Video training supplementation to reduce the risk of central venous catheter infection in patients discharged on home parental nutrition

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Background

Home parenteral nutrition (PN) is an alternative form of nutrition in patients in whom enteral nutrition is infeasible or insufficient in the long term.[1,2] Home PN improves the quality of patients' life and consequently also the course of the underlying disease, with optimization of nutrition status.[2] A study conducted in Australia found that home PN had a positive impact on the daily living of patients.[3] In recent years, more emphasis has been placed on delivering parenteral nutrition to patients at home, which may improve patient care and reduce costs.[4] Thus, more patients rely on TPN for lifesaving nutrition support. There were an estimated 20,883 adult patients receiving home PN in 2013 based on data from Medicare and Medicaid Services.[5] The use of home PN has increased in recent years in adult patients.[6–9] Although comprehensive data is lacking in the United States, there is a trend of increasing home PN use across many countries, including UK, Canada, and Spain.[8,10]

Studies have shown that patients receiving total parenteral nutrition (TPN) are at higher risk for bloodstream infections compared to other patients with chronic infusion needs[1–14]. Increased parenteral caloric intake is an independent risk factor for bloodstream infection in patients receiving TPN. A prospective study in 87 critically ill patients showed that patients who had catheter related bloodstream infection (CRBSI) received more parental calories (36 kcal/kg/day versus 31 kcal/kg/day, P = 0.003).[11,12] Catheter-related bloodstream infection is a major cause of mortality and morbidity in patients receiving TPN.[13,14] Therefore, it is important to maintain safe vascular access to prevent life-threatening complications.

Fortunately, there are interventions that reduce risk for bloodstream infection in home TPN. In a retrospective study, chlorhexidine gluconate transparent antimicrobial dressing reduced CRBSI from eight cases to zero case in 12 months.[15] Another research study found that patients with parenteral nutrition who are managed by a dedicated nutrition support team are less likely to develop CRBSI at 24 months than a variety of physicians (1.3% vs 26.2%).[1] More importantly, patient engagement and education program has been proven feasible and potentially effective. An oncology unit in Denmark developed an education program for 42 out of 82 randomized patients with tunneled central vein catheters. 88% of the 42 patients completed the training, and the 42 patients had 50% less CRBSI in a five-month period.[16] A group in MD Anderson Cancer Center designed an in-person and video education program for central catheter care. After 1 year, 95% of the participating patients caring for the catheters at home, and 97% of them reported confidence and satisfaction in catheter care.[17]

We developed an education video addressing the aseptic techniques to safely handle central catheters at home for TPN use. It will be hosted in a mobile app with a secure link. Our primary aim is to assess the effect of the video training supplementation prior to discharge on the rate of CRBSI over a 12-month period of time. Our secondary aims are

to assess the patient's comfort level when handling catheters for patients newly initiated home TPN.

Hypothesis

We hypothesize that 1) the video will improve rates of CRBSI compared to a control group receiving written catheter instructions; 2) the video will improve patients' comfort level with handing central catheters; 3) patients will find the video easy to use.

Participants

Inpatient adult patients who are discharged home for the first time on home TPN will be approached for consent and inclusion in this prospective study design.

Study duration
24 months

Methodology
Inclusion Criteria

1. Patient will be discharged to start TPN at home.
2. Age ≥18 yrs.
3. Ability to understand and sign written consent form.
4. English-speaking patients.
5. Patients who are willing to self-administer TPN at home.

Exclusion Criteria

1. Patients without consent
2. Patients who have been on home TPN prior to the index admission at any time in the past
3. Non-English-speaking patients
4. Patients who will not self-administer TPN.

During initial screening and recruitment, it will be necessary to acquire potential participants' names and medical record numbers. Medical record numbers will be used to confirm the patients' diagnosis and home TPN usage by reviewing electronic medical records. Names are necessary to obtain permission to approach the patients from the patients' physicians. This information will be stored electronically in a password-protected file on a computer in room M-421. After screening and recruitment, patient names will be replaced anonymous study I.D. numbers. For patients choosing not to participate in the study, medical record numbers will also be deleted, and standard of care will be continued.

Following consent, each subject will be asked to complete a "TPN Central Catheter Self-Care Questionnaire" (Appendix 1). The primary role of the enrollment questionnaire is to assess for baseline comfort level to manipulate a central catheter at home. In addition, following enrollment, electronic chart review will be performed to assess for clinical and laboratory variables within three months of enrollment (complete blood count, renal function, liver function studies, type of catheter placement, extent and duration of disease and comorbid conditions [Charlson score]).

All enrolled patients will receive baseline in-person hands-on training for catheter use. Then the patients will be randomly assigned to the control group (written instructions) or the intervention group (provided video link).

A baseline entry questionnaire will be administered to assess the patients' comfort level for central catheter use and indications for PN. Each subject will use their study I.D. in lieu of their name. Then patients in the intervention group will be given a link to the educational video, which they can access as many times as they prefer.

Six weeks following enrollment, study participants will be asked to complete a second "TPN Central Catheter Teaching and Self-Care Questionnaire" (Appendix 2) via an email or secure text link generated from patient.iq. to reassess participants' comfort level of catheter self-care.

Six months following enrollment, study participants will be asked to complete a "Conclusion of Study Questionnaire" (Appendix 3) via an email or secure text link generated from patient.iq. The role of the concluding questionnaire is to assess for subjective reports of their confidence and comfort level in central line self-care.

If a subject fails to respond to these electronic questionnaires, the IRB-approved study staff will approach he/she during a standard GI Nutrition follow-up clinic visit to obtain answers for the questionnaire via a secure link on a tablet device.

The follow-up period will not exceed one year beyond the inclusion date. At the end of one year, the IRB-approved study staff will gather clinical information from the electronic medical record to determine if each subject has had a CRBSI event. Per CDC, CRBSI is defined as a laboratory confirmed infection where a Central Venous Catheter (CVC) is in place for over 2 calendar days prior to a positive culture and is also in place the day of or day prior to culture. And not deemed as a result from contamination by the primary hospital team at the time of the treatment.

The subjects will undergo weekly laboratory tests (complete blood count, electrolytes, liver function, and kidney function) as part of their routine standard of care to ensure the TPN formula is up to date and meets subjects' nutritional and metabolic needs. If a subject seeks care outside of UChicago, subject's UChicago care team members will obtain permission to have the health information released to UChicago, as part of the subject's standard of care. If patient wishes to transfer care of their TPN and CVC permanently to another institution, then their participation in this study will be terminated.

Additionally, subjects will be followed-up weekly via phone by their care team at UChicago as part of subjects' routine standard of care to ensure safe use of CVC and TPN infusions.

Study Schema

Assessment/Procedure	Visit 1	Visit 2	Visit 3	Visit 4
Informed consent	X			
Data collection: Demography and medical history	X			
Randomization	X			

Watch video/ follow written instructions	X	X	X	
Complete questionnaire	X	X	X	
Review medical, surgical, and hospitalization records for CRBI evaluation				X

Location

Patients will be consented at the University of Chicago's Center for Care and Discovery and Mitchell Hospital. All obtained data will be stored in a password protected computer or a locked drawer in the research office in M-421.

Potential risks and benefits

There is a minor risk of loss of confidentiality with participation in this study since subject identifiers will be collected. However, all study data will be recorded in a database where names and medical record numbers will be removed and replaced with a study I.D. Only the study staff will have access to the key which links the study code to the subject's identity.

Patients may receive no direct benefit from participation in this study, but it is anticipated they will benefit from improve catheter self-care techniques, and an improved physicians' understanding of catheter associated bloodstream infections.

Special Precautions

No specimens will be collected during this study. Standard precautions will be provided during all patient encounters and clinical care.

Special precautions will be taken by research staff to ensure confidentiality. All data review will be performed electronically on a password-protected computer in a locked and limited access area.

Data will be coded in case the study team needs to go back and re-check data or look into abnormalities. Subjects are assigned a unique study code in place of their name and MRN. Only the study staff will be able to link data with subjects' identifiable information. Upon termination of the study, the coding link will be destroyed, leaving only completely de-identified data.

Experimental controls and use of placebos

N/A

Number of experimental subjects

One hundred (100) subjects will be included in the study.

Data Analysis

The rate of CRBSI will be determined. Risk factors for the CRBSI will be assessed in univariable and multivariable analysis based on pre-defined clinical and subjective risk factors.

Statistical justification
The rationale for the number of subjects is as follows. With 30% rate of bloodstream infection, and a 70% power and 95% confidence interval, the total sample size required would be 93 patients in order to see a reduction in the rate of bloodstream infection. Suppose a 10% rate for loss to follow-up, the total subjects will be 100 patients.

At the end of the study, the rate of CRBSI will be calculated and compared between the TPN video group and the control group using an unpaired Student's T test. The frequency of TPN video use will be reported as quantitative data based on discrete values. The comfort level of CVC handling will be aggregated, and the mean value will be compared between the video group and the control group using an unpaired Student's T test.

Informed Consent

Written consent will be obtained in standard fashion using an IRB-approved consent form. The patient will be approached by the PI, Co-I, or a trained study staff member. All ethnic populations will be eligible and recruited. The study will be explained in detail during a standard-of-care inpatient GI nutrition consultation visit, all patient questions will be answered and sufficient time will be allowed for the subject to make a decision regarding participation. The original signed consent form will be stored in a locked drawer in M-421.

Patients that do not agree to participate in the study will continue to receive standard-of-care treatment. At the time of consent, patients will also be informed that they are free to withdraw from the study at any time they wish.

Confidentiality

During initial data collection, patient names will be used. However, after entering the selected data values into our study database, the medical record numbers and names will be stripped from the information to insure confidentiality. Unique, study-specific identifiers will be assigned to individual subjects' data. Manipulation of data and reporting results will be performed in aggregate fashion and in no way will identify individual subjects. In addition, all data and any information that has specific medical record numbers recorded will be maintained in a secure location (M-421) and locked cabinet or password protected database. Only the P.I., Co-I's and IRB-approved study staff will have access to these identifiers.

Recruiting methods

Patients will be referred from all inpatient primary services at the University of Chicago for eligibility of home TPN, who will grant permission for us to approach their patients for recruitment to this study.

A rationale for excluding women, minorities and/or children from participation

N/A

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Appendix 1: Central Catheter Teaching and Self-Care Initial Questionnaire

Name: _____ Subject ID: _____
Date: _____ Email: _____

1) What type of central venous catheter do you have?
   ☐ PICC line ☐ Tunneled catheter (Hickman)

2) How many lumens (or "ports") on your catheter? _____

3) What are the cycle hours of your PN (parenteral nutrition)? _____ hours

4) Do you use any other IV medications through the catheter (excluding heparin lock, etc for catheter maintenance only)? Yes ☐ No ☐

   What IV medications?
   _____

	Yes	**No**
Do you currently have an ostomy?		
Do you currently have a fistula anywhere in your body?		
Do you currently have a G tube?		
Have you ever worked with IVs in a home or employment setting?		

5) How comfortable do you feel about taking care of your central venous catheter?
   ☐ Very uncomfortable
   ☐ Somewhat uncomfortable
   ☐ Neutral
   ☐ Somewhat comfortable
   ☐ Very comfortable

Appendix 2: Central Catheter Teaching and Self-Care Follow-up Questionnaire

Name: _____ Subject ID: _____
Date: _____ Email: _____

1) What are the cycle hours of your PN (parenteral nutrition)? _____ hours

2)

	Yes	No
Do you currently have an ostomy?		
Do you currently have a fistula anywhere in your body?		
Do you use any other IV medications through the catheter?		

If yes, what IV medications?
_____

3) How comfortable do you feel about using your central venous catheter?
- ☐ Very uncomfortable
- ☐ Somewhat uncomfortable
- ☐ Neutral
- ☐ Somewhat comfortable
- ☐ Very comfortable

4) How do you find the TPN education material?
- ☐ Very confusing
- ☐ A little confusing and not as helpful
- ☐ The information is clear, but it had no effect on my self-care practice
- ☐ Somewhat helpful
- ☐ Very helpful

5) How often do you watch the TPN educational material on average?
- ☐ I have not watched the video since discharge
- ☐ Less than once a week
- ☐ 1-2 times a week
- ☐ 3-6 times a week
- ☐ Daily or more

Appendix 3: Central Catheter Teaching and Self-Care Conclusion Questionnaire

Name: _____ Subject ID: _____
Date: _____ Email: _____

1) What are the cycle hours of your PN (parenteral nutrition)? _____ hours

2)

	Yes	**No**
Do you currently have an ostomy?		
Do you currently have a fistula anywhere in your body?		
Do you use any other IV medications through the catheter?		

If yes, what IV medications?
_____

3) How comfortable do you feel about using your central venous catheter?
- ☐ Very uncomfortable
- ☐ Somewhat uncomfortable
- ☐ Neutral
- ☐ Somewhat comfortable
- ☐ Very comfortable

4) How do you find the TPN education material?
- ☐ Very confusing
- ☐ A little confusing and not as helpful
- ☐ The information is clear, but it had no effect on my self-care practice
- ☐ Somewhat helpful
- ☐ Very helpful

5) How often do you watch the education material on average?
- ☐ I have not watched the video since discharge
- ☐ Less than once a week
- ☐ 1-2 times a week
- ☐ 3-6 times a week
- ☐ Daily or more