneal dialysis, hemodialysis, and CKM), as is done overseas [7]. Patients have the right to know their options, and healthcare teams should provide them with all necessary information. Healthcare teams are expected to comprehensively judge patients' disease status and comprehension levels and appropriately provide information about the timing, procedure, intensity, and details of medical care options.

Healthcare teams should provide information about CKM in ACP for patients and their families who request the *Miawase* approach. Further, ACP should also be encouraged even for patients who are not terminally ill. It is necessary to establish the nature of palliative care for patients who opt for CKM in collaboration with their physicians responsible for home-based care, with differences between Japan and Europe and North America taken into account.

Abbreviations

ACP: Advance care planning; CKM: Conservative kidney management; EOL: End-of-life; ESKD: End-stage kidney disease; SDM: Shared decision making; RRT : Renal replacement therapy; JSDT: The Japanese Society for Dialysis Therapy; MHLW: The Ministry of Health, Labour and Welfare.

Acknowledgements

Not applicable.

Author contributions

KO contributed to the intellectual discussion during manuscript drafting, revision, and the approval of the final version. All authors read and approved the final manuscript.

Funding

None.

Availability of data and materials

Not applicable.

Declarations

Ethics approval and consent to participate

Not applicable.

Consent for publication

Not applicable.

Competing interests

The author declares that there are no competing interests.

Received: 6 July 2022 Accepted: 30 August 2022
Published online: 15 September 2022

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