

Customized versus Conventional Video Counseling for Peritoneal Dialysis Decision-making in Chronic Kidney Disease Stage 5 under PD First Policy, A Randomized Controlled Study

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Abstract

Purpose Un-decision for start peritoneal dialysis (PD) was a challenging problem with conventional video counseling in CKD stage 5. This study aims to evaluate customized (for local context) versus conventional video counseling for PD decision-making in CKD stage 5 under PD first policy. **Methods** In 120 CKD stage 5 in tertiary-care hospital, Thailand who indicated initiate PD between May 2016 to January 2017 were enrolled in a randomized, open-label, controlled study. Patients were randomized to customized and conventional video counseling. The primary outcome was the acceptance rate along with PD catheter insertion on schedule. The secondary outcomes included changing the patient's knowledge and confidence in PD and unplanned start PD rate. **Results** 120 patients were analyzed (customized n=60; conventional n=60). The two groups were similar for age (55.7 ± 12.3 vs. 56.2 ± 13.4 years), BUN (89.8 ± 30.8 vs. 86.8 ± 29.5 mg/dL), Cr (10.37 ± 5.39 vs. 11.29 ± 4.90 mg/dl) and eGFR (4.78 ± 2.79 vs. 5.62 ± 2.82 mL/min/1.73m²). Acceptance rate along with PD catheter insertion on the schedule in customized video counselling group was not significant difference with conventional video counselling group (66.6% vs. 63.3%, relative risk 0.97, 95% confidence interval 0.73 to 1.29, p = 0.86). Patient's knowledge and confidence in PD were increasing but not significant difference between both groups. **Conclusions** Among CKD stage 5 in PD first policy, customized counseling was not a significant difference in rate of accept for start PD along with PD catheter insertion on schedule with conventional video counseling. Other counseling method to improve the accept rate for start PD need to further investigation.

Introduction

Unplanned start peritoneal dialysis (PD) which defined as need temporary hemodialysis with hemodialysis catheter before stable peritoneal dialysis at home is a global problem(1). The incidence of unplanned start PD is approximately 33-50% worldwide (1–3). Unplanned start PD is not only increasing the cost of treatment, increase resource used but also leading to worse clinical outcomes(4). There are many causes related to unplanned start PD, e.g. delayed referring to a nephrologist, waiting for PD catheter insertion, unpredict worsening renal function, multiple comorbid, old age, etc. (5). Patient defers making the final decision to accept PD is one of the most common challenges for unplanned start PD. Transit from CKD stage 5 to PD is a crucial step. PD patients and caregivers need to change status quo, daily routine and way of living thus effective counseling and education are needed in this step to push the CKD stage 5 patient for accept PD at the appropriate time(6).

Thailand has a mandatory peritoneal dialysis first policy in a universal coverage scheme, which accounts for about 75% of the total population(7,8). Therefore, continuous ambulatory peritoneal dialysis (CAPD) is the first free modality of choice in CKD stage 5 for those who are eligible for PD. However, many patients start PD with unplanned due to deferring final decision to accept PD until they get to late stage 5 CKD or are hospitalized with CKD complications. Effective counseling and education for a final decision in CKD stage 5 can overcome this challenge.

Thailand already achieved an upper middle-income country. However, economic inequity is a persistent challenge. In 2016, Gross provincial product (GPP) per capita in Bangkok, the capital city of Thailand was 13,730 United States Dollar (USD) per year. Bangkok's economy mainly on manufacturing (22.8%) and trades (19.3%). Meanwhile, the GPP per capita in the Northeastern region is 2,192 USD per year. Its economy comprises 20.5% agriculture and 12.6% trades(9). This diversity in income, occupation, way of living can affect the health-related problem, especially in self-care disease, including CAPD (10,11). In CAPD, patients and caregivers need to adjust their lifestyle, home environment, and time available for changing PD fluid four times every day for life or until a kidney transplant is performed. Living habits, lifestyle, household income, and cultural factors in each region may affect PD decision-making. Therefore, counseling for accept PD should be tailor-made for each diversity of PD center for each region. Our hypothesis is customized counseling for specific patients setting in our region would be helpful in the decision to accept PD. The main objective of this study is to compare a customized video counseling session (for our local setting) with a conventional video counseling session (for general use and design for urban society) on the acceptance rate of dialysis decision-making in stage 5 CKD under the PD first policy.

Materials And Methods

Study Design

We conducted a randomized, open-label, controlled clinical trial between May 2016 and January 2017 at a tertiary care referral hospital in northeastern Thailand. The Institutional Research Ethics Review Committee approved the study protocol. Informed written consent was obtained from all the participants or their family members.

Patients and randomization

Patients aged 18 – 75 years, who had CKD stage 5 and expected to start PD within 4-6 weeks in a universal coverage program for the PD first policy were enrolled from both outpatient and inpatient setting by a nephrologist. The participants were randomly assigned by a PD nurse into blocks of four with a sealed opaque envelope in a 1:1 ratio to have either conventional or customized video counseling for final PD decision-making. Patients who had clinical contraindications for PD (e.g., a lower midline abdominal scar from previous surgery, severe mental problem, blindness in both eyes, an abdominal or inguinal hernia, BMI > 35 kg/m²), or obvious social barriers for PD (e.g., homelessness, living alone with a disability) were excluded. Patients with advanced malignancy or a life expectancy of fewer than three months were excluded. Patients who had previously been exposed to video counseling, patients who were willing to choose hemodialysis by self-payment, and candidates who were to have a preemptive kidney transplant were also excluded.

Video counseling and educational program

CKD stage 5 patients were followed up in the CKD clinic by a nephrologist or referred from a network hospital by an internist or general practitioner. General counseling for living with CKD, slow progression, diet, drugs, and plans for a PD or kidney transplant was given during routine CKD clinic visits since CKD stage 4. When eGFR declined and PD was expected to start within 4-6 weeks or the patient was urgently referred from a network hospital because of CKD complications, the patient was sent for an educational and counseling program for final PD decision-making. This four-step PD counseling protocol to help patients make the final decision for PD was run by a PD nurse for approximately one-and-a-half hours. The first step involved creating a relationship with patients and family members; the second step was setting a goal for the planned start of PD and information on how to avoid CKD complications; the third step included the use of customized or conventional video counseling for education; the last step was to answer any questions the patients were concerned about or the obstacles they perceived in having PD. Ten questions pretest and posttest patient's knowledge and confidence with PD were assessed during this process. Consent from patients and family members for PD was given after finishing the counseling process. If the patients decided to accept PD, a nephrologist put a coiled double-cuff PD catheter in place by percutaneous bedside technique within two weeks; followed by a break-in period of 2 weeks and training was given to patients and caregivers in the CAPD program for one week. If patients had severe CKD complications, temporary hemodialysis was performed before the PD catheter was inserted depending on the nephrologist's judgment. After finishing this process, patients were regularly followed up at the CAPD clinic. CAPD used 1.5% PDF 2 liters 4 times a day with the manual exchange by patients or the caregiver; 4.25%PDF could be used if patients had clinical volume overload. If the patients could not make a final decision to accept PD, PD nurse makes an interview for reasons of postponing PD and the patients were sent back to the CKD clinic. Patients were then started on counseling and joined the educational program on their next visit. During this period, the PD nurse would phone the patients to establish whether there were any CKD complications.

Customized and conventional video counseling

We used a video as part of the educational and counseling program during the third step. A conventional, 40-minute counseling video was sponsored by a pharmaceutical company from central Thailand and is currently used in daily practice. The content of the conventional counseling video provides basic knowledge about CKD, the choice of modality for dialysis, how to run a home CAPD, and the patient's experience. All the content in the video was in the Thai language, with the formal central Thai accent. Patients who participated in the video were middle-class people with a degree and a good home environment. As we mentioned above, many factors can influence decision-making, including cultural, beliefs, home environment, and way of living that these patient's social background was different in each region of Thailand. The 32-minute customized video was created to overcome these issues. The video content was in the Thai language with a northeastern Thai accent and a large Thai subtitle. A wide range of PD patients, representing diverse income and education background appear in the video. The participants range from lower-class patients with primary school education and a limited home environment to middle-class people from a quite perfect home environment.

Moreover, misconceptions and fear related to PD-related complications were clarified in this video, especially concerning PD catheter insertion and PD-related peritonitis. Lastly, the consequences of indecision concerning dialysis were shown, including CKD complications, and patients' experience of temporary hemodialysis catheter insertion. A summary of the difference between the conventional and customized multimedia videos is shown in a Table1.

Outcomes

The primary outcome was the acceptance rate along with PD catheter insertion on schedule. The secondary outcomes were changing the patient's knowledge and confidence in PD by the end of the counseling program, which was assessed by ten true or false questions. Rate of unplanned start PD (the need for temporary hemodialysis before starting CAPD) and reasons for postponing PD in each video group were also reported.

Statistical analysis

These studies required 104 participants to detect differences between the two groups with 80% of power Cronbach's alpha 0.05(12). The acceptance rate along with PD catheter insertion on schedule in conventional video counseling was 55% based on data in our center. The increase to 80% in the acceptance rate with PD catheter insertion on schedule among patients after watching the customized video counseling was clinically significant. Nominal variables were analyzed by a chi-square test. Continuous variables were analyzed using Student's t-test for analysis. Univariate and multivariate analysis by stepwise logistic regression was used to find potential factors for not accepting PD. Descriptive statistics were used as the mean with standard deviation, the median with the interquartile range, and the number with a percentage. Intention to treat was used for the analysis. All the reported P values were the two-sided test, and <0.05 was statistically significant. Analyses were performed using the Stata Statistical Software: Release 12 (Statistical Software, College Station, TX; StataCorpLP).

Results

One hundred and forty-four patients who had CKD stage 5 in the PD first policy were canvassed during the study period. One hundred and twenty of 128 eligible participants (93%) were enrolled in this study. The reasons for exclusion and the CONSORT Statement are shown in Figure1 (2 patients were candidates for pre-emptive living related KT, two patients had hemodialysis by self-payment, four patients had obvious social barriers to PD). One hundred and twenty participants were randomized and assigned to a customized video counseling group and a conventional video counseling group at the beginning of a 4-step protocol for education and counseling program for final PD decision-making. There were no exclusions after randomization or dropout participants. Baseline characteristic showed no significant difference between the two groups, as shown in Table2. Most of the participants were of low socioeconomic status (79% with primary school education; 53% were unemployed and had an average household income of USD156 per month). More than half of the patients (62%) had a follow-up with a nephrologist after less than four weeks, and most of the patients (91%) had symptoms of CKD (uremia,

history of volume overload, fatigue due to anemic symptoms) during enrollment. Laboratory data showed no significant difference between the two groups (Table3). BUN was 86-89 mg/dl, Cr was 10-11 mg/dl, and eGFR was 4-5 ml/min/1.73m². There were 43 out of 60 participants accepted for PD immediately after customized video counseling and 42 out of 60 patients accepted for PD after conventional video counseling. However, the acceptance rate along with PD catheter insertion on the schedule was 66.6% (40 out of 60) in customized video counseling group and 63.3% (38 out of 60) in the conventional video counseling group (Figure 2). There was 7 participants (3 in customized, 4 in conventional video counseling group) who accept PD after counselling immediately but did not come along with PD catheter insertion on schedule. There was no significant difference in the acceptance rate along with PD catheter insertion on the schedule between the customized and conventional groups (RR 0.97, 95% CI 0.73 to 1.29, p=0.86). The reasons for postponing PD were shown in Table4. The patients' knowledge and confidence, assessed by a questionnaire with ten true/false questions, increased after they had received education in both groups, but there was not a statistical difference between the customized and conventional groups (78.3% vs. 75.8%, 95% CI -0.80 to 0.30, p=0.37). In addition, there was no significant difference between the two groups in the incidence of unplanned start PD (30% vs. 40%, p=0.35 in the customized and conventional groups, respectively).

Discussion

In this study, customized video counseling which designed for local context in terms of socioeconomic status, home environment, northeastern regional Thai dialects and added the common concerns for PD, including PD catheter insertion, PD-related peritonitis and the consequences of delayed PD, was not significant difference to conventional video counselling video in term of the acceptance rate along with PD catheter insertion on schedule in CKD stage 5 under PD first policy. Moreover, patients' knowledge and confidence of PD after the counseling process with both customized and conventional video counseling increased, but there was no significant difference between both groups. However, the reasons for postponing PD in each group were obvious differences.

We try to overcome the challenge of un-decision to PD in CKD stage 5 at the suitable timepoint before life-threatening CKD complication occurred with customized video counseling. For the background hypothesis in the diversity of patients in each region of PD center in term of household income, home environment, way of life, and illness belief will affect PD dialysis decision making. Our study found the reasons for un-decision to start PD were different between 2 video counseling groups. The barrier to start PD in term of concern for infection from limited home environment and fear for PD catheter insertion were fewer in customized video counseling than conventional video counseling group (3 vs. 13 and one vs. 5, respectively). These finding may explain from our customized video counseling was added the example from successful PD patient not only middle socioeconomic status with the quite perfect home environment but also low household income patient with a limit home environment. The baseline socioeconomic status and education background of PD was different in each region of Thailand. One PD center in Bangkok, the capital city of Thailand, 65% of PD was high school education and household

income per month was 1,240 USD. Meanwhile, our center in Nakhonratchasima Provinces, Northeastern region of Thailand, Most of CAPD patients (79%) had a primary school education, 156 USD in household income per month. Because the difference in these patient's background of each region, so the customized video counseling for accepting to PD was needed. Moreover, the customized video counseling added the common concern in PD especially PD catheter insertion procedure, so the reasons of fear for PD catheter insertion in patients who postpone the decision to accept PD in customized video counseling was diminished.

However, the acceptance rate along with PD catheter insertion on schedule among those who watched the customized video counseling was not significantly differenced with conventional video counseling. This finding may from the reasons as follow; Firstly, a counseling video of short duration is not sufficient to change a patient's attitude. Secondly, most of the participants (67.5%) had a short follow-up duration and a lack of pre-dialysis care by a nephrologist, so they had a high tendency to refuse dialysis. Thirdly, even though the surrogate outcome, the patients' knowledge and confidence in PD were increasing after video counseling, but it was not a significant difference between customized and conventional video counseling group. Deciding to have dialysis depends on many abstract aspects such other than knowledge and confidence in dialysis as personal values, beliefs, and feelings toward life, suffering, death and other patients experience(13–16). In-depth interviews on this issue should be further evaluated.

There was some doubt in the rate of acceptance along with PD catheter insertion on schedule. In our center before conducting this study, acceptance rate along with PD catheter insertion with conventional video was 55%. However, the acceptance rate along with PD catheter insertion with the same conventional video increased to 70% during conduct this study. The increase in the rate of accept PD along with PD catheter insertion was increasing 27% despite the same conventional video counseling but the protocol for counseling and education had been systematized. In this study, we create a systematized protocol including a script for PD nurse who counselor the CKD stage 5 that aims to reduce bias between 2 groups of video counseling. The rate of accept PD may not only depend on the content of the video counseling but also protocol and process including a script for counseling and education.

Our study aimed to answer the hypothesis that video counseling with a sample of patients in a local setting could help overcome barriers for accepting CAPD. To the best of our knowledge, our study was the first randomized controlled trial to answer this question, especially in the PD first policy setting. Nowadays, there are few proven strategies for improving survival in PD patients including planned start dialysis (1,17–21). However, in the real world, more than half of the patients start PD with unplanned. Thus, dialysis decision-making is the first step for planned start dialysis. Our study encourages health care providers to focus on customized educational and counseling programs. These easy interventions may lead to planned start dialysis and improve PD patients' survival. Another advantage of our study was that there were no dropout participants.

However, there were points of concern in our study. First, the nurse who was involved in the counseling process and asked for a patient's final dialysis decision was not blind to video counseling groups, so bias could have occurred in the outcome assessment. Second, we calculated the sample size based on optimism that the accept rate along with PD catheter insertion with conventional was increasing from 55% to 80% with 80% power. However, when conduct the study; the acceptance rate was increased to around 70% in both groups, so this study had underpowered. Third, there were contamination factors in the period around two weeks during finished PD decision-making to schedule PD catheter insertion. Some patients who accept PD after counseling protocol but did not come along with PD catheter insertion on schedule. They may influenced from other people during 2 weeks that were contamination factors. Lastly, due to late presentation and counseling, patients who said they would accept PD may not always go ahead with planned start dialysis. Some patients need temporary hemodialysis for improve uremic symptoms, then come along with PD catheter insertion.

We encourage each PD center to focus on counseling and the educational process for PD decision-making at an appropriate time. This will lead to a planned start PD. In addition, customized video counseling in the local contexts should be set in place in each PD center, especially in the PD first policy setting. Moreover, we suggest to systematized protocol counseling process including a script for the counselor. The systematized counseling process may increase in the accept for PD other than the content of video counseling. Lastly, the counseling and educational process for dialysis decision making in PD first policy is still a challenge and needs to improve. The randomized controlled trial to compare only video counseling with other methods or combined methods, e.g., focus groups, sharing patients' experiences, motivational interviews, or interactive interviews regarding the rate of acceptance of PD or the rate of planned start dialysis in CKD stage 5 should be urgently needed. Furthermore, in-depth interview in reasons for deferring PD was necessary to a feedback loop to improve the counseling process.

Conclusions

Our study showed evidence that customized video counseling was not significantly different from conventional video counseling for PD decision-making along with PD catheter insertion in CKD stage 5 under the PD first policy. However, we encourage each PD center to focus on counseling and the educational process to improve the acceptance rate of PD among patients, which will then lead to planned start PD. Evidence supporting counseling methods for PD and the appropriate content required for PD counseling urgently needed to improve dialysis decision-making in CKD stage 5.

Declarations

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Conflict of Interest: All authors declare that they have no conflict of interest.

Informed consent: Informed consent was obtained from all individual participants included in the study.

Ethical approval: All procedures performed in studies involving human participants were in accordance with the ethical standards of Maharat Nakhon Ratchasima Ethics Committee of Human Research, Maharat Nakhon Ratchasima Hospital, Thailand. Approval number 031/2016.

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Tables

Table 1 Content of customized and conventional video counselling

	Customized multimedia	Conventional multimedia
Duration (minute)	32	40
Language	Northeastern Regional Thai Dialects with Thai subtitle	Formal Thai language
Introduction to kidney disease	Yes	Yes
Choice for treatment of CKD stage 5	Yes	Yes
Consequence of delay dialysis	Yes	No
Introduction to PD	Yes	Yes
How to change PD fluid	Yes	Yes
Patient experience	Lower, middle income	Middle income
Patient experience before and after PD	Yes	No
Caregiver experience	Yes	No
Fear and barrier to PD		
- PD catheter insertion	Yes	Yes
- PD-related peritonitis	Yes	No
- Logistic of PD fluid	Yes	No
- Home environment	Perfect to limited home environment	No

PD = Peritoneal dialysis

Table 2 Baseline characteristic

	Customized video (n=60)	Conventional video (n=60)	P-Value
Age (years, mean \pm SD)	56.2 \pm 13.4	55.7 \pm 12.3	0.81
Male (n, %)	22 (36.7%)	32 (53.3%)	0.06
Have caregiver (n, %)	56 (93.3%)	58 (96.7%)	0.40
Primary school education (n, %)	46 (76.7%)	49 (81.7%)	0.82
-	-	-	
Occupation		-	-
- Unemployed (n, %)	34 (56.6%)	30 (50%)	0.46
- Farmer (n, %)	6 (10%)	8 (13.3%)	0.56
- Employee (n, %)	8 (13.3%)	6 (10%)	0.56
-		-	
Household income per month (USD, mean, IRQ)	156 (33, 312)	156 (50, 312)	0.97
DM (n, %)	33 (55%)	35 (58.3%)	0.715
Symptom of CKD (n, %)	56 (93.3%)	54 (90%)	0.513
Nephrologist follow up less than 3 month (n, %)	44 (73.3%)	37 (61.6%)	0.17
CKD unawareness (n, %)	37 (61.7%)	23 (38.3%)	0.01
OPD Setting (n, %)	18 (30%)	22 (36.6%)	0.44

SD = standard deviation; CKD = chronic kidney disease; DM = diabetes mellitus; IQR = interquartile range; OPD = outpatient clinic

Table 3 Laboratory at randomization

	Customized video (n=60)	Conventional video (n=60)	P-Value
Hb (g/dL, mean \pm SD)	7.8 \pm 1.3	7.7 \pm 1.6	0.59
BUN (mg/dL, mean \pm SD)	89.8 \pm 30.8	86.8 \pm 29.5	0.59
Creatinine(mg/dL, mean \pm SD)	11.29 \pm 4.9	10.37 \pm 5.39	0.32
eGFR (mL/min/1.73m ² , mean \pm SD)	4.7 \pm 2.7	5.6 \pm 2.8	0.10
Na(mEq/L, mean \pm SD)	134.9 \pm 6.3	135.1 \pm 5.8	0.79
K(mEq/L, mean \pm SD)	4.99 \pm 5.04	4.48 \pm 0.74	0.43
HCO ₃ ⁻ (mEq/L, mean \pm SD)	19.2 \pm 4.8	19.6 \pm 5.4	0.63
Ca ²⁺ (mg/dL, mean \pm SD)	8.0 \pm 1.1	7.7 \pm 1.1	0.25
PO ₄ ³⁻ (mg/d, mean \pm SD L)	6.3 \pm 2.2	6.0 \pm 2.1	0.41
Albumin (g/dL, mean \pm SD)	3.21 \pm 1.34	2.97 \pm 0.69	0.07

SD = standard deviation; BUN = blood urea nitrogen; Cr = creatinine; Hb = hemoglobin; K = potassium; HCO₃ = bicarbonate; PO₄³⁻ = phosphate; Ca²⁺= calcium

Table 4 Reasons for postponing PD in each video counselling group from patient's self-report (One patient can have multiple reasons)

	Customized video (n=17)	Conventional video (n=16)
I feel unhealthy but don't want to change status quo	8	5
I feel healthy, why should I need dialysis?	2	1
I don't want to be burden of family member	13	10
I think my home is not a perfect environment for change PD fluid, so I will suffer from PD-related infectious complication	3	13
I fear for the PD catheter insertion procedure	1	5
I will be died soon if I start PD	1	0

Figures

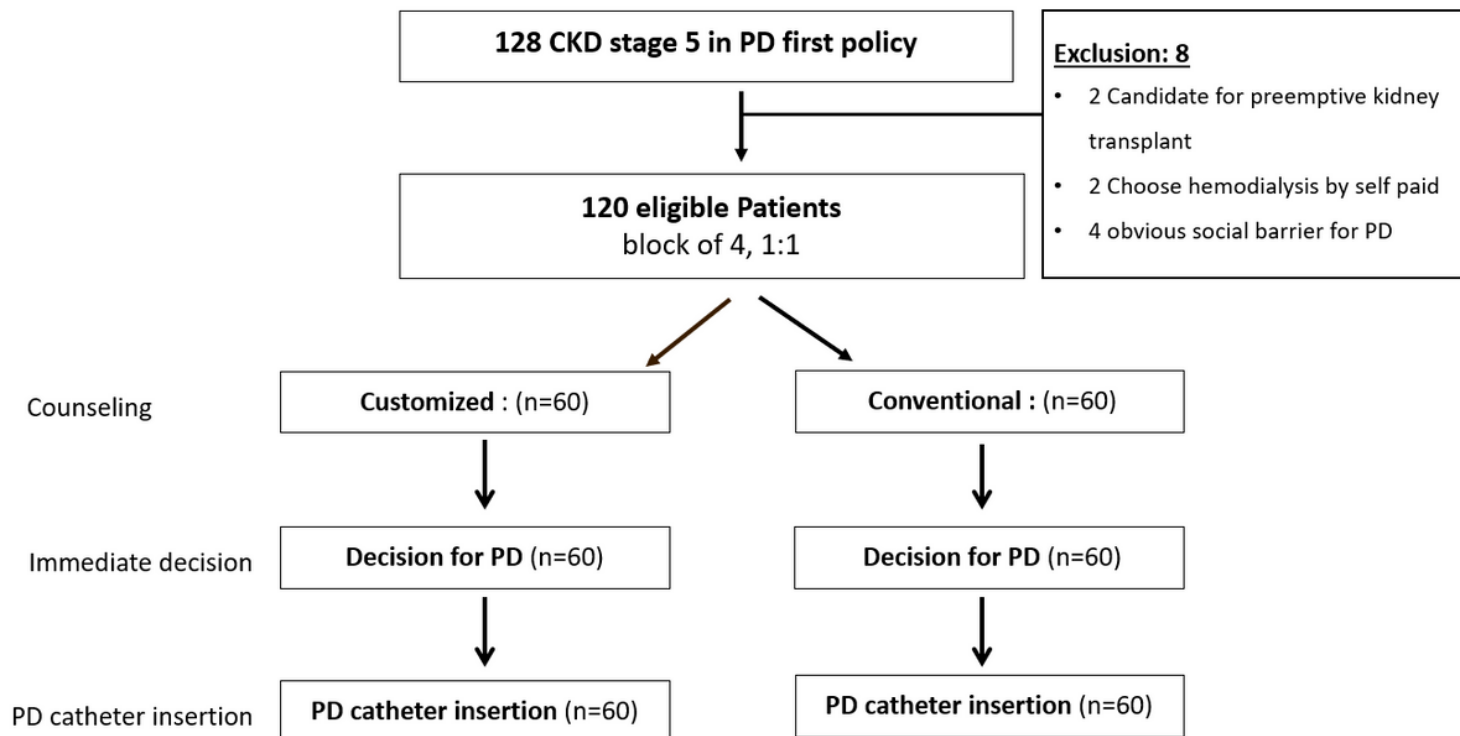


Figure 1 Study flow as CONSORT Statement

Figure 1

Study flow as CONSORT Statement

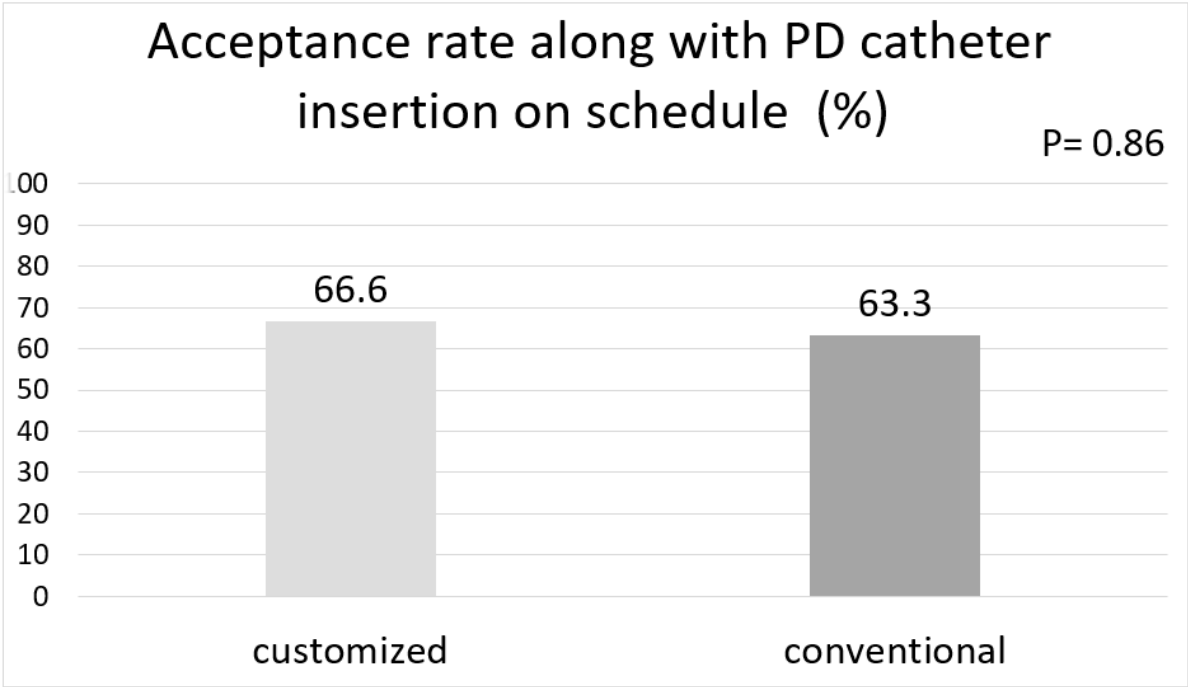


Figure 2 The acceptance rate along with PD catheter insertion on schedule

Figure 2

The acceptance rate along with PD catheter insertion on schedule