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PRADOC: a trial on the efficiency of a transition care management plan for hospitalized patients with heart failure in France

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Abstract

Aims Transition care programmes are designed to improve coordination of care between hospital and home. For heart failure patients, meta-analyses show a high efficacy but with moderate evidence level. Moreover, difficulties for implementation of such programmes limit their extrapolation.

Methods and results We designed a mixed-method study to assess the implementation of the PRADO-IC, a nationwide transition programme that aims to be offered to every patient with heart failure in France. This programme consists essentially in an administrative assistance to schedule follow-up visits and in a nurse follow-up during 2 to 6 months and aims to reduce the annual heart failure readmission rate by 30%. This study assessed three quantitative aims: the cost to avoid a readmission for heart failure within 1 year (primary aim, intended sample size 404 patients), clinical care pathways, and system economic outcomes; and two qualitative aims: perceived problems and benefits of the PRADO-IC. All analyses will be gathered at the end of study for a joint interpretation. Strengths of this study design are the randomized controlled design, the population included in six centres with low motivation bias, the primary efficiency analysis, the secondary efficacy analyses on care pathway and clinical outcomes, and the joint qualitative analysis. Limits are the heterogeneity of centres and of intervention in a control group and parallel development of other new therapeutic interventions in this field.

Conclusions The results of this study may help decision-makers to support an administratively managed transition programme.

Keywords Heart failure; Readmission; Mixed-methods study; Transition programme

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Introduction

Aside of clinical determinants, it was demonstrated that potential determinants of morbidity in heart failure (HF) patients include demographic factors,¹ use of care,^{2,3} primary care organization,⁴ primary care accessibility,¹ and hospital care organization.⁵ Health service organizations may have

transition care programmes that facilitate coordination between health care facilities.^{4,6} These programmes rely on the conceptual framework of coordination of care, which assumes that informational continuity allows for coordination of care⁷ and that coordination of care improve the quality of care.⁸ These programmes are particularly necessary in the transition phase, because patients are more prone to

readmissions.⁹ Several meta-analyses showed an efficacy of transition care programmes on HF readmissions [relative risk (RR) of 0.51 to 0.74], all cause readmissions (RR of 0.75 to 0.88), and all cause deaths (RR of 0.75 to 0.87),^{10–14} but results were not consistent between studies.

Alas, experimental papers on transition care efficacy are not sufficient to predict actual efficacy of real-world transition care programmes, for three main reasons. First, the internal validity of these studies was often weak, due to the complexity of the interventions; consistently, the Cochrane review¹¹ attributed only a moderate evidence level to this result. Second, experimental trials enrolled selected patients, often without providing selection rules that allow for replication in non-experimental settings. Third, trials were conducted by investigators who designed the interventions. In a single-centre trial, favourable consequences would be more likely as the intervention was adapted to their setting and optimized during the intervention period. As a consequence for healthcare workers, the implementation of transition care programmes in non-selected settings and patients may not lead to the expected health improvement.⁶ Moreover, the addition of financial incentives to these interventions may have led to adverse consequences. For example, the Hospital Readmissions Reduction Program was associated with a reduction of readmissions in patients with HF, but also with an increase of mortality.¹⁵ Therefore, more research is needed to assess the efficacy of transition care programme in real-life settings.

In addition, several secondary outcomes are rarely assessed in this literature. (i) Medico-economic analyses are limited to costs analyses¹⁰ or to cost–benefit analyses and do not provide utility assessment. Therefore, they do not allow to compare cost-effectiveness to willingness to pay. Moreover, as hospitalizations are the greatest expense item of HF care pathways, cost savings may hide an increase of costs in the primary care setting. (ii) The impact of interventions on observed care pathways (i.e. the visits that are actually carried out) is rarely reported: Di Palo *et al.* reported a rate of follow-up visits¹⁶ and Ferman *et al.* will report care pathways, adherence, and knowledges.¹⁷ (iii) Qualitative studies are scarce: Ahmad *et al.* interviewed different stakeholders on HF care management,¹⁸ and Kilgore *et al.* studied the organization of clinical nurses.¹⁹

In France, all inhabitants are covered by a public mandatory health insurance, managed by the *Caisse Nationale d'Assurance Maladie* (CNAM). Coordination of care between hospitals and primary care mainly relies on local decisions, and too few patients with HF follow national guidelines regarding care pathway after discharge: in 2013, 54% did not visit any general practitioner (GP) in 7 days, and 64% did not visit any cardiologist in 3 months (CNAM data). Hospitals try to decrease the rate of readmissions through local initiatives (remote monitoring, early follow-up hospital visits ...). But this does not include coordination with

ambulatory care system, it requires a strong investment on the part of physicians, and there is no certainty that funding will continue. Also, there is no guarantee that educational and social support is systematically delivered to each patient in the acute hospital setting. In consequence, the availability of transition care to any patient is not guaranteed. Therefore, the CNAM and the French Society of Cardiology designed a transition care programme so that it would be easily available to any patient in France. This programme is called *Programme de Retour à Domicile après une Insuffisance Cardiaque* (PRADO-IC). The PRADO-IC was generalized in France in 2014, with the aim to reduce the annual death rate by 20% and the annual HF readmission rate by 30%. Target population consists of patients with HF living at home. The PRADO-IC consists in an administrative assistant who visits patients during hospitalization to schedule follow-up visits with the GP and the cardiologist and to apply to social benefits of the CNAM; a nurse follow-up during 2 (NYHA I–II) to 6 months (NYHA III–IV), to assess clinical signs and symptoms of HF and provide pragmatic advices on self-care; and a coordination notebook, held by the patient. The PRADO is easily available because it is entirely funded by the CNAM, without conditions for hospitals or patients and because it is not time-consuming for usual healthcare workers.

No previous RCT of the PRADO-IC was done. The National Health Insurance realized a quasi-experimental study on the first patients, which was not published in a peer-reviewed journal. In the light of our literature review, many questions remain. (i) Is the PRADO-IC cost-effective 1 year after inclusion? (ii) Is the PRADO-IC clinically effective 1 year after inclusion? (iii) Does the PRADO-IC shift health expenditure from hospital to primary care? (iv) Does the PRADO-IC promotes guideline-concordant care pathways? (v) Do healthcare providers perceive areas for improvement? In this study, we aim to assess the efficiency of this programme, that is the cost to avoid a readmission for HF at 1 year, vs. usual management. The cost considered is the cost for the society. Secondary quantitative aims are the efficacy on readmissions, death, quality of life, costs, and care pathways. Qualitative aims are to assess perceived areas for improvement.

Study design

a Study design overview

The PRADOC study is a controlled randomized open-label mixed-method trial of the transition programme PRADO-IC vs. usual management in patients hospitalized with HF. The trial is being conducted by a multidisciplinary team from the University of Montpellier: cardiologists, a public health physician, and an associate professor in Information Sciences in charge of the qualitative analyses. The study protocol and

methods were reviewed by the Ethics Committee CPP SE-I (Ref 2017-64) (NCT03396081). All patients gave informed consent to enter the study.

b. Settings and sample

This study takes place in a multicentre setting, including centres who were not involved in the design of the intervention. Despite a nationwide and exhaustive implementation strategy, the CNAM accepted to follow a patient-level randomized design in the centres participating to this study. Recruitment takes place in the cardiology wards of six centres of the southwest of France, including three university hospitals (Montpellier, Nîmes, and Toulouse), two public hospitals and one private hospital. University hospitals provide basic care for patients within a narrow area (HF) and specialized care for patients in a broader area (HF accompanied by multiorgan deficiencies). In the University hospital of Montpellier, 80% of patients hospitalized for HF are admitted in cardiology ward (including cardiac ICU) during their hospitalization. The three other centres (Montauban, Béziers, and Alès) provide levels 1 and 2 care.²⁰ Patients are consecutively assessed for eligibility, and eligible patients are included during weekdays.

The selection criteria are mainly those of the PRADO-IC: adult patients, hospitalized for HF, discharged to home and independent at home, without terminal kidney failure, significant cognitive impairment, or behavioural disorders; patients in palliative care, or with a programmed aetiologic treatment at short-term (valvular surgery, transcatheter aortic valve implantation, removal of arrhythmogenic focus, and heart transplantation), are also excluded. Moreover, in order to limit the loss of data during study, we excluded patients with a programmed moving in Elderly Care Home in the next 6 months, or who did not understand French; and for ethical concerns, we excluded pregnant women, prisoners, or patients included in another research protocol. After inclusion, the only criteria for exclusion was a consent removal.

c. Interventions

The experimental intervention is a transition care programme between acute and ambulatory care settings, for patients hospitalized for HF. The hospital physician in charge assesses the eligibility of patients and prescribes the programme, which comprises three elements. (i) An administrative assistant visits patients during hospitalization and checks if they need help to make an appointment with their health providers (GP, cardiologist, and nurse). If patients do not have usual health provider, the administrative assistant provides them a list of health providers in their living area. If needed, the administrative assistant makes the three separate appointments for shortly after discharge: 1 week

for GP and nurse and 2 months for cardiologist. Moreover, the administrative assistant asks patients if they need social benefit and organizes an appointment with the social service of the National Social Insurance if needed. (ii) A systematic nurse follow-up is organized at home. For all patients, an initial pattern of one nursing visit weekly is scheduled during 2 months (eight visits in total). For patients with NYHA III and IV, bimonthly visits carry on for an additional 4 months. During these half-hour visits, the nurse monitors the HF signs and symptoms and delivers patient education, including self-care development. Nurses are not HF specialists. They all received the same training, using an e-learning programme developed by the French Society of Cardiology and the CNAM. (iii) A follow-up notebook is delivered to patients during the hospitalization. It contains personalized clinical monitoring advices, treatment prescribed at discharge, contact details of health providers, dates of appointment, and any pertinent follow-up information that health providers need to share with colleagues.

Usual case management is characterized by its inconsistency. If the hospital team finds that a patient needs help making follow-up appointments or obtaining social benefits, the nurse coordinator of the service will arrange this assistance by counselling the patient, family, or by calling the hospitals social services department. The physician in charge may prescribe a nurse follow-up and/or a remote monitoring. Because shared charts do not exist between all care providers, sharing of information occurs via mails or e-mails.

Besides, in both groups, it is common that patients receive strong recommendation from the hospital team to visit a GP in the week following discharge, and a cardiologist in the 2 months following discharge. Further, the GP may also prescribe a nurse follow-up, independently of the hospital physician.

d. Randomization

Patients are individually randomized using a centralized method based on a minimization algorithm, accessible online 24/7 (Ennov Clinical Software). Stratification criteria are the inclusion centre and the current attending of patients to a patient education programme.

The latter deserves to be explained. The PRADO-IC includes a self-management programme, which is a core component of patient education programmes. Self-care is also included in telemonitoring programmes in France [SCAD (CHU de Caen), PIMP's (CH Pontoise), OSICAT/Chronic Care Connect (CHU Toulouse) ...]. Thus, self-management education by multiple programmes can promote competing effects, which would bring undesirable heterogeneity, and/or a confusion bias in case of unbalanced groups. In current recruitment site practices, two centres propose a remote monitoring (Chronic Care Connect). In current practice, none

of these programmes is restricted to patients benefiting of other programmes, and they are becoming a frequent part of standard of care; therefore, we did not wish to exclude patients benefiting of other programmes in our study. Rather, the stratification of the sample by the current attending of patients to a patient education programme will guarantee the absence of unbalance and allow to perform exploratory subgroup analyses.

e. Quantitative assessments

To answer to the three first research questions (cost-effectiveness, clinical efficacy, and health expenditure shift), we will assess efficacy, utility, and costs. The primary efficacy outcome is the number of hospitalizations for HF, which are defined as hospitalization with a principal diagnosis of HF [I500, I501, I509, I110, J81, and R570 (ICD 10)] and are collected during 1 year in claim data. Secondary efficacy outcomes are the number of hospitalizations for any cause, death from cardio-vascular cause (codes I00 to I99, ICD 10), and death from any cause, collected in claim data during 1 year. The utility of the health status of a participant will be the area under the curve of the EuroQol-5D measures during the study (inclusion, 6 months, and 1 year). In case of death, a value of zero will be attributed at the death date, and missing values will be imputed by the nearest value. Costs will include direct costs: hospitalizations, transportations, ambulatory care, nursing home, and all collected in claim data during 1 year. Hospitalizations will be valued using a gross costing process, and other costs will be valued by their price. To compute the cost of the administrative assistants, we will use a top-down method: $\text{cost} = \text{number of administrative assistants in each inclusion centres} * \text{median salary of administrative assistants in France} / \text{number of patients with the PRADO in each inclusion centre}$. The cost of the administrative assistant plus the cost of the scheduled nurse visits will be the cost of the intervention and will be measured at 6 months.

To answer the question of care pathways, we will assess the adequacy of the care pathway with guidelines (GP visit in 7 days after discharge, cardiologist visit in 2 months after discharge). Other outcomes are defined as (i) the operational objectives of the intervention (refusal rate and incomplete realization of the PRADO scheme), (ii) intensity and quality of care pathway [mean delay between two programmed visits with the principal GP, number of consultations with a cardiologist, rate of emergent care (unforeseenness index), and Continuity of Care Index], therapeutic management (persistence of long-term HF treatment prescribed at inclusion and variability of diuretic dose), and (iii) accessibility to all categories of patients (socio-economic and medical status of included patients and zip codes of included patients and of PRADO-IC nurses). All secondary outcomes will be assessed during 1 year after inclusion.

f. Ancillary qualitative study

To answer the question of the perception of the programme, an ancillary qualitative study will be completed. The researcher will interview 30 patients of the PRADO-IC group, 15 GPs, 15 nurses, and 15 cardiologists. Interviews with healthcare professionals will be conducted by telephone or e-mail at any time during the programme. Eligible healthcare professionals will be those who have cared for a patient included in the study. They will be asked about the number of patients included in the PRADO they care for, their use of the coordination notebook, the points of vigilance for the continuity of information and care management, their expectations of the PRADO, their perception of the advantages and disadvantages of the PRADO, and the need to develop new skills to participate in the PRADO. Interviews with patients will be conducted by telephone 1 month after their discharge. Eligible patients will be those randomized in the PRADO group and who have signed a specific consent for the qualitative study. They will be asked about their use of the coordination notebook, their expectations of the PRADO, and their perception of the advantages and disadvantages of the PRADO. Interviews will be coded by the thematic analysis method by two independent researchers.²¹

g. Data analysis

Analyses will be performed by the Medico-Economic Research Unit of the University Hospital of Montpellier (France), using the SAS 9.4 statistical software (Cary Inc.), and the level of significance for each test will be set at 0.05.

In the absence of cost assumptions, the calculation of the number of subjects required is based on the effectiveness criterion of the main outcome. The objective of the PRADO is to achieve a relative reduction in the risk of rehospitalization for IC of 30%, and a readmission rate in the control group of 45% is expected. To demonstrate this risk reduction, with a 5% alpha risk and with a power of 80%, 404 subjects must be analysed. As the main judgement criterion is collected in national claim data, there will be no lost to follow-up (exhaustive database of the French mandatory health insurance). The principal analysis will be a univariate, intent-to-treat cost-effectiveness analysis, performed following the ISPOR guidelines. No cost actualization will be performed due to the short follow-up. The effectiveness criteria will be the occurrence of hospitalization for HF at 1 year. The incremental cost-efficacy ratio (ICER) will be computed at 1 year, with its bootstrap 95% confidence interval. This ICER is the marginal cost needed to avoid a hospitalization for HF. An acceptability curve will draw the probability that the PRADO-IC is cost-effective for a range of decision thresholds, relatively to the usual management. Univariate sensitivity analyses will be performed to tackle uncertainty in unit costs and resource use.

A secondary medico-economic analysis will estimate the incremental cost-utility ratio (ICUR), with the same methodological framework than for the ICER. Utility values will be derived from the EQ 5D-3L questionnaire (total score).

A budget impact analysis will be performed from the CNAM perspective (National Health Insurance). Total hospitalization costs, total ambulatory care costs, and their ratio will be performed in each group.

Secondary analyses will also include a description of operational outcomes in the PRADO-IC group, and a comparison of clinical outcomes and of care pathways between groups, using multilevel methods to take into account the inclusion centre.

Enrolment results

In January 2020, 220 patients were included (55% of sample size). We intend to have completed inclusions by September 2020.

Discussion

The PRADO-IC programme has been implemented everywhere in France, with the aim to reduce the annual death rate of 20%, and the annual HF readmission rate of 30%. Evidence of the actual impact of this programme is scarce.

Theoretically, this programme is of interest, as it addresses some weak links in the chain between persons involved in patient care. The basic hypothesis is rational and the ways to reach the clinical aim are already available, although expensive. Nevertheless, efficacy of the system is challenging in routine practice, as physicians may be reluctant to order administrative-led transition programme due to the burden created and moreover, because of the low level of evidence for efficacy.

To date, implementation of the system has been challenging. In France, less than 20 000 patients were included in 2018,²² although more than 200 000 patients are hospitalized for HF each year.²³ Our study may add new knowledge about the programme, its efficacy and effectiveness.

a. Strengths

The randomized control design allows a high level of evidence.

Our settings allow a high degree of extrapolability. Indeed, participating centres had not been included in the design of the PRADO-IC, as the majority of centres in France. This is an important selection criterion, as this lack of involvement in design is responsible for a probably imperfect application and less motivation. Yet the motivation bias leads to overestimated efficacy.⁶ Besides, both public and private

centres participate, as well as very large tertiary centres or smaller centres; therefore, all types of patients case-mix are included in our study.

The initial aim advocated by the CNAM was a 30% reduction of readmissions for HF. Readmissions are clearly of clinical importance. However, at the population level, economic criteria remain of great importance too. Therefore, it should be acceptable for the PRADO to be clinically ineffective but economically efficient, thus justifying the improvement of our organizations and transition programmes. This is why a cost-effectiveness criterion was chosen as main outcome of this study.

Secondary exploratory endpoints could provide important features to better understand the strengths or weaknesses of this transition programme and how to improve it and facilitate the implementation in various settings. To this purpose, the qualitative evaluation is original and should explore unknown aspects in this clinical setting.

This trial is unusual for clinicians as we evaluate organizational modifications from the hospital to home, involving other care providers such as the GPs, cardiologists outside of the hospital or nurses. This impact of organizations and their quality is tremendous although scarcely taken into consideration until now. As care pathways improvement are a major operational aim of transitional care, we consider that a multicriteria description of care pathways is necessary in this research area.

b. Limitations

The evaluation of organizational processes appears both as a strength and a weakness because of the difficult assessment in relation to actual care pathways. Although the control group is supposed to follow international and national guidelines, local heterogeneity remains likely. Moreover, the centre effect is probably stronger here when compared with trials with drugs. Nevertheless, a usual care group is recommended as control group in pragmatic trials.²⁴ In order to control bias, randomization was stratified on the inclusion centre and the current attending of patients to a patient education programme, which are the main factors responsible for heterogeneity of care processes. The stratification should limit the subsequent confounding bias, but not the selection bias; therefore, the ability to extrapolate results to other centres could be further discussed. Alas, we could not perform on-site quality audits in this study, due to limited funding.

There is a theoretical risk of contamination bias. Nevertheless, administrative assistants do not manage patients in the control group and cannot be responsible for a contamination bias, and education is carried out by ambulatory nurses during specific visits. Even if they wish, it is unlikely that they will have the opportunity to do effective education with

patients who do not participate in the programme and therefore who do not receive these specific visits.

Many improvements have been obtained in the past decade for the management of patients with HF that include sacubitril-valsartan for patients with HF with reduced left ejection fraction and telemonitoring. In France, telemonitoring has been available in routine practice for more than 1 year, particularly for all the patients admitted for acute HF. In evaluation, we will take into consideration this potential bias, as the implementation of telemonitoring could improve the clinical outcomes and modify the organizations locally, thus interfering with our study. Currently, the number of patients benefiting from telemonitoring remains small.

The number of patients to be recruited is relatively small, as it was calculated in order to demonstrate the hypotheses on impact chosen by the CNAM, which were close to RR reported in systematic reviews.^{10–14} If these hypotheses are reliable, we will be able to prove such an effect.

c. Future directions

This study should allow for explanations of the mechanisms that led to results. In future studies, the specific impact of the PRADO system should be investigated further in relation with other interventions, especially telemonitoring programmes. Indeed, their relationships, additional values or not remain to be determined by dedicated studies.

Conclusions

The results of this study may help decision-makers to support an administratively managed transition programme.

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Conflict of interest

The authors do not have any conflict of interest directly regarding this work.

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