


BMJ Open From hospitalisation to primary care: integrative model of clinical pharmacy with patients implanted with a PICC line – research protocol for a prospective before–after study

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ABSTRACT

Introduction Clinical pharmacy improves patient safety and secures drug management using information, education and good clinical practices. However, medical device management is still unexplored, and proof of effectiveness is needed. A PICC line (peripherally inserted central catheter) is a medical device for infusion. It accesses the central venous system after being implanted in a peripheral vein. However, complications after implantation often interfere with smooth execution of the treatment. We hypothesise that clinical pharmacy for medical devices could be as effective as clinical pharmacy for medications. The main objective is to assess the effectiveness of clinical pharmacy activities on the complication rate after PICC line implantation.

Methods and analysis This is a before–after prospective study. The study will begin with an observational period without clinical pharmacy activities, followed by an interventional period where pharmacists will intervene on drug and medical device management and provide personalised follow-up and advice. Sixty-nine adult patients will be recruited in each 6-month period from all traditional care units. The main inclusion criteria will be the implantation of a PICC line. The primary outcome is the decrease in the number of complications per patient and per month. Secondary outcomes are the consultation and hospital readmission rates, the acceptance rate of pharmaceutical interventions, the patients' quality of life, the direct hospital induced or avoided costs and the participants' satisfaction. Data will be collected using case report forms during hospitalisation and telephone follow-up after discharge. The analysis will compare these criteria during the two periods.

Ethics and dissemination The study has received the approval of our Ethics Committee (Clermont-Ferrand Southeast VI, France, number AU1586). Results will be made available to the patients or their caregivers, the sponsor and other researchers when asked, as described in the consent form.

Trial registration number NCT04359056.

INTRODUCTION

Clinical pharmacy is a patient-centred health discipline whose practice aims to optimise

Strengths and limitations of this study

- This is the first study to assess the effectiveness of clinical pharmacy interventions for medical devices.
- As a primary objective, strong clinical criteria will be evaluated by measuring skin redness or fever (as signs of an infection), oedema, thrombosis and pain.
- This study proposes an integrative model of clinical pharmacy, from hospitalisation to primary care.
- The main limitations of this study are the lack of randomisation and the lack of blinding for patients and healthcare professionals.

therapy at each stage of the care pathway. Clinical pharmacy actions contribute to patient safety and the relevant and efficient use of health products.¹ To ensure health products are used in a safe and appropriate manner, pharmacists analyse physicians' orders to identify errors or potentially inappropriate prescriptions based on guidelines and evidence-based medicine. Moreover, they optimise drug intake, inform patients and caregivers, organise the discharge to primary care and disseminate clinical good practices. Pharmacists also focus on patient education, information and training for healthcare professionals.

Regarding medication approaches, the effectiveness of clinical pharmacy is well known. Several clinical studies have demonstrated significant impacts on rehospitalisations,^{2–5} drug management⁶ and treatment compliance,⁷ patients' quality of life⁸ as well as a decrease of iatrogenic risk.^{9–12} However, studies on clinical pharmacy in the context of medical devices (MDs) are rare.¹³ To our knowledge, no study has described the clinical impact of a pharmacist's intervention when an MD is implanted in patients. Only

one recent article refers to clinical pharmacy in dressings for complex wounds.¹⁴ The need for further clinical studies is undeniable.

MD classification is based on their risk of invasiveness and duration of use. Infusion equipment, such as catheters, can induce iatrogenic events, especially infections.^{15 16} Peripherally inserted central catheters (PICC lines) are associated with numerous clinical (eg, infections¹⁷) and mechanical complications (eg, catheter occlusions).^{18–27} PICC lines are useful for the administration of irritating products or for the repeated collection of blood samples. PICC lines are recommended when the duration of catheterisation ranges from 7 days to 3 months.²⁸ PICC line implantations are carried out in the interventional radiology operating room.

Our working hypothesis is that clinical pharmacy interventions will prevent clinical and mechanical complications and thereby reduce hospital costs.²⁹ Reducing complications could also prevent its consequences such as rehospitalisations³⁰ and physician visits.

METHODS AND ANALYSIS

A scientific committee (selected by the Research and Innovation Board of the Toulouse University Hospital) composed of scientific and methodological experts and statisticians oversaw the feasibility and methodology of the study. This committee ensures the quality and relevance of the research organisation. The study procedures and assessments comply with the Standard Protocol Items: Recommendations for Interventional Trials³¹ checklist.

Design

A pragmatic single-centre design is used. This is a before–after prospective study with two consecutive phases: observational (no clinical pharmacy activities) and interventional (execution of clinical pharmacy activities and logistics optimisation). Randomisation of patients is not possible in this study due to the high risk of contamination bias. Once the clinical pharmacist arrives in the care unit, he or she should address any medical apprehension by the PICC prescribers and nurses, explaining good clinical use, affecting all the future study patients, even the control group. This is an open study. Due to the nature of the pharmaceutical interventions, blinding is not possible for patients and care providers.

Setting

The study will take place in the Toulouse University Hospital Center. Every PICC line prescription will be picked up in the interventional radiology unit, and patients will be screened for eligibility. Patients will be recruited from their hospital ward prior to the PICC line insertion. All selected participants will be asked to read and sign a consent form (online supplemental file). Each phase (observational and interventional)

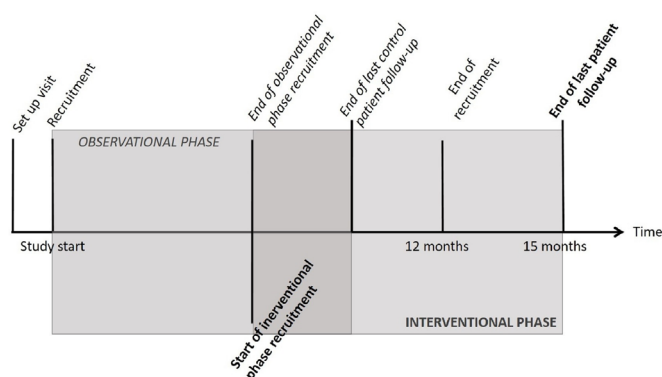


Figure 1 Study design.

will last approximately 9 months taking into account recruitment and patient follow-up. See [figure 1](#) for the study timeline.

Recruitment began on Monday, 25 May 2020 and will end 1 year later on 25 May 2021. The study is scheduled to end on 25 August 2021.

Characteristics of participants: inclusion and exclusion criteria

Eligibility criteria are listed in [table 1](#). For all included patients, the Charlson Comorbidity Index³² will be used to assess the degree of comorbidity at baseline.

Table 1 Inclusion and exclusion criteria

Inclusion criteria	<ul style="list-style-type: none"> Adult patient, 18 years of age or older. Patient capable of giving free and informed consent. Patient insured by the Social Security System in France. Patient living at home. Patient with a PICC line prescription. Patient whose discharge prescription should contain drugs and MDs. Patient for home discharge implanted with a PICC line. Patient reachable by phone.
Exclusion criteria	<ul style="list-style-type: none"> Under-aged patient, less than 18 years old. Patient not insurance by the Social Security System in France. Patient not living at home: <ul style="list-style-type: none"> Institutionalized patient. Patient living in a facility for elderly dependent persons. Nursing home resident. ‘Hospital at Home’ patient. Patient deprived of their freedom by a judicial or administrative decision. Patient under guardianship, curatorship or safeguard of justice. Patient unreachable by phone. Pregnant or breastfeeding women.

MDs, medical devices; PICC, peripherally inserted central catheter.

Patient and public involvement

No patient involved.

Process

Regardless of the phase of the study, the occurrence of complications due to the PICC line will be recorded during hospitalisation and at home during a follow-up phone call. Patients are monitored for the entire duration of the PICC line implantation or for a maximum of 3 months. Data will be collected at days 3 and 7 (D3 or D7, respectively) after implantation and then after 1, 2 and 3 months (M1, M2 and M3, respectively).

The control period corresponds to usual care and represents the observational phase, where no pharmaceutical interventions will be done, unless necessary for the patient's safety (eg, life-threatening situations³³).

One participant can be included in only one phase. The interventional phase will start when the last patient is included in the observational phase. Physicians and nurses, as well as other healthcare professionals, will attend training sessions on updates, recommendations, indications and maintenance related the use of PICC lines. If necessary, training sessions will be repeated once to make sure the research team met all the healthcare professionals involved.

Two pharmacists and a pharmacy resident will participate in each phase.

The table 2 describes the research procedures and activities in the two phases.

At the end of the study, a satisfaction survey will be sent to every participant (patients and caregivers).

Outcomes and expected benefits

Primary outcome

The primary outcome is the number of complications per patient and per month. Complications will be documented on specific forms to harmonise data collection. Mechanical complications are defined as obstruction or occlusion,¹⁸ breakage or damage to the catheter,²⁷ migration³⁴ or dislodgment (accidental withdrawal) of the catheter.³⁵ Clinical complications are defined as redness around the insertion site (diameter >2 cm), oedema (size difference between the two hands), pain (numeric rating scale) and fever (internal temperature >37°C) as signs of an infection^{17 36} and thrombotic events³⁷ (confirmed by a medical modality such as echography).

Secondary outcomes

The number of consultations and rehospitalisations post-discharge will be used to determine the clinical impact beyond the initial hospitalisation.^{11 38–40} The expected result is a decrease in the consultation and rehospitalisation rates at the end of the intervention phase compared with the observation phase.

The acceptance rate of pharmaceutical interventions during the interventional phase is used to assess the appropriateness of pharmaceutical interventions.^{41–45} A higher acceptance rate means the pharmaceutical interventions

are justified and relevant to the care providers. The criticality of the pharmacist's intervention⁴⁶ will be evaluated. Moreover, conformity of the hospital prescriptions for primary care after the discharge will be assessed. The aim is to avoid treatment breaks.

Another secondary outcome involves the conformity analysis of the PICC line logistics circuit (checklist related to stock, supply chain and traceability). Management of the hospital supply chain is a major financial challenge⁴⁷ and generally leads to decreased treatment risk and costs.⁴⁸ The objective is to streamline the various stages of the PICC line logistics circuit, from ordering to implantation. By streamlining the logistics, improved patient safety and reduced costs are expected.

The conformity of the PICC line indication will be evaluated according to recommendations.⁴⁹ Prescriptions too often seem to be trivialised and little guided by attending doctors. Therefore, errors are possible. The aim is to improve the team's knowledge and the communication between hospital units.

The patients' quality of life before and after the follow-up will be measured with the EQ-5D-5L questionnaire.⁵⁰ As previously described by Andrade *et al*,⁵¹ a standard value set for converting the profiles on the five dimensions onto a score will be used.

An improvement in the quality of life score is expected during the intervention phase.

Satisfaction of the patients and the healthcare providers involved will be evaluated. To develop clinical pharmacy activities in healthcare services, collaboration and communication with healthcare teams is essential.

The direct hospital costs will be estimated and described. The objective is to estimate whether additional costs are induced or whether costs are spared through better organisation and logistics management.⁵²

Statistical analysis

Sample size calculation

According to the ENEIS studies (2004 and 2009) and their final report,⁵³ at least 50% of iatrogenic serious adverse events are preventable whether due to medications or MDs. Assuming that clinical pharmacy integration could theoretically lead to a 25% decrease in the complication rate during the interventional phase, 62 patients are needed in each group (80% power, alpha 5%). Thus, 138 patients need to be recruited assuming that 10% are lost to follow-up. All early exits from the study will be considered as lost to follow-up, and the affected data will be processed in the statistical analysis as intent to treat.

Statistics

Statistical tests will be used that are appropriate for the distribution of the variables. All tests will be performed at an alpha risk of 5%. Categorical variables will be described by counts and percentages. Means and SD will be reported for continuous variables with normal distribution, and median and quartiles for other continuous variables.

Table 2 Detailed research process

Timepoint	Research steps	Observational phase	Interventional phase
Hospitalisation	<i>PICC line prescription</i>	Screening: eligibility assessment	
	<i>Intervention scheduled</i>	Enrolment: informed consent	
	<i>PICC line indication</i>	Document purpose and duration of catheterisation	Pharmaceutical analysis to identify errors or potentially inappropriate prescriptions*; discussion with prescribers; pharmaceutical interventions in the event of unjustified deviation from existing guidelines.
	<i>In the operating room (OR) before the implantation</i>	Verify that all necessary equipment is available for the surgery.	Help with ordering if necessary.
		Conformity assessment of the expiration date for all PICC lines stored in the OR's supply room.	Help with ordering if necessary. Rationalisation of the medical device stock if necessary.
		Conformity assessment of traceability from receipt of the medical device order by the pharmacy to delivery to the care unit.	Corrections if necessary.
<i>Implantation of PICC line=day 0</i>	Number of medical devices used during the operation (implantation failures or non-functional devices). Implantation traceability to ensure lot numbers match in the patient's record, the OR book and the computer software.	Corrections if necessary.	
<i>Remainder of the hospitalisation</i>	Record possible complications during the remainder of the hospital stay.	Corrections and help if complications occur.	
Discharge	<i>Discharge prescription</i>	Pharmaceutical analysis of the patient's discharge order. The analysis will focus on drugs and MDs related to the PICC line (eg, dressing repair set). Conformity analysis of the hospital prescriptions issued by local pharmacy.	Pharmaceutical analysis of the patient's discharge order and optimisation* if necessary. Discussion with the physician and correction.
	<i>Patient discharge</i>	Quality of life assessment (EQ-5D-5L scale).	Pharmaceutical interview with the patient: Discuss the different treatments on the discharge order, answer any questions. Provide information about the PICC line, how to use it, maintain it and how to detect potential complications. Make sure that traceability documents are provided. Make sure that the PICC line's user booklet is provided. Transmission of the discharge order to the community pharmacist.
Primary care	<i>Day 3</i> <i>Day 7</i>	Phone calls to collect complications or any events regarding the PICC line and drugs ▶ Patient. ▶ Private nurse.	Provide personalised and appropriate advice. Pharmaceutical interventions if necessary.
	<i>M1, M2</i>	Phone calls to collect complications or any events regarding the PICC line and drugs: ▶ Patient. ▶ Private nurse. Phone calls to community pharmacist to record information related to care consumption.	Provide personalised and appropriate advice. Pharmaceutical interventions if necessary.
	<i>M3</i>	Quality of life assessment (EQ-5D-5L scale). Phone calls to collect complications or any events regarding the PICC line and drugs: ▶ Patient. ▶ Private nurse. ▶ Community pharmacist to record information related to care consumption. ▶ General practitioner to identify any consultations related to the PICC line and any other relevant information. Sooner if there is a need to confirm clinical data on complications such as thrombotic events.	

*According to the gold standard or START and STOPP method⁶⁴ or European PIM list⁶⁵ for older adults.
MDs, medical devices; PICC, peripherally inserted central catheter.

Table 3 Statistical analysis for the secondary outcomes

Variables types	Variables of interest	Description*	Tests*
Quantitative	<ul style="list-style-type: none"> ▶ Consultations and rehospitalisations after discharge. ▶ EQ-5D-5L scores. ▶ Direct hospital costs. 	Means±SD or medians and quartiles. Frequency table.	Student's t-test or non-parametric Wilcoxon's test.
Qualitative	<ul style="list-style-type: none"> ▶ Conformity rates (logistics, indications for implantation and prescriptions issued by local pharmacy). ▶ Satisfaction levels. 	Frequency table.	χ^2 test or Fisher's exact test.

*According to the distribution of variables.

Patient demographics and clinical characteristics will be described.

To assess the effectiveness of the intervention, means or medians of the number of complications per month and per patient for each phase will be estimated, and a Poisson regression will be used. An adjustment for confounding factors such as sex, age and Charlson Comorbidity Index is planned.

The secondary outcomes will be analysed as described in [table 3](#).

DISCUSSION

The main objective is to demonstrate the effectiveness of clinical pharmacy activities in preventing complications in patients implanted with a PICC line. This is a strong clinical criterion. There is abundant literature about the occurrence of complications following the insertion of a PICC line, in a hospital^{20–24} or at home.^{27 54 55} At the same time, reported rates vary widely across studies. These rates were pooled to estimate an 'average' complication rate. This method was used to calculate the number of subjects needed for this study. These assumptions have an impact on the robustness of the study and may require the use of statistical adjustments when analysing the results. As for complications, the numbers of consultations and rehospitalisations postdischarge have been used in several studies, particularly the 30-day readmission rate^{11 40 56–58} to assess the clinical effectiveness of a pharmacist's interventions. Despite the wide assortment of these rates in the literature, this indicator is relevant for comparing our study with others. However, it will be difficult to obtain exhaustive results, as the data will be derived from statements made by the different participants. The information will only be formally verifiable if the patient in question is readmitted or consults in one of our hospital's departments.

The acceptance rate of pharmaceutical interventions is a widely used and recognised indicator^{41 59} for assessing the appropriateness of interventions and an indicator routinely used in hospitals. A conformity analysis of the hospital prescriptions for primary care is one of the secondary endpoints. It seems essential to secure these prescriptions also because the patient's transition is known to be a high risk event.⁶⁰ Good clinical practices

allow health professionals to decrease errors and avoid potential errors in prescription. Iatrogenic events are associated with additional costs.⁶¹ A checklist of items was developed to evaluate the conformity of the PICC line's logistics circuit. This list is particularly exhaustive and will be used by all those who collect data. This will avoid an evaluation bias that could be linked to the large number of healthcare providers involved. The checklist will help to identify the most common errors or pitfalls encountered and to establish adequate corrective measures. Current guidelines are available for the device's logistics.⁴⁹

The prospective study design allows to assess the patients' quality of life using the EQ-5D-5L Scale before and after the intervention. This criterion is needed to assess the patient's point of view, as the patient is the central element in the care pathway. To avoid interference or influence due to the presence of pharmacists, they will not be present at the time of the first evaluation (day of discharge). However, the subsequent assessments will be done by telephone, thus pharmacists could influence patient responses. Likert scales have been developed to collect patient and healthcare professional satisfaction data.⁶² These tools are valid and reliable for collecting the opinions of different research participants. These scales capture more nuanced opinions, help to better understand the feedback and to identify areas for improvement. The various parties involved generally appreciate these tools. It should not be particularly difficult to collect and analyse these results. Nevertheless, different patients will be enrolled during the observational and interventional phases. Consequently, the differences in satisfaction, if any, may also be due to a difference in individuals between the two groups. A low response rate from professionals to the satisfaction survey is expected, as described in the literature.⁶³

This study involves only one hospital and focuses on one type of implantation. This is a preliminary study before scaling up a larger, multicentre and randomised trial with several implantable medical devices (IMDs). This future study will follow a stepped-wedge method consisting of randomisation by centre and not by patient for the deployment of before-and-after phases in each of the participating centres. This study is a major step towards evaluating the efficacy of clinical pharmacy



applied to IMDs with the aim of a larger scale study with valuable randomisation. At this moment, the before–after design appears to be the closest to the stepped-wedge method since they share separate observational and interventional periods. Indeed, randomisation is not possible given the nature of the intervention and the high risk of contamination bias. This point is critical. Moreover, the measurement and analysis of costs is limited to direct hospital medical costs, which does not allow an overall analysis of the costs of care. Additional health economics analyses are planned for the multicentre study.

This study will investigate the impact of the integration of clinical pharmacy activities during the overall care pathway. This is the first step towards a change in practices, improved communication between professionals, better collaboration and the integration of a clinical pharmacist into multidisciplinary teams, including surgical ones. This study is the first, to our knowledge, to focus on clinical pharmacy for implantable MDs with a hard, clinical endpoint.

Potential limitations and bias

Since the study is not randomised, the selection bias and two non-comparable samples are risky. To overcome this limitation, an adjustment on the main confounding factors (such as age, sex and comorbidity index) will be considered.

Blinding is not possible due to the nature of the intervention. To limit a measurement bias, a blind methodologist will analyse the primary endpoint.

Recruitment may take longer than expected because all the PICC lines are placed in the operating room and are not a priority as opposed to life-threatening emergencies.

Phone calls to collect clinical data on complications, deaths and rehospitalisations are limited. The collected data are based solely on the patients' and care providers' statements. It is possible that they may intentionally or unintentionally omit some information. The plurality of involved counterparts may help to corroborate the given information. Data collection will be harmonised by double-checking the collection forms and the information collected at the time of the pharmaceutical interviews and phone calls.

Trial status

Recruiting since 25 May 2020.

National registration number: 2019-A02475-52.

Ethics and dissemination

The regional French Ethics Committee (CPP South-East VI, Clermont-Ferrand, France) assessed the scientific ethics of the protocol (version dated 3 February 2020) and approved this study.

All data collected will be anonymised, and access to the data will be restricted to those participating in the research (investigators, pharmacists and pharmacy residents).

The results of the study will be published when available.

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