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Timing of initial discussions of advance care planning among patients on maintenance dialysis: A protocol for cross-sectional study

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ABSTRACT

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- 1 Timing of initial discussions of advance care planning among patients on maintenance dialysis: A protocol for cross-sectional study

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Introduction

Advance care planning (ACP) defined as a process “whereby a patient, in consultation with health care providers, family members and important others, makes decisions about his or her future health care, should he or she become incapable of participating in medical treatment decisions” (1). Studies have shown encouraging participation in ACP is associated with reductions in the number of hospitalizations and costs for terminally ill patients as well as reducing stress and increasing satisfaction among patients and their families (2, 3).

Annual mortality rates among patients on dialysis is around 15%, with the highest rates occurring soon after initiation of dialysis (4, 5). However, patients undergoing dialysis are less likely than members of other seriously ill populations to engage in ACP (6, 7). Barriers to ACP among patients with advanced kidney disease identified in qualitative work include complexity of medical care, lack of a shared understanding and vision of ACP, unclear locus of responsibility and authority for ACP, and lack of active collaboration and communication around ACP among different providers caring for the same patients. Although a proactive approach to ACP is generally recommended, however clinicians sometimes worry that starting these discussions too early in the illness trajectory may not be productive and may cause undue alarm (8-10). Nonetheless, at least one study among primary care patients suggested that the majority were willing open to starting ACP before their health is severely compromised (11).

We here describe the protocol for a study to both elicit the preferences of patients on dialysis related to timing of ACP and describe the prevalence of ACP and the associated factors in this population. We will also elicit the perspectives of healthcare providers engaged in dialysis care.

Methods

Study design, setting, and sampling

Patients on dialysis and clinicians involved in caring for members of this population will be recruited from one of 10 different dialysis centers across Japan. Those who agree to participate in the study will be asked to complete a questionnaire to elicit their experiences and perspectives on ACP. All study participants will provide written informed consent. The study protocol is based on the STROBE checklist for reporting of cross-sectional studies (12).

Participants

The study will include patients with end-stage kidney disease (ESKD) undergoing hemodialysis or peritoneal dialysis aged 65 years or older who are within 10 years of dialysis initiation at the time of recruitment. We will exclude patients who are unwilling to participate and those who are cognitively able to provide informed consent due to moderate or severe dementia, a neurodegenerative disorder, or cerebrovascular disease.

The study will also include clinicians involved in caring for recruited patients including medical doctors, nurses, pharmacists, clinical engineers, nutritionists, and social workers.

Survey design and administration

For patients

We asked a nephrologist (the first author), a general practitioner (the third author), and two nurses who care for patients at one of the participating centers to draft four different clinical scenarios (cerebral infarction, heart failure, incurable lung cancer, and complex cardiovascular disease with infection). Diseases in the scenario were selected based on the most common cause of death among dialysis patients in Japan(13). Each scenario has been designed to conform with a simplified four-stage trajectory model in which patients develop progressive frailty over an approximately five year time span (Table 1). The four stages of this model include: 1) a 1st stage in which patients initiate dialysis in relatively good health; 2) a 2nd stage in which patients begin to develop fatigue and “tire more easily than before”, 3) a 3rd stage in which patients begin to slow down and “get tired much more easily and moved more slowly than before”, and 4) a 4th stage in which patients begin to lose weight and experience functional decline “declining physical functioning, and lost 10 kilograms of weight [...] needed support to sit up and to stand up”(11, 14).

For each stage in the trajectory, participants will be asked: “If you were the patient described here, what would you say about starting to discuss advance care planning including life-sustaining treatments at this time?” Possible responses will include: “too early”, “slightly early”, “appropriate”, “a little late”, and “too late”. Those who respond that this would be “appropriate”, “late” or “too late” will be instructed to skip to the next step in the survey. Those who select “too early” or “slightly early” will be asked to proceed to the next stage in the scenario.

Draft scenarios will be iteratively refined based on feedback from clinicians and patients at each center during a pilot phase of the study.

Our survey will also include questions to ascertain participants age, sex, dialysis modality, time since dialysis initiation, number of comorbidities(15), marital status, living arrangement (alone or not), education, income, prior experience with end-of-life care, social support, physical functioning status, mental health status, health literacy, quality of care based on patient experience, prognostic expectation, preferences of end-of-life care, and moving from unclear the dialysis unit where the patient initiated dialysis. We will use the shortest version of several available Lubben social network scales (LSNS-6) for social support(16). We will use physical functioning (PF) and mental health (MH) subscales of the 12-Item Short Form Survey (SF-12) for physical functioning status and mental health status, respectively. We will use Communicative and Critical Health Literacy (CCHL) and the longitudinality domain of the Japanese version of Primary Care Assessment Tool(JPCAT) for health literacy and quality of care based on patient experience, respectively(17, 18). Prognostic expectation will be based on the response to the following question; “How long would you guess people your age with similar health conditions usually live?” Possible answers included “less than 6 months,” “6 to 12 months,” “1 to 2 years,” “2 to 5 years,” “5 to 10 years,” “more than 10 years,” and “I’m not sure.” Regarding the preference of end-of-life care including chest compression, a breathing machine, and a feeding tube, participants were asked if they will want these interventions if they “have to decide right now” with possible responses including “definitely yes,” “probably yes,” “probably not,” “definitely not,” or “Leave the decision of whether or not to receive life-sustaining treatment to their family”.

For clinicians

We will ask the clinicians to answer the same questionnaire regarding the timing of initial discussion of ACP for clinicians. We will also ask about the following items; age, sex, years of experience in dialysis care, and job title.

Study participants will be randomly assigned to one of the four scenarios using a computer-generated random number with a block size of four. Participants can choose to complete self during dialysis session or have study coordinators record their survey responses. After completing the survey, patients will be compensated for time spent completing the survey with a payment of 500 yen (approximately US \$5).

Outcomes

The primary study outcome is the proportion of participants who indicate that they would consider it “appropriate” “a little late” or “too late” to conduct ACP at dialysis initiation (the first step in each trajectory).

Secondary outcomes will include the proportion of patients who report that they have completed ACP and whether this included discussion of preferences related to life-sustaining treatment and dialysis discontinuation. We will ask questions about whether the patients have discussed ACP and if so, with whom they have shared it.

Sample size

This study aims to describe preference and prevalence of ACP among dialysis patients. If the proportion of participants who indicate that conducting ACP before or at time of dialysis initiation would be acceptable is around 70 to 75% from the previous study(11), we estimate that recruitment of around 400 sample will allow us to include at least 10 covariates in multivariable analyses(19).

Statistical analysis

Patient preferences

We will describe the number of participants stratified by the timing of acceptance and the scenarios. We will conduct exploratory analyses of patient characteristics associated with the early acceptance of ACP using bivariate logistic regression. We will then use multivariable logistic regression model to identify independent associations with the following pre-specified characteristics age, sex, education, dialysis vintage, dialysis modality, comorbidities, mental health, and physical functioning, social support, and prognostic expectation(11, 20).

In sensitivity analyses, we will use bivariate and multivariate mixed-effect logistic regression with a random intercept for facilities and scenarios to take the clustering effect into account.

We will also examine the relationship of these same characteristics with the secondary outcomes; completing ACP and whether this included discussion of preferences related to life-sustaining treatment and dialysis discontinuation

Comparison of preferences of patients with those of healthcare providers

We will compare the acceptable timing of ACP between patients and healthcare providers involved in caring for them. We also describe the characteristics of healthcare providers stratified by the early acceptance of ACP.

We will use Stata/SE, V.14.2 (StataCorp, College Station, Texas, USA) for all analyses.

Table 1. The questionnaire with scenario 1

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Table 1. The questionnaire with scenario 1

Read the explanation of the following terms before completing the questionnaire.
What is Advance Care Planning?

Advance Care Planning is discussion(s) with healthcare providers in advance of treatment about medical treatments (e.g. life sustaining treatments) you would or would not want to receive in the future if you became unconscious following a serious illness or injury and could not express your own wishes.

※Life sustaining treatments include the following:

- Massaging the heart if it stops beating
- Inserting a tube into your airway and putting on breathing machine to help you breathe
- Feeding you via a stomach tube if it is too difficult for you to eat normally

We want to know your opinion on the appropriate timing to start a discussion about advance care planning. Read the following story of "Patient A" and answer the questions from Patient A's standpoint.

Stage 1

Patient A is 75 years old. Patient A has a longstanding kidney problem for which he/she has been under the care of a nephrologist, but has otherwise been well and able to go about his/her daily life. Recently Patient A started to notice swelling and tiredness and his/her nephrologist suggested that it was time to start dialysis, so he/she was admitted to the hospital and started on dialysis.

Question 1

If you were Patient A, how would you feel about starting to discuss advance care planning at this stage?

1. It is too early (Proceed to Stage 2)
2. It is slightly early (Proceed to Stage 2)
3. It is an appropriate time (Skip to Question 5)
4. It is a little late (Skip to Question 5)
5. It is too late (Skip to Question 5)

Stage 2

About a year after starting dialysis, Patient A experienced sudden onset of chest pain. He/She was admitted to the hospital and found to have had a heart attack for which he/she underwent a procedure to widen the blood vessels in his/her heart. After leaving the hospital, Patient A found that he/she was more tired than he had been before, but was still able to complete his/her daily routine with no assistance.

Question 2

If you were Patient A, what would you say about starting to discuss advance care planning at this stage?

1. It is too early (Proceed to Stage 3)
2. It is slightly early (Proceed to Stage 3)
3. It is an appropriate time (Skip to Question 5)
4. It is a little late (Skip to Question 5)
5. It is too late (Skip to Question 5)

Stage 3

Three years after starting dialysis, Patient A began to feel short of breath. One day he/she became so short of breath that his/her family called an ambulance. He/She was diagnosed with congestive heart failure and admitted to the hospital for treatment. Following discharge, he/she felt less short of breath but found that he/she tired much more easily and moved more slowly than before. He/She now needs a cane to walk around his/her home but is still able to live independently and complete his/her daily routine.

Question 3

If you were Patient A, what would you say about starting to discuss advance care planning at this stage?

1. It is too early (Proceed to Stage 4)
2. It is slightly early (Proceed to Stage 4)
3. It is an appropriate time (Skip to Question 5)
4. It is a little late (Skip to Question 5)

5. It is too late (Skip to Question 5)

Stage 4

Five years after starting dialysis, Patient A developed a foot infection that was very painful. He/She was told by his/her doctor that his/her toes would have to be amputated and was admitted to the hospital for surgery. After discharge from the hospital, Patient A had lost 10 kg of weight and found that he/she was able to do much less than before. He/She now needed a wheelchair to be able to go outside the home and needed help from his/her family to prepare meals, help him sit up in the chair and move around the house. Patient A spent most of his/her time in the house sitting in a chair and with the help of his/her family.

Question 4

If you were Patient A, what would you say about starting to discuss advance care planning at this stage?

1. It is too early (Proceed to Question 5)
2. It is slightly early (Proceed to Question 5)
3. It is an appropriate time (Proceed to Question 5)
4. It is a little late (S Proceed to Question 5)
5. It is too late (Proceed to Question 5)

Question 5

If a clinician starts discussing ACP earlier in the course of patient A's life than you consider "appropriate," would you feel discomfort in initiating the discussion?

1. Yes
2. No

Question 6

Have you ever thought about where and what kind of medical treatments you would or would not want to receive in the future? Have you shared these thoughts with the people you trust?

1. I have shared the thoughts
2. I've thought about it, but I haven't shared it.
3. I have not thought about it or shared it

Question 7

If you have shared the thoughts, with whom?

1. Nephrologist managing your dialysis
2. Other medical doctors
3. Nurses
4. Social workers
5. other medical staffs (please specify _____)
6. Family
7. Friends

Question 8

If you have shared the thoughts, have you also shared whether or not you will receive life-sustaining treatment (e.g., chest compression, breathing machine, feeding tube, etc.)

1. Yes
2. No

Question 9

In the end stage of your life (i.e., when you are expecting to live a few days to a few months), have you thought about whether to continue or discontinue dialysis?

Have you shared your thoughts with people you trust?

1. I have shared the thoughts
2. I've thought about it, but I haven't shared it.
3. I have not thought about it or shared it

Question 10

If you have shared the thoughts, with whom?

1. Nephrologist managing your dialysis
2. Other medical doctors
3. Nurses
4. Social workers
5. other medical staffs (please specify _____)

6. Family
 7. Friends
- Question 11
- If you have to decide right now, would you prefer life-sustaining treatment when your heart or breathing stops?
1. Definitely yes
 2. Probably yes
 3. Probably no
 4. Definitely no
 5. Leave the decision of whether or not to receive life-sustaining treatment to their family
- Question 12
- If you have to decide right now, would you prefer to continue on dialysis when you are in the end stage of your life (i.e., when you are expecting to live a few days to a few months)?
1. Definitely yes
 2. Probably yes
 3. Probably no
 4. Definitely no
 5. Leave the decision of whether or not to continue on dialysis to their family
- Question 13
- How long would you guess people your age with similar health conditions usually live? "less than 6 months," "6 to 12 months," "1 to 2 years," "2 to 5 years," "5 to 10 years," "more than 10 years," and "I'm not sure."
1. Less than 6 months
 2. 6 to 12 months
 3. 1 to 2 years
 4. 2 to 5 years
 5. 5 to 10 years
 6. more than 10 years
 7. I'm not sure
-

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