

# Implementation of advance care planning decision aids for patients undergoing high-risk surgery: A field-testing study

KANAKO YAMAMOTO (✉ [ykanako@slcn.ac.jp](mailto:ykanako@slcn.ac.jp))

St. Luke's International University

Toshimi Kaido

St. Luke's International Hospital

Tadao Yokoi

St. Luke's International Hospital

Gen Shimada

St. Luke's International Hospital

Takashi Takeda

St. Luke's International Hospital

Kazuhiro Nakayama

St. Luke's International University

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## Research Article

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# Abstract

**Background:** Patients undergoing high-risk surgery are at risk of sudden changes in worsening. Advance care planning (ACP) support for patients who want active treatment is insufficient in setting outcomes, as it only targets better end-of-life care. Therefore, it is necessary to clarify how ACP support is implemented in the field and its effects. This study aimed to assess whether the development of two patient decision aids (PtDAs) can support preoperative ACP in patients undergoing high-risk surgeries.

**Methods:** This field-testing implemented two PtDAs that met the international criteria developed by the researchers to patients before surgery. The study participants included patients who were scheduled to be admitted to the intensive care unit after surgery at one acute care hospital in Japan and their families. The primary outcome was decision satisfaction evaluated by the SURE test, and the secondary outcomes were perception of the need to discuss ACP before surgery and mental health status. Data were collected before (preoperative outpatients, baseline) and after providing PtDAs (in the hospital) and after discharge. Results were analyzed using a mixed-methods approach.

**Results:** Nine patients were enrolled, of whom seven and their families agreed to participate. The SURE test result after discharge was four points (indicating no decisional conflict) for patients who were able to discuss with the researcher, patient, and family before discharge. Assisting patients with ACP before undergoing a high-risk surgery allowed them to recognize in advance the need for ACP, have an opportunity to share their thoughts with family members, and begin planning their own lives. Patients and their families were prepared to promote shared decision-making with healthcare providers and implement ideas into action.

**Conclusions:** Two PtDAs supporting ACP in patients undergoing a high-risk surgery were developed, evaluated, and accepted; however, they did not involve any discussion of patients' ACP treatment wishes with their families. Medical personnel should be coached to connect with adequate support. PtDAs for ACP before surgery could promote shared decision-making among patients, families, and healthcare providers.

## Background

Patients undergoing high-risk surgery may face a life-threatening crisis. Shared decision-making (SDM) is important for physicians and patients to make decisions, including that on the risk of the operation, through discussion and collaboration [1–3]. Patient decision aid (PtDA) is an intervention that promotes SDM and improves the quality of patient decision-making [4].

PtDAs are tools designed to help patients participate in health care and care decisions. The characteristics of PtDAs provide information regarding options, including benefits and risks, and help clarify patient values [5, 6]. As healthcare providers and patients engage in SDM through communication, PtDAs enable the patient to visualize information, thus leading to more satisfied choices and promotion of SDM.

However, the effect of PtDAs for advance care planning (ACP) support in patients undergoing high-risk surgery has not been clarified. ACP is defined as the ability of an individual to define goals and preferences for future medical treatment and care, discuss these with their families and health care providers, and record and review these preferences as needed [7, 8].

In surgical treatment, a type of proactive treatment, it is a complicated decision to consider the intention of treatment in case of a crisis before surgery. Information on the risks of treatment should be provided to patients according to their needs, and support methods should be considered to enable patients to make their desired level's life-sustaining treatment decisions and informed decisions despite time pressure.

Using PtDAs to help patients make the medical care decisions they want to receive, including during critical life situations related to ACP, can help them reflect and become aware of their thoughts and values. Moreover, PtDAs are expected to support the expression of the decision in the decision-making process and the decision. However, ACP is not routinely implemented in advance, and advance directives (ADs) are not required to be documented. By understanding the possible risks during high-risk surgical operations, providing support to those who wish to explore and define the treatment they wish to receive in advance can lead to patient-centered care in any treatment setting [9].

Previous studies on ACP and ADs in perioperative patients have challenged participants who often felt anxious or refused to participate because they do not recognize the need [10–13]. One study of ICU patients and their families reported that providing information about cardiopulmonary resuscitation and preferences for resuscitation treatment during hospitalization did not increase anxiety [14]; however, clinical evidence remains unclear. We hypothesize that in patients who wish to receive proactive treatment, such as those undergoing high-risk surgery or those in critical care, ACP is insufficient to achieve better end-of-life care. Since discussion between healthcare providers, patients, and their families is important for ACP, it is necessary to determine its implementation and effect in clinical setting.

This study aimed to develop and implement PtDAs for ACP for patients who are undergoing high-risk surgery before the operation. The effects of PtDA implementation process were evaluated.

## Methods

### Study participants, setting, and design

Patients scheduled for gastrointestinal surgery, as well as their families, and thereafter scheduled for admission to the intensive care unit were included in this study. The eligibility criteria were as follows: age  $\geq 20$  years, able to communicate, permission from the attending physician, and decision to undergo surgery. The exclusion criteria included a history of dementia or current cognitive decline and emergency surgery.

This study was conducted in an acute hospital with 500 beds in Japan from August 2021 to November 2021. This was an intervention study using PtDAs for ACP for patients undergoing high-risk surgery that

were developed by the researchers. A mixed-method study approach was used to verify the feasibility and acceptability of ACP intervention.

## **PtDAs**

The PtDAs used for this study were developed following a systematic model development process [15] (Additional file 1) by the researchers based on a survey of the needs of patients and families who had undergone high-risk surgery and the healthcare providers [9, 16]. The Ottawa decision support framework conceptualizes the support patients, families, and healthcare providers need for difficult decisions [16, 17]. The framework assesses the patient's decision support needs and interventions using the decision tool PtDAs to determine the impact of PtDAs' support on the outcome of the patient's decision, including the quality of the decision and the decision process itself. PtDAs developed from this framework have improved the quality of patient care, including the decision-making processes, compared to conventional care [1]. The PtDA developed by the researchers met this conceptual framework and the international standards of IPDAS [18, 19] (Qualifying criteria 6/6, Certification criteria 38/40).

The configuration of the PtDAs is shown in Table 1. PtDA\_A determines whether a patient considers a treatment preference and communicates it to a surrogate decision-maker or health care provider. PtDA\_B determines whether a patient decides to continue or stop treatment with the hope of prolonging life if recovery becomes difficult.

[insert Table 1 here]

## **Data collection and outcome measurements**

Patients were considered candidates if they decided to undergo surgery. After the candidate patient completed the outpatient visit, the investigator provided written and oral explanations of the study. Candidates were provided a few days to consider participating in the study. If the patient consented to study, the patient is instructed to contact the researchers directly. In addition, families of the candidates' patients were provided with written and oral explanations of the study and were contacted at a later date regarding their participation in the study.

The data collection procedure is shown in Fig. 1. Data were collected from the participants at the following time points: prehospital outpatient visits (baseline\_T0), during hospitalization (T1), and at first outpatient visit after discharge (T2). At each timepoint, they were asked to fill out a questionnaire. Interviews were also conducted on the period from the first outpatient visit to one month after discharge (T3).

The primary outcome of this study was decisional conflict as measured by SURE test. The Japanese version of the SURE test [20], which assesses the quality of decision-making, was used for patient survey items [21]. This scale can assess whether a person is making a satisfactory decision based on four questions and has been evaluated for validity and reliability [20, 22].

The secondary outcomes were as follows: perception of the need to discuss ACP before surgery, which was evaluated by a numerical rating scale (NRS; range: 0–10); and mental health status, which was assessed by the Hospital Anxiety and Depression Scale (HADS) [23]. The researchers also reviewed and assessed the options and writing status of the PtDAs. The survey administered patient's a family members included NRS (0–10) to confirm the patient's preferred treatment options and their perception of the need to discuss ACP with the patient before surgery, HADS to evaluate mental health status, and the degree of confidence as a surrogate decision-maker was assessed by NRS (0–10). Moreover, patients were interviewed after discharge (T3) to ascertain how they used the PtDAs during the pre- and post-discharge. Data on age, sex, families, medical history, employment, and decision-making preferences were also collected.

## **Intervention using PtDAs**

Only one researcher implemented PtDAs and was involved with the patient and family as a researcher and not as a healthcare provider at the study site. We explained to the participants that the researcher has a nurse qualification but was not a nurse belonging to the research cooperation facilities. During the study, researchers were conscious of constantly dealing with patients and family members in a neutral manner. The investigator and patient were scheduled to have four face-to-face meetings at the following time points: pre-admission outpatient (baseline), on admission (T1), first discharge outpatient (T2), and interview survey within one month of discharge (T3).

PtDAs were not provided until the baseline questionnaire was completed. After the baseline (T0) study, two PtDAs, namely PtDA\_A and PtDA\_B, were provided to the patients, and they were asked to read both. Some pages of the PtDAs instructed patients to check and write as they read, so follow the instructions on the page as far as you can understand. If patients' anxiety increases or if they experience pain in the middle of the session, reading of the PtDAs was halted. The patients were informed that should they have any questions, especially about PtDAs, they can always contact the study investigators. At this point, the researchers did not read PtDAs together.

On admission (T1), the investigator visited the patient's room and gave the questionnaire to be answered. The writing status of PtDAs was checked. The researchers did not discuss the content of PtDAs; PtDAs were discussed only when patients asked questions, consulted, or provided topics. At the time of the inpatient visit, the patient was asked whether the researcher would like to visit the patient several times during hospitalization, and the patient who wanted to visited the patient's room when the researcher could visit. During hospital visits, the researchers tried to keep the topic of PtDAs unknown and only talked about PtDAs when patients asked questions or offered topics. At the first outpatient visit and one month (T2-T3) after discharge, the investigator was contacted at a convenient time for the patient's outpatient visit or visited the outpatient clinic during the patient's scheduled outpatient visit.

## **Statistical analysis**

Basic statistics were calculated from the obtained quantitative data. In addition, the description status of the PtDAs were mainly evaluated by whether it was described or not. SPSS Statistics ver. 25.0 was used

for statistical analyses. Qualitative data, including whether the patient's pre-operatively provided PtDAs were read and used to understand ACP before surgery and why the patient chose this option, were collected during post-discharge interviews (T3). Qualitative data were analyzed using qualitative description [24, 25].

The results were analyzed by integrating the quantity and quality data of the SURE test with the process by which patients made decisions using PtDAs.

## Ethical considerations

Participants were informed in writing of the purpose of the study, method, participation and refusal in the study, protection of personal information and management of data, access to medical records, public disclosure of results, and withdrawal of synonyms. All study participants provided written informed consent. In addition, the study was cautiously conducted, with the assumption that patients and their families would be more anxious about surgery, to avoid increasing their mental burden. The Ethics Board of the St. Luke's International University approved the study protocol (approval number: 21-A007).

## Results

The flow diagram of this study is shown in Fig. 2. Seven patients and seven family members were included in the analysis. Table 2 provides an overview of the patient characteristics. The mean  $\pm$  SD of the patient's age was  $61 \pm 11.6$  years, and that of the family was  $49.9 \pm 13.2$  years. Among the patients, those with cancer were those in whom surgical treatment was planned for a complete cure. No patient was diagnosed with postoperative complications; however, one underwent exploratory laparotomy only because elective surgery was not performed owing to disease progression. One patient had heard or knew about ACP at the time of preoperative outpatient visit (T0) before PtDA implementation. The patients or their families did not ask any questions to the researchers during the period between the prehospital outpatient visit (T0) and the time of admission (T1).

### [insert Table 2 here]

Seven patients responded that they had read all of PtDA-A by the time of admission (T1). There were six patients with PtDA\_B, and one of them read the rest with the researcher during hospitalization. All seven patients were able to check all items in the PtDA\_A. Four patients filled out the free entry space. In PtDA\_B, five patients were able to check everything. However, based on the answers, all patients found it difficult to select the details of life-prolonging treatment by themselves.

Four patients used PtDAs with their families during the period from baseline (T0) to admission (T1). The discussion was also carried out with the patient, family, and researcher on the admission of the two persons. In addition, by the post-discharge survey, two patients had discussed with their families and researchers, and by the time of discharge, one patient and researcher had discussed. Six of the seven patients had an opportunity to discuss ACP with three family members and investigators by discharge (T2).

Although the researchers did not propose to talk about PtDAs or ACP during their stay in the hospital, five patients started talking about PtDAs or ACP. In addition to discussing ACP, patients talked to the researchers about their course of treatment and recovery. Some participants described their needs in the perioperative healthcare support system. None of the patients scored four on the SURE test of PtDA\_B at baseline (T0) (Table 3). However, on admission (T1), four patients scored a perfect score, and after discharge, six scored a perfect score, indicating a satisfactory decision-making.

**[insert Table 3 here]**

Patients who scored < 4 points by discharge (T2) could not read the PtDAs by themselves. Patients had the highest scores for baseline HADS-A, HADS-D, and HADS-T, and the scores tended to decrease gradually. In contrast, the scores of the family members did not decrease according to the treatment process and tended to increase slightly after discharge.

Patients were also interviewed after discharge about how they used the PtDA (Table 4). From baseline to admission (T1), some patients mentioned increased anxiety about the surgery. In addition to the fact that they were able to make their own decisions using PtDA, many respondents expressed a higher satisfaction with being able to express their feelings to their families.

**[insert Table 4 here]**

## **Discussion**

To our knowledge, this is the first study to investigate the implementation of ACP support in high-risk patients using PtDAs. We found that the PtDAs implemented in this study could be used to support ACP in patients scheduled for high-risk surgery, without increasing the requirement for human resources and posing a time burden on healthcare providers.

Providing PtDAs for ACP to patients before high-risk surgery had four main effects on patients and their families. First, it helped patients to understand ACP. One outcome cited was increased knowledge of PtDAs [1]. The provision of two PtDAs to help explain the ACP process and provide knowledge about life-prolonging treatment was an opportunity to deepen the understanding of patients and their families. Patients' knowledge and understanding of ACP may have led them to consider long-term treatment and lifestyle rather than solely end-of-life care decisions. ACP in high-risk preoperative patients is considered in the initiation of discussion and ACP support. However, the timing of ACP support before high-risk surgery may not be appropriate for perioperative patients as it may also increase anxiety and stress regarding treatment among patients and family members. Advance life planning or ACP could be used to support early healthy stages. However, it is difficult and impractical to approach the target person as the support starts in the acute care hospital. A significant reduction in interest in ADs in postoperative patients compared with preoperative patients was previously reported [11].

This study showed that ACP support for patients gave patients and their families a positive feeling that they were receiving treatment in anticipation of recovery. It did not necessarily increase the participants' anxiety but instead encouraged them to think about the treatment they wanted based on their values and life. The patients were also satisfied with the discussion process and sharing sessions with their families and researchers. By providing the patient with an opportunity to think about ACP before surgery, the patient may be able to continue to think about their life plan, including future treatment, and depending on the situation, discuss it with their family and health care provider to revise treatment goals.

The second effect is encouragement of patients to think about their values and how to think about the way they want to live and the treatment they want to receive based on those values. Most patients considered the medical treatment they wanted to receive based on their values only after being offered PtDAs. To express patients' feelings to their families and healthcare providers, it is necessary to identify these feelings and verbalize what they value. A previous study on ACP investigated the patient's ability to document ADs and agreement of intent with the surrogate decision-maker [26]. The essence of an ACP is as much about the process of discussion leading to a decision, as it is about being able to make one [7–8, 27]. The ability of patients to express their desire for treatment based on their values is an essential factor.

The third point was the opportunity for the patient and the family to talk. In this study, all patients expressed their treatment thoughts to surrogate decision-makers. Only 50% of patients could initiate discussion with their family members by themselves during the period until admission; thus, it is difficult for patients to initiate ACP discussion proactively. Although family members perceived discussion with patients as important, they generally avoid it in practice [28]. The involvement of family members in ACP is essential [29], and the preferences of family members tend to be as important as respect for autonomy [30, 31]. Problems related to treatment decisions for patients undergoing perioperative or critical care often blur the line between treatment and life-prolonging treatment owing to the rapid worsening of patient status and difficulties in predicting prognosis [32]. In addition, the patient's ability to make decisions is likely to deteriorate, leading to surrogate decision-makers and healthcare providers [33]. Thus, it is important for family members, including surrogate decision-makers, to understand the patient's treatment preferences and preferences for life-prolonging treatment. When patients want to communicate their wishes for treatment or life-prolonging treatment to family members, including surrogate decision-makers, healthcare providers should consider supporting their dialogue.

This study also found that family members have as much or higher anxiety levels than patients. Family members had unchanged or higher HADS scores even when patients completed the procedure successfully. Many patients had the same need for support during their treatment as their families, suggesting the importance of family care in the comprehensive implementation of ACP support for patients undergoing high-risk surgery.

Moreover, PtDAs may promote SDM. PtDAs. They have been shown to improve physician–patient communication and patients be not passive in decision-making [1]. This study clarified that creating

opportunities for patients and their families to interact with ACP themes is a challenging task for patients. Implementation created opportunities for patients and their families to discuss ACP via PtDAs and facilitated discussions with healthcare providers. High-risk preoperative decision-making is a complex process that requires a mutual understanding between physician and patient and is important to ensure patient understanding, so patients can make decisions based on their values and preferences [34, 35].

ACP is defined as the process of understanding an individual's values, life goals, and preferences for future health care and sharing them with family members and health care providers to support adults of all ages and stages of health [7] and the ability to record and confirm these as needed [8]. An important common feature of SDM and ACP is their focus on the decision-making process and patient's ability to make decisions based on their values and preferences. The use of PtDAs for ACP may facilitate SDM for ACPs by encouraging discussions between patients, family members, and healthcare providers.

Challenges to promoting ACP include difficulty in timing discussions and missed opportunities [36, 37] and a lack of knowledge and skills among healthcare providers [16, 38, 39]. Our findings suggest that family members also need ACP support, and that promoting family acceptance may lead to a discussion between the patient and family members and SDM involving healthcare providers.

This study had some limitations. First, this study was conducted on patients from one hospital and one department; thus, there is a limit to the generalization of our findings to patients undergoing high-risk surgery. Second, our results were affected by the fifth wave of SARS-CoV-2 infection, as the study was implemented when there was hospital restriction on the attendance of family members and a tremendous pressure on the medical system. Third, as this study was designed to assess the feasibility of implementation by combining quantitative and qualitative data, we were unable to determine effectiveness. This study evaluated the implementation by combining quantitative and qualitative data. The condition of the patient who received peripheral operation and critical care and the thought or needs of the patient/family are easily changeable. Our results indicate that it might not be able to evaluate effectiveness as an outcome of ACP based only on quantitative data. Future studies can improve the quality of data analysis by combining qualitative and quantitative evaluation when conducting outcome evaluation.

According to this study, patients undergoing high-risk surgery at acute care hospitals and their families were supported by various healthcare providers; thus, it was difficult for the same medical personnel to provide unified support to patients and their families. Therefore, in the future, it is necessary to examine the method for supporting patients and families. In particular, our results suggest that the involvement of one investigator with patients and their families in all timelines may improve the relationship between patients and their families. For example, there is usually no opportunity for a designated healthcare provider to continue interacting with the patient during the perioperative period, and there is family other than the attending physician. The fact that patients and their families were able to discuss ACP during the surgical treatment process may have been influenced by the ease of identification and judgment. For acute care hospitals, where it is difficult for specific nurses, other than the attending physician, to support

patients and their families, it will be necessary to consider better methods. For instance, cross-sectoral support of patient and family care by nurses who can work across organizations, such as advanced practice nurses (e.g., clinical nurse specialist), may be effective.

## Conclusions

ACP support for patients undergoing high-risk surgery is important; however, it should not be the sole focus and should be comprehensively included as necessary care in the pre- and post-discharge treatment process. It would be effective if all patients and their families were confirmed to have treatment preferences, and if ACP support were provided in all stages according to patient needs. Supporting ACP during this period can lead to an effective discussion between the patient and family on end-of-life care. These support interventions may increase patient and family satisfaction with the decision-making process. To implement and disseminate PtDAs for ACP in high-risk preoperative patients, there is a need to provide support, including provision and coaching of PtDAs, and to develop procedures for supporting healthcare providers.

## Abbreviations

ACP: advance care planning

AD: advance directive

PtDA: patient decision aid

## Declarations

### *Ethics approval and consent to participate*

The study was approved by the ethics committee of the St. Luke's International University (approval number: 21-A007) and was conducted in accordance with the Declaration of Helsinki guidelines. Participants were provided written explanations of the survey's purpose, research methods used, details of participating in and withdrawing from the survey, protection of personal information, and data management methods used in the study. All study participants provided written informed consent. Further, data such as basic attributes were coded to maintain participant anonymity.

### *Consent for publication*

Not applicable.

### *Availability of data and materials*

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

## ***Competing interests***

The authors declare that they have no competing interests.

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## ***Authors' contributions***

KY designed the study, collected, analyzed, and interpreted the data, and prepared the manuscript. KN contributed to the research idea and designed, analyzed, and interpreted the results; advised the whole research process; and helped prepare the manuscript. TK, GS, TY and TT contributed to the research designed, material development, and interpreted the results. All authors read and approved the final manuscript.

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## Tables

Tables 1 to 4 are available in the Supplementary Files section

## Figures

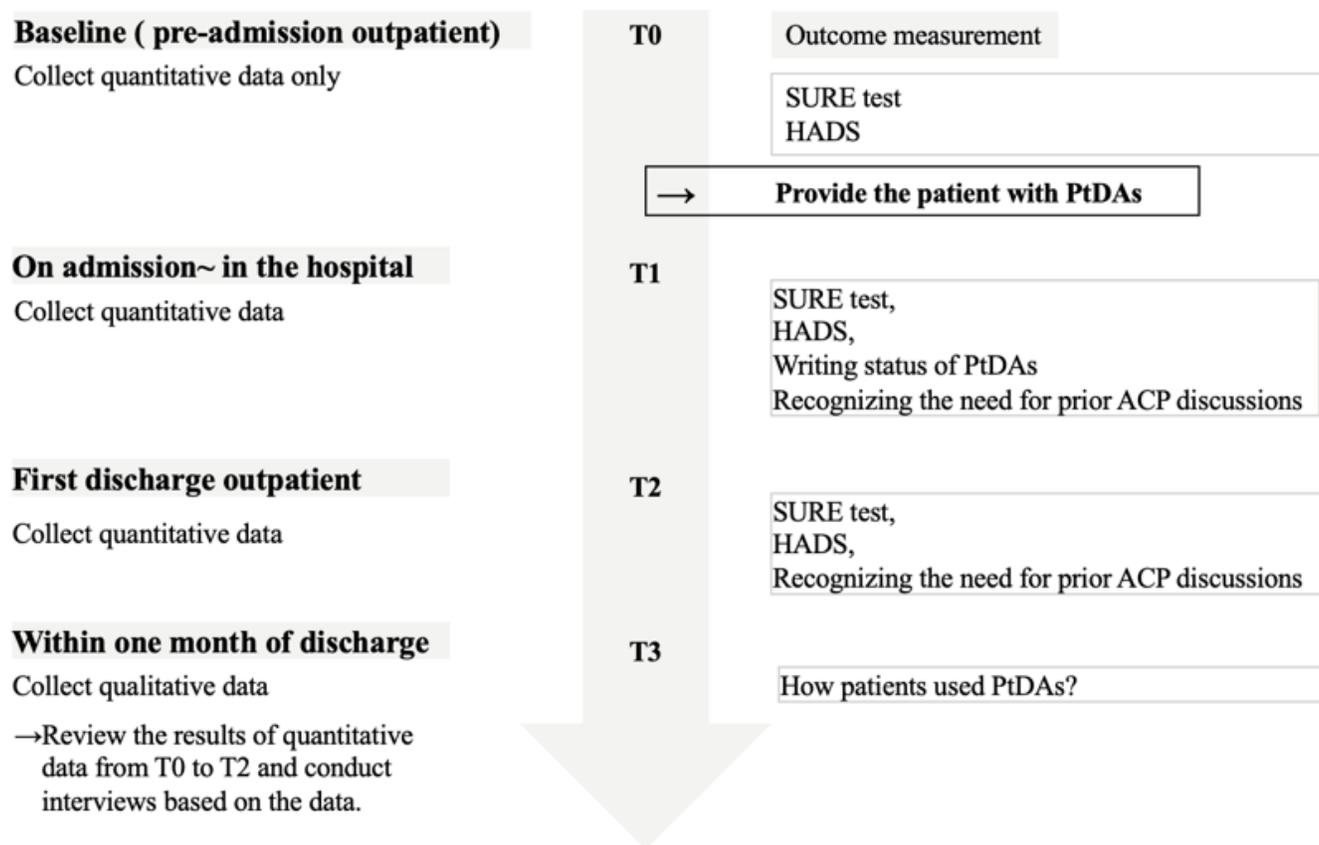


Figure 1

### Date collection diagram

NOTE:

After T0, when the patient and families discussed PtDAs with a researcher, data on the conversations were collected.

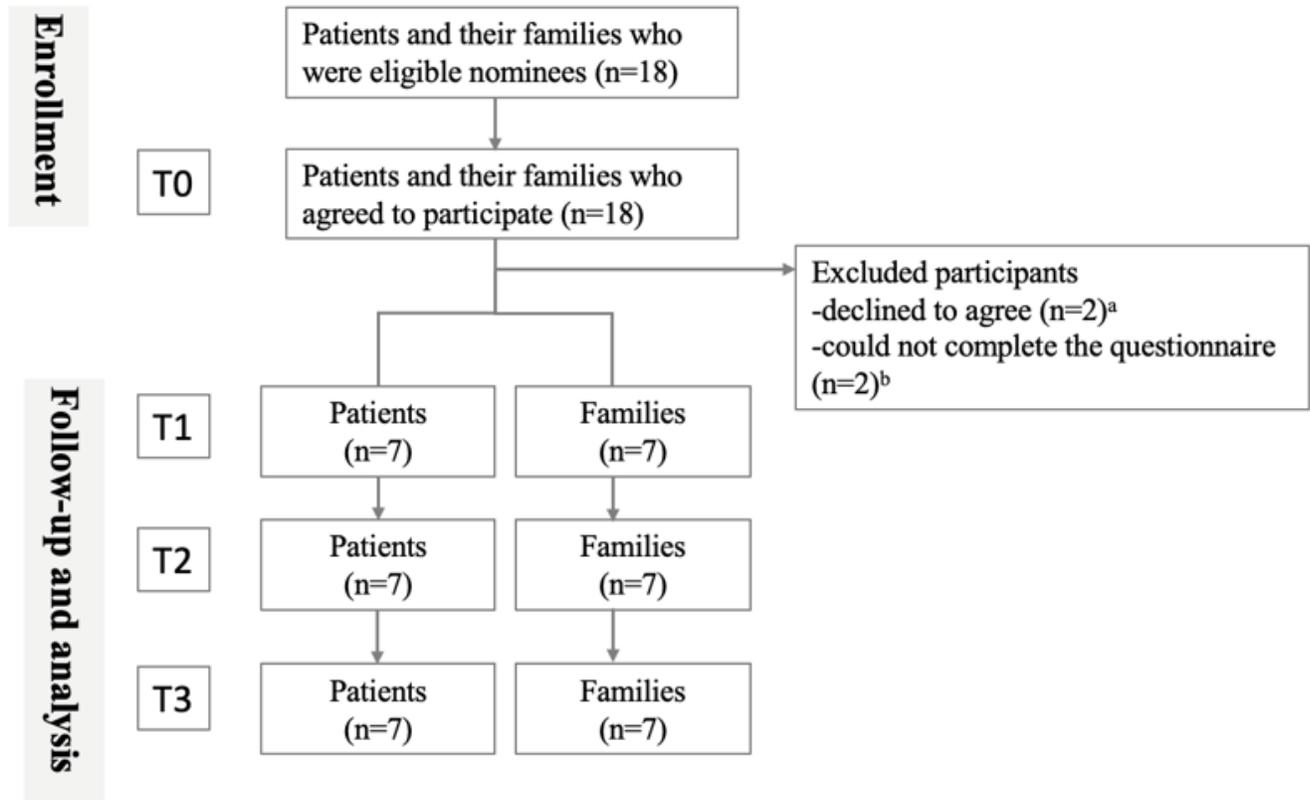


Figure 2

### Diagram of study flow

NOTE:

<sup>a</sup>One patient had a family member who declined to participate in the study after obtaining consent to hospitalization.

<sup>b</sup>One patient was excluded because although he could read the PtDAs, he could not answer the questionnaire.

## Supplementary Files

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

- [BMPCtable.xlsx](#)
- [BMPCAdditionalFile1.docx](#)